LOK SABHA

THE PATENTS BILL, 1965

(Report of the Joint Committee)



LOK SABHA SECRETARIAT NEW DELHI

INDIAN MERCHANTS' CHAMBER

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LALE MARANJI MENORIAL BIDIAN MENGHANYE GIANGE SUEDEG 76, VEER, NARDAAN ROAD, CHERCHARK, FORT

Bombay, Necember 28. 196 5.

The Chairman Joint Committee of Parliament on the Patents Bill 1965 Lok Sabha Secretariat <u>NEW DELHI.</u>

Dear Sir:

THE PATENIS BILL 1965

The Committee of the Indian Merchants' Chamber have given careful consideration to the provisions of the Patents Bill, 1965 which was introduced in the Lok Sabha on the 21st September, 1965 and which has been referred to your Committee for reporting thereon. As directed by my Committee, 1 give below their views and suggestions on some of the provisions of the Bill.

The Bill has been brought forward with the object of 2. enacting a comprehensive legislation on the subject with a view to ensure that patent rights are not worked to the detriment of the consumer or to the prejudice of the trade or the industrial development of the country. While my Committee are in entire agreement with the above objectives and are one with Government in adopting such steps as are necessary to ensure that the patent system is used in the best national interests and to eliminate any misuse or abuse of the existing patent rights, they feel that some of the provisions, as drafted in the Bill, will come in the way of stimulating inventions by scientists and research workers of India and of encouraging the development and exploitation of new inventions for industrial progress in this country. Though the Bill is based on the recommendations submitted 3. by Shri N. Rajagopala Ayyangar, a retired Judge of the Supreme

¿ Court, in his comprehensive report, my Committee find that in certain fundamental aspects serious departure has been made from these recommendations. To illustrate, Shri, Ayyangar has recommended that patents as well as designs. shall be binding on Government. The Bill, as worded, does not make patents binding on Government. Again, while the recommendation in regard to the term of a patent was that the term of every patent shall be 16 years from the date of the patent without any extension and that there need not be any distinction in the term of a patent between different classes of inventions, differentiation is sought to be made in the Bill between the terms of patents in respect of food, medicine and drugs on the one hand, and other kinds of inventions and patents on the other. Furthermore, the provision regarding ment automatic endorse/ of the words "Licences of right" on patents relating to articles of food, medicine or drug contained in Clause 87 of the Bill is contrary to the recommendation of Shri Ayyangar. Apart from this, some of the other provisions of the Bill, such as those empowering Government to import patented articles or acquire patent rights without compensation etc. impinge on the fundamental right of a citizen that he shall be paid due compensation for any property acquired by the State from him and go counter to the concept of patents being an intangible property and the patentee's right in and to such property.

4. With the above preliminary observations, my Committee would now proceed to give their views and suggestions on certain Clauses of the Bill:-

(i) Clause 2(h): Sub-Clause (h) of Clause 2 defines "Government Undertaking" as including the Council of Scientific and Industrial Research and or any University established by law in India as also any other institution for scientific or technical education which is financed wholly or for the major part by Government. This definition is very wide and is contrary to the recommendation of Shri Rajagopala Ayyangar.

It should be confined to only any department of the Government or any other undertaking wholly managed by Government. A University which is a statutory body cannot be considered as a Government Undertaking nor can the Council of Scientific and Industrial Research nor institutions which impart technical or scientific education be deemed to be Government Undertakings. All such bodies should, therefore, be excluded from the provision of this sub-Clause.

(ii) <u>Clause 27:</u> According to this Clause, the Controller can suo motu refuse to grant a patent if he, at any time after the acceptance of the complete specification filed in pursuance of an application for the patent and before the grant of the patent thereon, receives information, otherwise than in consequence of proceedings opposing the grant under the provisions of the Bill, regarding prior publication. The provisions of this Clause are very wide. In receipt of information as to prior publication, the Controller can compel the applicant to amend the complete specification to his entire satisfaction and within such time as he may prescribe, failing which he can reject the application. Furthermore, there is no provision under which the applicant can contest the information received by the Controller nor is he given an opportunity to deny it. This goes against the principles of natural justice. My Committee, therefore, suggest that a provision should be made in this Clause as a result of which an opportunity could be afforded to the applicant to show cause why his application siould not be rejected.

(iii) <u>Clause 48:</u> This Clause provides that -

- (a) the importation by or on behalf of the Government of any patented machine, apparatus or other article for the purpose merely of its own use, or
- (b) the importation by or on behalf of the Government of any patented medicine or drug for the purpose merely of its own use or for distribution in any

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dispensary, hospital or other medical institution maintained by or on behalf of the Government or any other dispensary, hospital or other medical institution which may be specified by the Central Government in this behalf by notification in the Official Gazette, or

- (c) the making of a patented machine, apparatus or other article or the use of a patented process or the making of an article by the use of the patented process by or on behalf of the Government for the purpose merely of its own use or by persons on its behalf who may be specially authorised for the purpose, or
- (d) the making or use of a patented machine or apparatus or other article or the use of a patented process or the use of an article made by the use of the patented process, machine or apparatus for the purpose merely of experiment or research includ ing the imparting of instructions to pupils,

will not constitute an infringement of the rights conferred on the patentee by this legislation. While the provision contained in sub-Clause (d) of this Clause can be justified, the provisions of the other sub-Clauses (a), (b) and (c) virtually amount to an abrogation of the patents and will come in the way of indigenous industrial development. Moreover, no provision has been made for payment of composition to the patentee concerned who would be put to a great loss by such import and distribution. There is also no provision for affording the patentee an opportunity to explain his case or show cause against such importation, use or manufacture by or on behalf of Government. Such provisions do not also find a place in the patent laws of most of the countries of the world. If it is at all felt that these provisions are necessary, my Committee would suggest that they should apply only so long as the patents are not

Unce a patent is put to use, such imports, use or ufacture by or on behalf of Government, should not be allowed ind should be considered as an infringement of the patent right of the patentee.

(iv) Clause 53: This Clause provides that in respet of an invention claiming the method or process of manufacture of (pr \is a substance, where the substance is intended for use, capable of being used, as food or as a medicine or drug, it's term shall be ten years from the date of the patent; in respect of any other invention, the term shall be fourteen years from the date of the patent. This clause also provides that in respect of patents in force, the term for inventions relating to food, medicine, or drug, shall be ten years from the date of the patent provided that if at the commencement of the proposed legislation, the term of any patent has been extended under the existing Act such patent shall cease to have effect on the expiry of such extended period. It may be noted that at present the term of a patent whether it may be for food or drug or medicine or any other substance is 16 years with a provision for extending the period upto 10 years, if Government so approved. In the first instance, the justification for this discrimination between food, drug and medicine on the one hand and the other patentable products on the other is not explained or understood. Secondly, in reducing the period of patent for food, drug, medicine etc. to 10 years from 16 years the Bill fails to take into account the position that a substantial period elapses before a patentee is in a position to derive any benefit from his invention. A patented drug has to go through a large number of tests and clinical trials before it could be marketed and these tests and trials may run into several months, if not years. This provision is also against the recommendation of Shri Rajagopala Ayyangar who had proposed a 16 year period. Whatever reasons Government may have for

Hiscriminatory treatment, my Committee feel that, in order

to provide for deferving and appropriate cases, the bution contain a provision for extending the period of 10 year by a period of not exceeding four years in the case of a patent relating to food, medicine or drug.

(v) Further the term of a patent is to be reckoned from the date of the patent, whilst Clause 45 of the Bill provides that every patent shall be dated as of the date on which the complete specification is filed. As some time will elapse between the filing of the complete specification and the sealing of the patent during which period the patentee will have no advantage, my Committee feel that the term of a patent should commence from the date of the sealing of the patent and not . from the date of filing of the complete specification as now provided.

(vi) <u>Clause 64:</u> This enumerates various grounds on which a patent could be revoked by the High Court on the petition of any person or by the Central Government. In this connection, reference may be made to the grounds contained in paragraph (e) and (f) of sub-Clause (1) of this Clause which read as follows:-

- "(e) that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was known or used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in Section 13;
 - (f) that the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was known or used in India or what was published in India or elsewhere before the priority date of the claim."

Sub-Clause (2) of this Clause provides that for the purposes of the above paragraphs (e) and (f), the importation int_{0} Jpc² of the product made abroad by a patented process shall not

knowledge or use in India of the invention on the date of importation. This sub-Clause imposes a strain on one's credulity that mere importation of a patented product would constitute a prior knowledge and would be a ground for the revocation of the patent. It will be appreciated that before a product under a patented prodess can be manufactured in this country, it is necessary to have market and clinical tests as to the usefulness of the product in this country and for this purpose, a token importation will require to be made. My Committee are therefore of the view that where the product is imported for the purpose of reasonable trial or experiment only, such importation should not be hit by the relevant, provisions of this Clause.

(vii) <u>Clauses 86 and 87</u>: According to Clause 87, every patent in force at the commencement of this legislation relating to articles of food, medicine or drug and the processes for their manufacture as also for the manufacture of chemical substances including alloys, optical glass, semi-conductors, and inter-metallic compounds, shall be deemed to be endorsed with the words "Licences of right" from the commencement of the Act. In the case of every patent granted after the commencement of the Act, in respect of processes for the manufacture of inventions referred to above shall be deemed to be similarly endorsed from the date of the sealing of the patent. Whereas according to Clause 87, patents already in force in respect of sub tances mentioned therein viz. articles of food, medicine or drug, would be deemed to be endorsed with the words "Licences of right" from the commencement of the Act, in respect of patents granted after the commencement of the Act, the endorsement of the words "Licences of right" shall commence from the date of the sealing of the patent. In respect of patents relating to other articles, Clause 86. \setminus provides for grant of "Licences of right" after the expiration "hree years from the date of the sealing of a patent on

the ground that the reasonable requirements of the public with respect to the patented inventions have not been satisfied.

(viii) The disctinction in respect of the endorsement of the words "Licences of right" viz. the automatic endorsement in the case of drugs, medicines, articles of food, etc. and the med to comply with certain conditions mentioned in Clause 86 in respect of patents relating to other articles is, in the opinion of my Committee, not justified. Further, the provisions of Clause 87 would seriously affect the drugs and pharmaceutical industry, since any person even before the patentee had an opportunity to work the patent could apply to the patentee to grant him a licence for the purpose of working the patent. The Bill does not lay down any tests of qualifications or financial ability or technical skill of the applicant and this lacuna in the Bill is in the opinion of my Committee open to serious objection. In the matter of food or drugs, certain minimum standards and criteria. cannot be tampered with in favour of expediency and it is therefore both necessary and desirable that this lacuna be filled in and suitable provisions be made in the Bill under which the Controller will be given powers to determine the ability and qualifications of the applicant to work the patent as a licensee. Granting of a licence without laying down any criterie goes against the very fundamental principle of granting a patent. In view of this, Clause 😽 should be deleted and even patents in respect of drugs, medicines, etc. should be governed by the provisions of Clause 86.

(ix) <u>Clause 88:</u> This Clause provides that in respect of a patent which has been endorsed with the words "Licences of right" any person who is interested in working the patented invention in India may require the patentee to grant him a licence for the purpose on such terms as may be mutually agreed upon. The Clause further provides that if the particept

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unable to agree on the terms of the lices, the Controller to whom an application may be made by eitheparty can decide the terms on which the licence shall be grant. Clauses 84 and 85 of the Bill indicate the matters to be ten into account in granting compulsory licences. My Committee feel that in granting a licence under Clause 88 also, the troller should take into account the considerations necessary formating the compulsory licences under the said Clauses 84 and

Sub-Clause (5) of Clause 88 makes certain reference (x) to Clause 87. In view of the suggestion for deletion of Clause 87, this sub-Clause should be amended suitably. This sub-Clause also provides that the royalty and other remuneration payable by a licensee to the patentee where the patent was given before or after the commencement of the legislation shall not exceed four per cent. of the ex-factory sale price in bulk of the patented article (exclusive of taxes levied under any law for the time being in force and any commissions payable). In his report Shri Rajagopala Ayyangar has recommended that no statutory ceiling on royalty should be fixed since fixation of a reasonable amount of royalty will have to be arrived at on a large number of factors depending upon the facts of each case. My Committee suggest that there should be no ceiling on the royalty payable and the amount of royalty be determined in each case with reference to the facts of the case and the Controller may be empowered to fix the royalty after taking into account the various circumstances of the case.

(xi) <u>Clause 91:</u> This Clause empowers the Controller to adjourn hearing of applications under Clause 84, 86 or 89 by a period not exceeding twelve months, if he is satisfied that the time which has elapsed since the sealing of the patent has for any reason been insufficient to enable the invention to be worked on a commercial scale or to an adequate extent or to enable the invention to be so worked to the fullest

extent that is easonably practicable. In Sub-Clause (1) of Clause 91 there is however reference to Clause 89 which reles to applications to the Controller for revocation opetents in respect of which either a compulsory

lipce has been granted or the endorsement "Licences of "Tht" has been made or is deemed to have been made. In view of this reference, it is necessary to add the words "or the endorsement 'licences of right' as the case may be" after the words "the sealing of the patent" appearing in line 4 of sub-Clause (1) of Clause 91.

(xii) <u>Clause 95:</u> Sub-Clause (2) of this Clause provides that no licence granted by the Controller shall authorise the licensee to import any patented article or an article or substance made by a patented process from abroad where such importation would, but for such authorisation, constitute an infringement of the rights of the patentee. Sub-Clause (3), however, provides that the Central Government may, if in its opinion it is necessary so to do in the public interest, direct the Controller to authorise any licensee in respect of a patent to import the patented article or an article or substance made by a patented process from abroad (subject to such conditions as may be imposed) and the Controller has thereupon to give effect to such directions. No provision has however been made in this Clause for payment of compensation to the patentee in cases where Government directs that imports be made of the patented articles. The powers contained in this Clause are also very wide and would, apart from causing serious loss to the patentee, come in the way of stimulating inventions. Sub-Clause (3) should, therefore, be deleted or in the alternative, provision should be made for payment of compensation to the patentee.

(xiii) <u>Clause 99:</u> This Clause defins the meaning of the term 'use of invention for the purpose of Government'. According to it, an invention can be said the used for the purposes of Government if it is made, used, excised or vended for the purposes of any industry even in the price sector, if the Government, having regard to the interests dehe general public, notify in the Official Gazette the name names of such industry or industries. The provision conf. on Government a very wide discretionary power which may be liable to be used in a discriminatory manner. The use of inventions contemplated by this provision should be confined only for the purposes of Government and should not be extended to the use by an undertaking in which the Government has no interest at all. In this connection, it may be pointed out that the Patents Enquiry Committee only recommended the extension of the concept of Government "use" to use by a Government Undertaking. The clause should, therefore, be so amended as to confine the use of the invention for the purposes of Government or a Government Undertaking. In this regard, my Committee would draw attention to their suggestion on the definition of the term "Government Undertaking" made earlier in connection with Clause 2(h).

(xiv) <u>Clause 100</u>: This Clause empowers the Central Government to use inventions for purposes of Government. It also empowers any person authorised in writing by the Central Government to use the invention for the purposes of Government. Such user need not necessarily be confined to user by a Government Department or a Government Undertaking, but may extend as user to any other individual or Undertaking. As pointed out in the comments on the earlier Clause such uses should not be allowed. If, however, such use is made by any one other than a Government Department or a Government Undertaking, it is but proper that the patentee should be entitled to compensation for such use. Hence a provision on the lines contained in the U.K. Act in this regard for payment of compensa-

(xv) Clause 112; This places certain restrictions on the power of Court to cant injunction and compensation in cases of infringement c detent. According to this Clause, if in the proceeding the infringement of a patent endorsed or deemed to be f god with the words "Licences of right" (otherwise than fortation of the patented article from other countries) by ; +. *viringing defendant is ready and willing to take a licence* A terms to be settled by the Controller, no injunction shall e granted against him. The word "shall" contained in this Clause absolutely deters a Court from applying its judicial mind to the circumstances of the case and deciding whether an injunction would be justified or not. Placing restrictions on the powers of the Courts of Justice would amount to interference with them. A Judicial authority should not be fettered with restrictions sought to be placed on it under this Bill and should have the freedom to decide the case as the circumstances may warrant. My Committee, therefore, suggest that the word "shall" should be substituted by the word "may" so that the Court can go into the question and come to an impartial judicial decision,

(xvi) <u>Clause 116 (Appeals)</u>: According to sub-Clause (1) of this Clause, no appeal will lie from any decision, order or direction made or issued under the Act by the Central Government or from any Act or order of the Controller for the purpose of giving effect to any such decision, order or direction.

(xvii) Sub-Clause (2), however, provides that, save as otherwise expressly provided in sub-Clause (1), an appeal will lie to a High Court from any decision, order or direction of the Controller under the various provisions of the Bill enumerated therein. Since a patent constitutes an intangible property, any decision of the executive affecting such property should not be final and such decision should be subject to revision or appeal by either a judicial or quasi-judicial body. Hence in respect of such orders or decisions from which no appeal has been provided to the High Court, an appeal should lie to a statutory body like the Copyright Board under the Copyright Act, 1957 presided over

by a person who is, or has been, a Judge of the Supreme Court or a High Court or is qualified for appointment as a Judge of a High Court. Since copyright is also an intangible property just as a patent is, it would be just and proper that a Board on the lines of the Copyright Board should be constituted for the purpose of appeal against orders or decisions of the Central Government or the Controller under this legislation.

5. Patents not binding on Government.

Section 21 of the Patents and Designs Act, 1911 provides that subject to the other provisions of that Act, a patent shall be binding on Government as it is against any person. This provision in the existing Act has been specifically omitted in the present Bill which if passed will mean that patents will no longer be binding on Government. Item 6 of the Schedule to the Bill which contains amendments to the Indian Patents and Designs Act to repeal provisions which relate to designs, substitutes the present Section 51B of the Act by a new Section providing that a registered design will however be binding on Government. Thus a discrimination is being sought to be made between patents and designs by providing that while designs will be binding on Government, patents will not be. This discrimination cannot be justified and is against the recommendations of the Patents Enquiry Committee as well as that of Shri Rajagopala Ayyangar. My Committee therefore submit that the relevant Section of the Act should be continued and that patents should be binding on Government equally with designs. Necessary amendments should, therefore, be made in the Bill so as to restore the position regarding patents as prevailing at present.

6. My Committee would request your Committee to give due and proper consideration to the above views and suggestions while submitting your Report to Parliament. My Committee would also request that their representatives be given an opportunity to

appear before your Committee to give evidence and for offering any clarification that your Committee might require.

Yours faithfully,

CRShimps Secretary.

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Tolegname s "ÍNCHAMBU" LALE MABANE MINORAL BIDAN MERCHANTE CHANNE MEDING, 76, VEER NARMAN ROAD, CHINCHIGATE, FORT

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made from these recommendations. To illustrate, Shri Ayyangar has recommended that patents as well as designs shall be binding on Government. The Bill, as worded, does not make patents binding on Government. Again, while the recommendation in regard to the term of a patent was that the term of every patent shall be 16 years from the date of the patent without any extension and that there need not be any distinction in the term of a patent between different classes of inventions, differentiation is sought to be made in the Bill between the terms of patents in respect of food, medicine and drugs on the one hand, and other kinds of inventions and patents on the other. Furthermore, the provision regarding ment automatic endorse of the words "Licences of right" on patents relating to articles of food, medicine or drug contained in Clause 87 of the Bill is contrary to the recommendation of Shri Ayyangar. Apart from this, some of the other provisions of the Bill, such as those empowering Government to import patented articles or acquire patent rights without compensation etc. impinge on the fundamental right of a citizen that he shall be paid due compensation for any property acquired by the State from him and go counter to the concept of patents being an intangible property and the patentee's right in and to such property.

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- (d) the making or use of a patented machine or apparatus or other article or the use of a patented process or the use of an article made by the use of the patented process, machine or apparatus for the purpose merely of experiment or research including the imparting of instructions to pupils,

will not constitute an infringement of the rights conferred on the patentee by this legislation. While the provision contained in sub-Clause (d) of this Clause can be justified, the provisions of the other sub-Clauses (a), (b) and (c) virtually emount to an abrogation of the patents and will come in the way of indigenous industrial development. Moreover, no provision has been made for payment of compensation to the patentee concerned who would be put to a great loss by such import and distribution. There is also no provision for affording the patentee an opportunity to explain his case or show cause against such importation, use or manufacture by or on behalf of Government. Such provisions do not also find a place in the patent laws of most of the countries of the world. If it is at all felt that these provisions are necessary, my Committee would suggest that they should apply only so long as the patents are not

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to provide for deserving and appropriate cases, the Bill should contain a provision for extending the period of 10 years by a period of not exceeding four years in the case of a patent relating to food, medicine or drug.

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(vi) <u>Clause 64:</u> This enumerates various grounds on which a patent could be revoked by the High Court on the petition of any person or by the Central Government. In this connection, reference may be made to the grounds contained in paragraph (e) and (f) of sub-Clause (1) of this Clause which read as follows:-

- "(e) that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was known or used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in Section 13;
 - (f) that the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was known or used in India or what was published in India or elsewhere before the priority date of the claim."

Sub-Clause (2) of this Clause provides that for the purposes of the above paragraphs (e) and (f), the importation into India of the product made abroad by a patented process shall constitute

knowledge or use in India of the invention on the date of importation. This sub-Clause imposes a strain on one's credulity that mere importation of a patented product would constitute a prior knowledge and would be a ground for the revocation of the patent. It will be appreciated that before a product under a patented prodess can be manufactured in this country, it is necessary to have market and clinical tests as to the usefulness of the product in this country and for this purpose, a token importation will require to be made. My Committee are therefore of the view that where the product is imported for the purpose of reasonable trial or experiment only, such importation should not be hit by the relevant provisions of this Clause.

(vii) <u>Clauses 86 and 87</u>: According to Clause 87, every patent in force at the commencement of this legislation relating to articles of food, medicine or drug and the processes for their manufacture as also for the manufacture of chemical substances including alloys, optical glass, semi-conductors, and inter-metallic compounds, shall be deemed to be endorsed with the words "Licences of right" from the commencement of the Act. In the case of every patent granted after the commencement of the Act, in respect of processes for the manufacture of inventions referred to above shall be deemed to be similarly endorsed from the date of the sealing of the patent. Whereas according to Clause 87, patents already in force in respect of substances mentioned therein viz. articles of food, medicine or drug, would be deemed to be endorsed with the words "Licences of right" from the commencement of the Act, in respect of patents granted after the commencement of the Act, the endorsement of the words "Licences of right" shall commence from the date of the sealing of the patent. In respect of patents relating to other articles, Clause 86 provides for grant of "Licences of right" after the expiration of three years from the date of the sealing of a patent on

the ground that the reasonable requirements of the public with respect to the patented inventions have not been satisfied.

(viii) The disctinction in respect of the endorsement of the words "Licences of right" viz. the automatic endorsement in the case of drugs, medicines, articles of food, etc. and the need to comply with certain conditions mentioned in Clause 86 in respect of patents relating to other articles is, in the opinion of my Committee, not justified. Further, the provisions of Clause 87 would seriously affect the drugs and pharmaceutical industry, since any person even before the patentee had an opportunity to work the patent could apply to the patentee to grant him a licence for the purpose of working the patent. The Bill does not lay down any tests of qualifications or financial ability or technical skill of the applicant and this lacuna in the Bill is in the opinion of my Committee open to serious objection. In the matter of food or drugs, certain minimum standards and criteria cannot be tampered with in favour of expediency and it is therefore both necessary and desirable that this lacuna be filled in and suitable provisions be made in the Bill under which the Controller will be given powers to determine the ability and qualifications of the applicant to work the patent as a licensee. Granting of a licence without laying down any criteria goes against the very fundamental principle of granting a patent. In view of this, Clause 87 should be deleted and even patents in respect of drugs, medicines, etc. should be governed by the provisions of Clause 86.

(ix) <u>Clause 88:</u> This Clause provides that in respect of a patent which has been endorsed with the words "Licences of right" any person who is interested in working the patented invention in India may require the patentee to grant him a licence for the purpose on such terms as may be mutually agreed upon. The Clause further provides that if the parties are

unable to agree on the terms of the licence, the Controller to whom an application may be made by either party can decide the terms on which the licence shall be granted. Clauses 84 and 85 of the Bill indicate the matters to be taken into account in granting compulsory licences. My Committee feel that in granting a licence under Clause 88 also, the Controller should take into account the considerations necessary for granting the compulsory licences under the said Clauses 84 and 85.

Sub-Clause (5) of Clause 88 makes certain references (x) to Clause 87. In view of the suggestion for deletion of Clause 87, this sub-Clause should be amended suitably. This sub-Clause also provides that the royalty and other remuneration payable by a licensee to the patentee where the patent was given before or after the commencement of the legislation shall not exceed four per cent. of the ex-factory sale price in bulk of the patented article (exclusive of taxes levied under any law for the time being in force and any commissions payable). In his report Shri Rajagopala Lyyangar has recommended that no statutory ceiling on royalty should be fixed since fixation of a reasonable amount of royalty will have to be arrived at on a large number of factors depending upon the facts of each case. My Committee suggest that there should be no ceiling on the royalty payable and the amount of royalty be determined in each case with reference to the facts of the case and the Controller may be empowered to fix the royalty after taking into account the various circumstances of the case.

(xi) <u>Clause 91</u>: This Clause empowers the Controller to adjourn hearing of applications under Clause 84, 86 or 89 by a period not exceeding twelve months, if he is satisfied that the time which has elapsed since the sealing of the patent has for any reason been insufficient to enable the invention to be worked on a commercial scale or to an adequate extent or to enable the invention to be so worked to the fullest

extent that is reasonably precticable. In Sub-Clause (1) of Clause 91, there is however reference to Clause 89 which relates to applications to the Controller for revocation of patents in respect of which either a compulsory licence has been granted or the endorsement "Licences of right" has been made or is deemed to have been made. In view of this reference, it is necessary to add the words "or the endorsement 'licences of right' as the case may be" after the words "the sealing of the patent" appearing in line 4 of sub-Clause (1) of Clause 91.

(xii) Clause 95: Sub-Clause (2) of this Clause provides that no licence granted by the Controller shall authorise the licensee to import any patented article or an article or substance made by a patented process from abroad where such importation would, but for such authorisation, constitute an infringement of the rights of the patentee. Sub-Clause (3), however, provides that the Central Government may, if in its opinion it is necessary so to do in the public interest, direct the Controller to authorise any licensee in respect of a patent to import the patented article or an article or substance made by a patented process from abroad (subject to such conditions as may be imposed) and the Controller has thereupon to give effect to such directions. No provision has however been made in this Clause for payment of compensation to the patentee in cases where Government directs that imports be made of the patented articles. The powers contained in this Clause are also very wide and would, apart from causing serious loss to the patentee, come in the way of stimulating inventions. Sub-Clause (3) should, therefore, be deleted or in the alternative, provision should be made for payment of compensation to the patentee.

(xiii) <u>Clause 99:</u> This Clause defines the meaning of the term 'use of invention for the purposes of Government'. According to it, an invention can be said to be used for the purposes of Government if it is made, used, exercised or vended for the purposes of any industry even in the private sector, if the Government, having regard to the interests of the general public, notify in the Official Gazette the name or names of such industry or industries. The provision confers on Government a very wide discretionary power which may be liable to be used in a discriminatory manner. The use of inventions contemplated by this provision should be confined only for the purposes of Government and should not be extended to the use by an undertaking in which the Government has no interest at all. In this connection, it may be pointed out ' that the Patents Enquiry Committee only recommended the extension of the concept of Government "use" to use by a Government Undertaking. The clause should, therefore, be so amended as to confine the use of the invention for the purposes of Government or a Government Undertaking. In this regard, my Committee would draw attention to their suggestion on the definition of the term "Government Undertaking" made earlier in connection with Clause 2(h).

(xiv) <u>Clause 100</u>: This Clause empowers the Central Government to use inventions for purposes of Government. It also empowers any person authorised in writing by the Central Government to use the invention for the purposes of Government. Such user need not necessarily be confined to user by a Government Department or a Government Undertaking, but may extend as user to any other individual or Undertaking. As pointed out in the comments on the earlier Clause such uses should not be allowed. If, however, such use is made by any one other than a Government Department or a Government Undertaking, it is but proper that the patentee should be entitled to compensation for such use. Hence a provision on the lines contained in the U.K. Act in this regard for payment of compensation in such circumstances should be included.

(xv) <u>Clause 112</u>: This places certain restrictions on the power of Court to grant injunction and compensation in cases of infringement of patent. According to this Clause, if in the proceedings for the infringement of a patent endorsed or deemed to be endorsed with the words "Licences of right" (otherwise than by the importation of the patented article from other countries) the infringing defendant is ready and willing to take a licence upon terms to be settled by the Controller, no injunction shall be granted against him. The word "shall" contained in this Clause absolutely deters a Court from applying its judicial mind to the circumstances of the case and deciding whether an injunction would be justified or not. Placing restrictions on the powers of the Courts of Justice would amount to interference with them. A Judicial authority should not be fettered with restrictions sought to be placed on it under this Bill and should have the freedom to decide the case as the circumstances may warrant. My Committee, therefore, suggest that the word "shall" should be substituted by the word "may" so that the Court can go into the question and come to an impartial judicial decision.

(xvi) <u>Clause 116 (Appeals)</u>: According to <u>sub-Clause</u> (1) of this Clause, **no** appeal will <u>lip</u> from any decision, order or direction made or issued under the Act by the Central Government or from any Act or order of the Controller for the purpose of giving effect to any such decision, order or direction.

(xvii) Sub-Clause (2), however, provides that, save as otherwise expressly provided in sub-Clause (1), an appeal will lie to a High Court from any decision, order or direction of the Controller under the various provisions of the Bill enumerated therein. Since a patent constitutes an intangible property, any decision of the executive affecting such property should not be final and such decision should be subject to revision or appeal by either a judicial or quasi-judicial body. Hence in respect of such orders or decisions from which no appeal has been provided to the High Court, an appeal should lie to a statutory body like the Copyright Board under the Copyright Act, 1957 presided over

by a person who is, or has been, a Judge of the Supreme Court or a High Court or is qualified for appointment as a Judge of a High Court. Since copyright is also an intangible property just as a patent is, it would be just and proper that a Board on the lines of the Copyright Board should be constituted for the purpose of appeal against orders or decisions of the Central Government or the Controller under this legislation.

5. Patents not binding on Government.

Section 21 of the Patents and Designs Act, 1911 provides that subject to the other provisions of that Act, a patent shall be binding on Government as it is against any person. This provision in the existing Act has been specifically omitted in the present Bill which if passed will mean that patents will no longer be binding on Government. Item 6 of the Schedule to the Bill which contains amendments to the Indian Patents and Designs Act to repeal provisions which relate to designs, substitutes the present Section 51B of the Act by a new Section providing that a registered design will however be binding on Government. Thus a discrimination is being sought to be made between patents and designs by providing that while designs will be binding on Government, patents will not be. This disctimination cannot be justified and is against the recommendations of the Patents Enquiry Committee as well as that of Shri Rajagopala Ayyangar. My Committee therefore submit that the relevant Section of the Act should be continued and that patents should be binding on Government equally with designs. Necessary amendments should, therefore, be made in the Bill so as to restore the position regarding patents as prevailing at present.

6. My Committee would request your Committee to give due and proper consideration to the above views and suggestions while submitting your Report to Parliament. My Committee would also request that their representatives be given an opportunity to

appear before your Committee to give evidence and for offering any clarification that your Committee might require.

Yours faithfully,

CRBhum /s.

vs.

TRADE MARKS OWNERS ASSOCIATION OF INDIA

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> Memorandum on Patents Bill No.62 of 1965, being a Bill to amend and consolidate the law relating to Patents introduced in the Lok Sabha on 21st September,1965.

Clause 2(g)

Food is defined as including "any substance intended for the use of, or capable of being used by, babies, invalids or convalescents" which the Central Obvernment may specify. It is difficult to conceive of many foods not "capable of being used by convalescents". It is suggested that the words "intended to be used" are adequate.

Clause 2(h)

The C.S.I.R. and Universities should not be expected to make use of patented inventions on a commercial basis. Their needs for experimental and research use and for imparting instructions to pupils have already been taken care of by clause h8(d). These institutions should, therefore, not be included in the definition of "Government undertaking".

Apart from the above, the definition of "Government undertaking" is only important from the point of view of Chapter XVII. It is our submission that Corporations established by Central or State laws and owned and controlled by Government as well as Government companies are getting increasingly involved in fields of production directly in competition with the private sector and operate for profit and therefore, there appears to be no justification for any preferential treatment in their favour. We would suggest that these organisations should also be excluded from the definition of "Government' undertaking".

Clause 2(1)

This definition of 'drug' will have the effect of covering almost every known chemical. Most chemicals are capable of being used as intermediates in

manufacturing either a pharmaceutical product or another chemical which may not be a drug. There may also be solvents which by themselves are not drugs, but may be regarded as such merely because they are used in the drugs industry as solvents. These intermediates would be hit by the restrictive patent protection merely because one of their uses is to serve as intermediates in the pharmaceutical industry. If the essential utility of the chemical is for the production of a drug, it may be for the purpose of the definition regarded as a drug but not any chemical used in the manufacture of drugs.

Clause 3(e)

We would suggest that the non-patentability should apply only to a process for producing substances which merely aggregate the <u>known</u> properties of the components. In other words, the word 'known' should be inserted before the word 'properties' in the second line.

Clause 8:

The main object of this clause is to prevent unsubstantiated claims being protected. In view of the non-availability of trained man-power, this clause seeks to avail of the professional scientific expertise of other countries for the purpose of evaluating the claims contained in Indian patent applications. The system chosen is what is generally known as the system of universal, international or world-wide novelty, and therefore it is essential that all that is made available or made public should constitute "the state of art". While we agree that unsubstantiated claims should not get protection and that sufficient safeguards should be provided, the Controller's discretion to ask for all the information to determine the novelty or the patentability of the invention should be circumscribed. It is, therefore, submitted that sub-clause (2) of this clause should be amended to read as "if the Controller entertains reasonable doubt as to the novelty or the patentability of the invention, he may for reasons to be recorded in writing require the applicant to furnish the details relating to the objections, if any, taken to such application as is referred to in sub-section (1) on the grounds that the invention is lacking in novelty or patentability, the amendments effected

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in the specification, the claims allowed in respect thereof and such other particulars as he may require."

Furthermore, it is essential that the rules that may be framed under this clause should not only be simple and inexpensive, but should also prevent any needless authentication, certification or documentation.

<u>Clause 15 (2)(a)</u>

This sub-clause requires the Controller to refuse an application if it is made in contravention of the Chapter on Conventions. The contravention may be wilful or inadvertent and it would be a great hardship if in the latter case also the Controller is obliged to refuse the application. We submit that in the case of inadvertent contravention of the provisions of this Chapter, the Controller should have the power to treat the application as a non-convention application instead of refusing it.

Clause 25

Sub-clause (d) of this clause provides that if a product made by a process claimed in a patent application had already been imported in India before the priority date, such user will constitute a ground for epposition to the grant. While we agree with the principle behind this provision, we submit that importation of the products to constitute a ground of opposition should be clarified so as to exempt all imports made by the inventor or any other person for the purpose of reasonable trial and experiment. In fact, this principle has been recognised by the Government as evidenced by the proviso to clause 29(2)(b) which has excluded the working of the invention for purpose of reasonable trial as being made a ground of anticipation. It is submitted that a suitable explanation be added to the proviso. The explanation may read as "Provided that for the purpose of this sub-clause no account shall be taken of any use of the invention by way of importation before the priority date of the claim if such use is made for the purpose of reasonable trial or experiment only".

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Clause 47(1)

For greater clarity, we suggest that the word "import" should be inserted before the word 'use' in sub-clause (a) and the word 'importing' before the word 'using' in sub-clause (b). This will elarify that the patentee has also the exclusive right to import the patented articles or articles made by a patented process.

It is also suggested that in a case where the "product by process" patent results in a new product, the burden of proof in an action for infringement based on such patent, should be on the person charged with infringement; he must prove that the process used by him does not infringe the patented process. Under the law, as it stands today, the burden to prove that the defendant has used one of the patented processes, is on the patentee and this burden is exceedingly difficult to discharge in as much as, there are obvious difficulties in obtaining an access to the defendant's Plant. This difficulty becomes almost insuperable in a case where the defendant is a mere importer of a product from abroad. In such a case, it is almost impossible to have access to the Plant of the manufacturer abroad for the purpose of ascertaining the precise process by which the imported product had been manufactured.

The defendant would still have an opportunity of proving that the process used by him is outside the scope of the patent (if that be a fact) and, thus, there is no infringement involved. An innocent defendant would thus be adequately protected.

Clause 48

This provides for the importation, use, etc. of any patented article and the use, etc. of any patented process by or on behalf of the Government for its own use and for the importation of patented drug for use in Government hospital, etc. without any payment to the patentee and without any appeal. While this is justifiable for experimentation or research and for the imparting of instructions to pupils as provided in sub-clause (d), in other respects this amounts to a pro tanto nullification of the patent. We suggest that provision should be made for reasonable payment to the patentee

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and that the Government's decision should be subject to appeal. Only when it is necessary or expedient in public interest such as epidemics etc., Government should exercise its right to authorise importation by a private hospital, dispensory, or other medical institution.

Our specific comment on sub-clause (c) is that the power to Government to authorise the making of a patented machine, apparatus or other article for the use of a person who may be specially authorised for the purpose is too wide. It should be clarified that even such a person will be authorised to make the machine, apparatus or other article or use a patented process essentially for Government purpose and not for the purpose of commercial competition to the detriment of the patentee.

Clause 53

The period of protection varies in other countries from 14 years to 20 years. In no country it is as little as 10 years without an accompanying provision for renewal in certain circumstances. We do not believe that there is an adequate case for making a distinction so far as the period of protection is concerned between drugs and foods on the one hand and the rest of the patents on the other. A rigid period of 10 years for the former, which does not take into account special circumstances in which renewals may be necessary, will operate too harshly against the patentees. If it is not possible to apply a uniform period of 14 years, the shorter period should commence not from the date of the application but from the date of its acceptance by the Controller. Adequate provision should also be made for the extension of the period of protection in such cases by two periods of two years each. This will enable the appropriate authority to review the nature and extent of the exploitation of the patent and the national interest it has served or failed to serve and then decide whether a case has been made out for extention. It is also our submission that a shorter period of protection should only apply prospectively and not to the patents which are already in force. This principle has already been recognised in the Bill by providing that (1) in respect of patents other than those mentioned in sub-clause (a) the period of patent is as under the existing law and (2) where the period of patent has been extended, the

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patent will continue to be in force until the expiry of the extended period even though the total period of protection may thus exceed the limits now imposed. If this principle is applicable in respect of patents other than those mentioned in sub-clause (a) and to extensions already granted; it should be equally applicable to the original period of protection granted under the existing law.

Clause 66

This clause enables the Government to revoke any patent if it considers that it is mischievous to the State or generally prejudicial to the public.

The generality of these phrases calls for comment. The patentee is to be given 'an opportunity to be heard' but it does not say by whom.

It is submitted that a patent duly granted should not be revoked without due process.

Matters 'mischievous to the State' or 'prejudicial to the public' should not be left to the unfettered opinior of a Government department.

Clause 84

Under the existing law, the Controller's decisions are subject to appeal to the High Court. This right of appeal is now proposed to be substituted by an appeal to the Central Covernment. It is our submission that appeal from one executive arm of the Government to another tend to be illusory and we would strongly urge that the existing provision for appeals to the High Court should be continued.

Clause 87

Under the existing law, the Central Government has a right under certain conditions to apply to the Controller for any patent to be endorsed with the words "licence of right". In the normal circumstances, this provision should adequately take care of any special needs in the fields of drugs and foods and no automatic endorsement should be provided for as in clause 87.

The effect of the **ond**orsement "licence of right" is that any person (irrespective of his suitability) has a right to exploit a patent on his

agreeing to pay a royalty which is limited by clause 88 to a maximum of 4%. It will be noticed that in the provisions for compulsory licensing, the Controller has the power to enquire into the suitability of the applicant for a licence whereas in the case of medicines, drugs and foods, neither the technical and financial suitability of the person nor the motives in his wishing to exploit the invention can be enquired into by the Controller.

One should have thought that in the vital field of drugs, medicines and foods, it is even more necessary that the person, who exploits the invention, does so with public interest at heart and not merely for the sake of making quick gains at the expense of reliability and quality. It is our suggestion, therefore, that this automatic right to get a licence should be limited to the extent to which it should be open to the Controller to enquire into the suitability of the applicant. In this context, it will be useful to quote from Justice Ayyangar's Report (vide page 233) -"as this class of inventions touch public health, it is very necessary that there should be a guarantee that persons who are permitted to work the inventions are those who are qualified to work them honestly and effectively.........."

Clause 88(5)

Under the existing law the royalty payable to non-residents for exploitation of patents comes up for consideration by Government at a very senior level. It is our submission that the fixation of a cealing introduces an unnecessary rigidity in a matter which should best be left to the discretion of the appropriate wing of the Government on the merits of each case. While the primary purpose may have been to contain the foreign exchange outgoing, any rigid cealing is also likely to discourage the Indian Inventor.

We are, therefore, strongly of the opinion that each case of royalty should be decided on its merits without the imposition of any general cealing. Clause 90

We are not clear as to what is the precise meaning of the phrase "default" of the patentee to manufacture in India" in sub-clause (a). We assume that the consequences of revocation will only follow if the patentee has failed to manufacture the article to an adequate extent in India on insufficient grounds so that if the failure to manufacture either as a result of lack of commercial feasibility or because the invention relates to a matter for which the state of the Indian economy is not yet ripe, the penalty of revocation will not be imposed. This can be illustrated by

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inventions relating to the manufacture of T.V. sets which obviously cannot be done unless they are accompanied by broadcasting and other facilities.

By sub-clause (d)(iii) the reasonable requirements of the public shall be deemed not to have been satisfied if the patentee is not taking or has not taken proceedings for infringement. The patentees failure to institute infringement proceedings may be wilful or inadvertent. In some cases, he may not even be aware of the infringement. We submit that inadvertent failure on the part of the patentee to institute infringement proceedings should be outside the scope of this sub-clause.

Clause 93(3)

Where a compulsory licence is granted under Clause 84, the Controller may deprive the patentee of his right to use, etc., the invention or to grant any licence under it and may revoke all existing licences. There seems no justification for penalising the patentees in this drastic manner.

Any appeal against the order of the Controller should lie to a Judicial Tribunal instead of to the Central Covernment.

Clause 95(3)

We are assuming that a patentee has an exclusive right to import either a patented article or an article made by the patented process and this would be clarified by a suitable amendment to Clause 47. It seems to us that while it is reasonable that in the normal circumstances no compulsory licence should be granted by the Controller for the import of a patented article or an article made by the patented process, it is unreasonable that if the Government authorised such import in the public interest, no royalty should be payable on such use of the patent to the patentee.

The Government has powers under Clause 48 to import for its own use or for the use of dispensaries and hospitals. This being so, it is only fair that any import on broader considerations of public interest (such as shortage of a particular article) should be undertaken only against payment of suitable compensation to the patentee. Clause 96

A patentee's right to get a compulsory licence of someone else's patent should only arise if his invention is significant and not only trivial or frivolous merely to obtain access to the main patent. In this connection, we would recommend to the consideration of the Committee the model clause prepared by B.I.R.P.I. -

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"(2) For the purpose of sub-section (1) above the Controller shall not grant a licence unless he is satisfied that such other patented invention serves industrial purpose different from those of the invention forming the subject of the earlier patent, or constitutes noteworthy technical progress in relation to it."

We would also urge that sub-clause (5) should provide for a right of appeal to a Judicial Tribunal.

Clause 97

An appeal should lie to the Judicial Tribunal instead of to the Central Covernment as now provided in sub-clause (3).

Clause 99

We have already submitted in our comments on clause 2(h) that the definition of 'Government undertaking' should be restricted by excluding Corporations established by Government and Government companies.

As for clause 99(1), the use of inventions for the purpose of Government is extended to any "class or classes of industry" in the private sector which may be notified by the Central Government "having regard to the interests of the general public". There is no limitation whatsoever on what industries willbe included nor an indication of the circumstances. This gives to the Government sweeping general powers to give patent rights to persons who had otherwise no entitlement.

Clause 100

Our comments about the restrictive scope of the term 'Government undertaking' and too wide general powers to Government under clause 99 also apply to this clause. We would also suggest that the use of an invention for the purpose of Government should be limited to certain specified purposes as far as Defence, or Epedimics or some such similar public purpose in an Emergency, are concerned. We believe that the right to the use of patents for purposes of Covernment restricted as suggested by us together with provisions of compulsory licensing should adequately meet national interest.

Clause 102

This clause enables the Government to acquire compulsorily all the patent rights of an applicant or patentee in a particular invention 'if satis-fied that it is necessary.... for a public purpose'. This is effected by a mere publication of a notice and the only appeal is on the amount of compensation (clause 103(1)).

The note on the clause merely explains that it might be more economical to acquire the patent instead of a compulsory licence.

In line with our comment on clause 100, we would suggest that here again, the acquisition should be limited to purposes of Defence, Epidemic or similar public purpose in an Emergency.

Preface

1. The Indian Pharmaceutical Association is the premier national association representing the profession of pharmacy. Its membership, numbering over 3600, consists of persons having technical qualifications in the fields of pharmacy, science, medicine, etc. and engaged in teaching, research, industry, Drugs Control, retail pharmacy, etc. The Association is a non-profit organization devoted primarily to the advancement of the profession of pharmacy and secondarily to all matters affecting the profession, namely, education, pharmaceutical industry, trade, etc. It is from this point of view that the Association desires to submit the following memorandum in which attention is mainly directed to patents for inventions relating to pharmaceutical and medicinal substances.

2. The essential principles that should be borne in mind in any consideration of payents are the following :

"The theory upon which the papent system is based is that the opportunity of acquiring exclusive rights in an invention stimulates technical progress in four ways: first, that it encourages research and invention; second, that it induces an inventor to disclose his discoveries instead of keeping them as a trade secret; third, that it offers a reward for the expenses of developing inventions to the stage at which they are commercially practicable; and fourth, that it provides an inducement to invest capital in new lines of production which might not appear profitable if many competing producers embarked on them simultaneously. Manufacturers would not be prepared to develop and produce important machinery if others could get the results of their work with impunity." (Second Interim Report of the Swan Committee, para 9.)

3. Taking a global view, it should be admitted that the abovementioned objectives have, by and large been served for the purpose of promoting the development of new medicinal substances. The proof for this lies in the fact that the most significant inventions in the medicinal field have been made only in those countries like the U.S.A., U.K., Switzerland, Germany, etc. where the laws conferred adequate patent protection, but not in countries such as Italy and U.S.S.R. where patent protection did not exist for this eless of inventions or it was very weak.

4. From a national point of view, however, the benefits of the patent system available to under-developed or developing countries are limited to the extent that such countries cannot claim new inventions since they do not have flourishing industries equipped with vigorous research laboratories which are the essential pre-requisites for inventions. Nevertheless, they do need the import of technological know-how and the investment of capital in new ventures, both of which require the stimulus provided by effective patent protection. In developing countries, therefore, a judicious compromise should be made between effective patent protection and measures to safeguard against possible abuse of such protection to the detriment of the development of indigenious industries.

5. Foods and medicines are essential for the health and well-being of the entire population and they should be available to the public easily and at reasonable prices. It is conceded, therefore, that the patent law should contain special provisions regarding foods and medicines. But they should not lead to the weakening of the patent protection to the extent of defeating the very purpose of the patent system.

6. Viewed in this light, the present Patents Bill is to be welcomed as a desirable reform but it contains clauses which individually or collectively lead to the virtual negation of patent protection to newer medicinal substances. The Association is of the opinion that some of these clauses should be deleted while others should be suitably amended.

Patent Rights

7. Clause 48 provides that import of medicines or drugs or medical equipment by the Government for its own purpose or the production of a patented article by the Government for its own use shall not be regarded as an infringement of patent rights. This clause grants to the Government ullimited powers without any process of law or due compensation and, therefore, defeats the fundamental principles of the patent system (see also remarks on clauses 99, 100 and 102). Justice Ayyangar (p. 73 of his report) has assumed that reasonable compensation would be payable in any case of Government use.

Term of Patent:

8. Clause 53 provides that the term of a patent for inventions of food or medicine shall be 10 years while it is to be 14 years for other classes of patents. The proposed term is too short to allow reasonable benefits to the patentee. A patent application is filled as soon as some promising clinical results are obtained, but more intensive studies should be carried out for 2 to 4 years before the health authorities of the country give clearance to a new drag. Another 2 or 3 years are required for obtaining an industrial licence, import licences etc. and for commencing manufacture. It is often likely, therefore, that 5 to 7 years will elapse before the patentee can expect to start deriving benefit from his invention. The effective period of patent protection is thus reduced to about 4 or 5 years if the term of the patent is 10 years. Since the law provides other safeguards by way of compulsory licensing etc., there is no real need for discriminating against pharmaceutical inventions in the matter of the term of the patent. It is suggested that the present term of 16 years be retained for all closses of patents.

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Imports

9. Sub-clause 3 of clause 95 of the Bill empowers the Government to authorize any licensee to import the patented article from abroad on some undisclosed terms and conditions. There is no mention of payment of any royalty or compensation to the patentee. The patent system in general and the compulsory licensing provisions in particular (see clauses 83 and 94 of the Bill) aim at promoting the working of the patented process within the country. Importation, on the other hand, will hinder such working. Therefore, this sub-clause should be deleted.

Government Use

10. Clauses 99, 100 and 102 of the Bill empower the Government, by mere notification, (i) to authorize not only Government Departments but also Government undertakings or any undertakings to Lake use of a patented invention for purposes of the Government, (ii) even to acquire the invention outright for Government use. These clauses are too wide in scope and would lead to serious erosion of patent rights. They should be revised so as to restrict such use to some specific purpose such as for defence or in an unusual emergency. There is no need to extend it to public sector undertakings because, being commercial concerns, it is more appropriate that they too apply for compulsory licences, just as any other undertakings is required to do.

Appeals

11. Clause 116 denies the right of appeal to a court of law in respect of certain orders issued by the Government or the Controller. This is contrary to the democratic principles and the rule of law that form the basis of our country's constitution. It is particularly unjust since, in many cases a Government Department or undertaking may be one of the contestants. If the idea is to do away with the vexatious delays and heavy expenses of the usual court procedures, the desired reform can be effected without sacrificing espential principles, by providing for a special judicial patents tribunal and by fixing time limits for its decisions on specific matters.

General

12. There are some other clauses in the Bill which go counter to the well considered opinions of Justice Ayyangar. These clauses should be amended in accordance with recommendations made by Justice Ay/angar in his morimental report.

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MEMORANDEM

by

CURT ENGELHORN

to

JOINT COMMITTEE OF PARLIAMENT

on the PATENTS BILL 1965

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I am grateful to have the opportunity of submitting a memorandum on behalf of the Bundesverband der Pharmazeutischen Industrie (Association of the German Pharmaceutical Industry) to the Joint Committee of Parliament on the Patents Bill 1965, since we are observing with concern the grave limitations to the protection of the inventor contained in the present Draft. Adequate protection of industrial and intellectual property is, in our opinion, of the greatest importance for international economic relations and must be considered as important as the protection of other rights whether they pertain to property or privileges resulting from duly and properly executed agreements of an official or private nature.

The Bundesverband der Pharmazeutischen Industrie and its members have carefully examined the pending Patents Bill 1965 (Bill No. 62) and the deliberations which led to it. It is our considered opinion that the Bill in its present form would have a most harmful effect on inventors in India and abroad. It would therefore quite generally tend to adversely influence the overall economic advancement of India and, with that, the welfare of its people. We will try to show that the Bill contains several provisions which would, in practice, lead to a complete abolition of rights deriving from patents, especially in the field of pharmaceutical inventions.

The development of valuable drugs of sufficient inventive standing to be worthy of being protected by patents was in almost every case the result of a major long term and expensive research effort. The record shows that the major burden of this effort has been carried and the greatest successes have been achieved by private industry as compared to state institutions. Industry and inventors not supported by public funds are forced, however, to recover the money expended on research. It is evident, furthermore, that the development of new drugs is becoming steadily more expensive and time consuming. It was also pointed out already to the Committee by means of memoranda that there is no field of industrial activity in which more skill, time and money are spent than upon pharmaceutical research. It would be impossible for private industry to take upon itself this tremendous burden if there were not at least the possibility of obtaining protection, albeit of a temporary nature only, for those investigations crowned with success. Diminishing the patent protection must therefore be of major concern to the pharaceutical industry.

The patent protection granted by India heretofore has been satisfactory in principle from our point of view. We believe, on the other hand, that we, to a large part, have a grasp of the reasons that have led to criticism and to the attempt to cope with this criticism by changing the Indian Patent Law. We believe, however, that the changes in their present form tend to create more problems than they solve - the most important reason for our effort. We are also aware of the important role that India plays in the community of nations and are therefore concerned about the harm that could be done.

Specifically, we would like to submit our opinion to the following clauses of the Patents Bill:

Section 47

As a consequence of denying the patentability of inventions relating to substances intended for use as medicines or drugs, this clause provides that patent protection for a process imparts protection to the product produced by such process. However, we believe that the product should be protected as such. A corresponding clause of our own German Patent Law is being actively prepared. Process protection only is, however, provided for in many Patent Laws including our present law, that of Japon, Switzerland, Austria, and many others. Without shift of the burden of proof which is also provided in these laws, process protection is , however, without meaning. A shift of burden of proof is not provided for in the Indian Patents Bill. In practice, this would mean that it would be impossible to effectfully prevent infringements since the infringement cannot be proved. In agreement with approved patent principles, a subclause should be added pointing out that where a process results in a new product, that product should be prima facie considered to be produced by the protected process unless proven to the contrary.

Section 48

This section allows the Government or anyone on its behalf to import medicines or drugs for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or any other dispensary, hospital or other medical institution which may be specified by the Central Government in this behalf by notification in the Official Gazette without such importation being deemed to constitute an infringement. Not only is the patentee deprived of any remuneration, he furthermore has no possibility of appealing.

Such regulation, which amounts to a nullification of the patent, appears to be in disagreement with the fundamental concept of industrial property and is unknown elsewhere in foreign patent law. The German pharmaceutical industry therefore recommends that this section be deleted.

Section 53

This section provides that the term of patents relating to medicines and drugs shall be 10 years from the date of filing of the complete specification, differing from the term of 14 years for other patents.

It has to be pointed out, however, that the development and the clinical trials for new drugs take longer than ever before. In order to carry out the necessary pharmacological, toxicological, and clinical work to ensure safety and efficacy of a new drug, a <u>minimum</u> of 3 years is required today. In practice, the period today is 6 years on an average, and cases are on record where it took more than 10 years to develop important new drugs beginning from the time when a patent application could be filed.

The Bill discriminates against inventions in the pharmaceutical field. We fail to see any compelling reason for such discrimination against the valuable contributions of pharmaceutical research.

We recommend therefore that section 53 subclause 1 (a) be deleted and consequential amendments be made in section 53 subclause 1 (b) so that the term of a patent granted on any invention is the same. We also feel that the shortening of the life of patents should not be retroactive.

Section 66

This section enables the Government to revoke any patent if it considers that it is mischievous to the state or generally prejudicial to the public. No indication is given, however, as to what act or omission is deemed mischievous or prejudicial to the public. This section should thus be modified so as to limit the generality of these statements and to clearly define the Government's powers ensuring that a patent is revoked only under certain specified circumstances. Furthermore, we submit that a possibility of recourse to a judicial tribunal by way of appeal against the decision of the Government should be granted to the patentee.

Section 87 and 88

These sections provide that patents relating to foods, medicines, and drugs shall automatically be endorsed with the words "Licence of Right" upon sealing and furthermore enable any person to apply to the patentee for a licence on such terms as may be mutually agreed upon or decided by the Controller, the licence under no circumstances exceeding 4 % of the net ex-factory sale price in bulk.

No principle objection is made against regulations providing for compulsory licences on fair terms if this should be in the well-defined public interest. Adequate compulsory licence conditions have, in our opinion, been clearly set out in the Paris Union. These are the conditions which are followed by a great number of countries.

Endorsing a licence in the pharmaceutical field automatically with the words "Licence of Right", constitutes a serious discrimination as compared to patents in other fields for which we fail to see compelling reasons.

The same pertains to fixing a royalty ceiling. For judging the meaning of this royalty ceiling, it must be pointed out that the ex-factory bulk price of an active ingredient in a drug can be very low as compared to the final price of the finished drug suitable for medicinal application. In such cases, the inventor would have no significant income from such royalty, particularly as such income is not tax exempt.

Section 93 (3)

This section empowers the Controller to deprive the patentee of any right which he might have as patentee to make, use, exercise or sell the invention or to grant licences under the patent as well as to revoke all existing licences in respect of the invention. In our opinion, such regulation goes far beyond any measure reasonably necessary for the safeguard of the public interest. The provision appears quite unfair to the inventor since it would deprive him of using his own invention, would destroy the existing contractual licences and would in that way put the inventor and his licencees in a position worse than any other person. As a matter of fact, he would have been better off, had he not applied for a patent at all. We therefore submit that this subclause be deleted.

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This section enables the Government to direct the Controller to authorise licencees to import the patented article or an article made by the patented process if in its opinion it is necessary to do so in the public interest. Neither the payment of any royalty nor an appeal have been provided for. This provision appears also incompatible with the ordinary principles of patent law and should therefore be deleted.

This section would furthermore appear to be against the fundamental interests of the Indian home industry as, rather than encourage the building up of this industry by requiring that manufacture be effected within the country, it competes or stifles the Indian industry by allowing importation.

It is our opinion that the Patents Bill in its present form discriminates against the inventor in favour of such parties who could reap the harvest without having contributed anything. This includes the danger that knowledge and know-how available to the inventor only would not be transmitted to other parties. The result would be that drugs manufactured with insufficient information and know-how would be substandard and possibly dangerous and unnecessarily expensive. The danger also exists that such drugs would be applied without full knowledge of their characteristics.

We believe that the quick introduction of safe, modern drugs, developed in foreign countries, is best served by fair treatment of the inventor and inducing him to transmit his full knowledge. Quite generally it may be said that the patent law was conceived as an instrument

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to encourage full disclosure of new inventions as early as possible for the benefit of the general public. Effective patent laws have fulfilled this task extremely well, while the experiences with ineffective laws have been poor, a fact already explained to the Committee in other memoranda.

It has been our impression that India is interested in foreign investments generally and of the pharmaceutical industry in particular. for such investment, inducement has to be given. The simplest, most straightforward and most widely used inducement is that of financial compensation. We regard compensation for important inventions by way of royalties as one of the most valuable inducements from any point of view. We are therefore quite concerned that India wants to deprive herself of this instrument.

We are also aware of the interest displayed by the Indian Government in building up production facilities. We believe that the Bill in its present form will discourage severely any such plans. We also are of the opinion that investments by the most productive companies doing a substantial amount of research are particularly discriminated against and that discouragement is commensurate.

It is understandable that India with its large and rapidly increasing population should desire to avail herself of drugs at the lowest possible prices. It is furthermore understandable that India will undertake all necessary efforts to achieve this goal. Undoubtedly, were this goal to be achieved by the abolition or restriction of patent protection, India would avail herself of this measure, even if this would necessitate sacrificing to a substantial extent pharmaceutical research and industrial investment in India. We are convinced, however, that the matter is not so simple and restriction or even abolishment of patent protection would not have the effect of substantially lowering the prices of drugs. If patent protection were the sole or even the major factor in keeping drug prices high, then surely the prices of all drugs would necessarily fall drastically once the relative patents have expired. The fact that this is not so, has already been shown to this Committee even for cases where patent protection expired many years ago.

Certainly the Indian Government is aware of the economic advantages of most new drugs. Antibiotics, chemotherapeutics, psychotropic drugs and many other categories are not only life-saving in part but they also reduce hospital care and the duration of other treatments drastically. The cost of such drugs is generally incomparably lower than the savings realised by their effectiveness.

In concluding, we should like to substantiate our arguments by drawing attention to the course of events in the Federal Republic of Germany. You will remember the impoverished state in which Germany found herself after her defeat in World War II. Most of industry had been destroyed and there appeared to be no hope of recovery. Within the very few years which have elapsed since then, we have succeeded in reviving our economic and technological development to such an extent that it is now comparable with those countries whose industries suffered no set-backs. As a result of the lost war, German patents were expropriated in almost all foreign countries. After regaining sovereignty, it would have been very tempting to retaliate by expropriating foreign patents in Germany in order to support re-building of the destroyed industries. It was realised very soon, however, that such patent expropriation would not further this cause, but that stimulating new inventions in Germany and the use of foreign inventions would be better. Results confirm the wisdom of this decision.

On the basis of these submissions, we respectfully urge that the Joint Committee of Parliament refuse to approve the Patents Bill of 1965 in its present state as this Bill contains sections that are unique, one-sided, and far more drastic than those contained in the Patent Law of any other country.

It is our suggestion that the Committee recommend, in the interest of India, the acceptance of a Patents Law accrediting the inventor the protection due to him and not discriminating between any fields of research. Such Patent Laws have over the years proved beneficial to numerous countries, including our own, and we can say in all sincerity that it is undoubtedly an important reason that the German pharmaceutical industry has flourished.

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Mannheim, May 25th, 1966.

BUNDESVERBAND DER PHARMAZEUTISCHEN INDUSTRIE E.V.

DER VORSITZENDE

The Secretary Lok Sabha Secretariat Parliament House

New Delhi

India

FRANKFURT AM MAIN

May 25th, 1966 /le

Patents Bill 1965

Dear Sirs,

We have been informed that the Joint Committee of Parliament intends to continue in July its deliberations on the Patents Bill (Bill No. 62) introduced in Parliament on September 21st, 1965. Considering the fact that this Bill is causing great concern and anxiety amongst many people both in India and abroad, including our member firms, we take the liberty of herewith submitting a statement setting forth some views to the proposed legislation. We furthermore respectfully request permission to send Mr. Curt Engelhorn to personally present additional comments to the Committee.

The Bundesverband der Pharmazeutischen Industrie (Association of the German Pharmaceutical Industry) officially represents the entire drug industry of the Federal Republic of Germany, comprising about 600 large, medium and smaller firms producing chemicals and drugs. Main task of the Bundesverband is to give expert advice to the government and parliament of the Federal Republic of Germany in connection with legislative measures in the pharmaceutical field, to counsel member firms in technical and scientific questions and to safeguard their common economic interests.

Mr. Engelhorn is the president of our Association since 1964. He is part-owner and president of the C.F. Boehringer & Soehne GmbH., a company manufacturing drugs of the highest reputation and heavily engaged in research. In 1959, the enterprise headed by Mr. Engelhorn also established a production plant in India (Boehringer-Knoll Ltd.), where now more than 350 men are working, and an extension of which is planned.

In his testimony, Mr. Engelhorn will cover the points outlined in the attached memorandum and state in detail

- that the inventive work of all research-based industries must be encouraged by strictly ensuring patent rights and that the pharmaceutical industry needs at least the same encouragement, incentive, and security as other areas contributing to the national economy,
- that any restriction of patent rights tends to be most harmful not only to the research-based industry in India and abroad, but also to the Indian economy and thus be detrimental to the Indian people,
- that there are no compelling reasons for such far-reaching restrictions of patent protection, the government having sufficient means at its disposal to adopt adequate steps under existing legislation to prevent abuses.

We consider it of the utmost importance in the mutual interest that the opportunity be provided for Mr. Engelhorn to enlarge upon these views in person. We shall appreciate the favour of an early reply of the Committee.

Yours respectfully,

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Specifically, we would like to submit our opinion to the following clauses of the Patents Bill:

Section 47

As a consequence of denying the patentability of inventions relating to substances intended for use as medicines or drugs, this clause provides that patent protection for a process imparts protection to the product produced by such process. However, we believe that the product should be protected as such. A corresponding clause of our own German Patent Law is being actively prepared. Process protection only is, however, provided for in many Patent Laws including our present law, that of Japon, Switzerland, Austria. and many others. Without shift of the burden of proof which is also provided in these laws, process protection is , however, without meaning. A shift of burden of proof is not provided for in the Indian Patents Bill. In practice, this would mean that it would be impossible to effectfully prevent infringements since the infringement cannot be proved. In agreement with approved patent principles, a subclause should be added pointing out that where a process results in a new product, that product should be prima facie considered to be produced by the protected process unless proven to the contrary.

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Section 48

This section allows the Government or anyone on its behalf to import medicines or drugs for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or any other dispensary, hospital or other medical institution which may be specified by the Central Government in this behalf by notification in the Official Gazette without such importation being deemed to constitute an infringement. Not only is the patentee deprived of any remuneration, he furthermore has no possibility of appealing.

Such regulation, which amounts to a nullification of the patent, appears to be in disagreement with the fundamental concept of industrial property and is unknown elsewhere in foreign patent law. The German pharmaceutical industry therefore recommends that this section be deleted.

Section 53

This section provides that the term of patents relating to medicines and drugs shall be 10 years from the date of filing of the complete specification, differing from the term of 14 years for other patents.

It has to be pointed out, however, that the development and the clinical trials for new drugs take longer than ever before. In order to carry out the necessary pharmacological, toxicological, and clinical work to ensure safety and efficacy of a new drug, a <u>minimum</u> of 3 years is required today. In practice, the period today is 6 years on an average, and cases are on record where it took more than 10 years to develop important new drugs beginning from the time when a patent application could be filed.

The Bill discriminates against inventions in the pharmaceutical field. We fail to see any compelling reason for such discrimination against the valuable contributions of pharmaceutical research.

We recommend therefore that section 53 subclause 1 (a) be deleted and consequential amendments be made in section 53 subclause 1 (b) so that the term of a patent granted on any invention is the same. We also feel that the shortening of the life of patents should not be retroactive.

Section 66

This section enables the Government to revoke any patent if it considers that it is mischievous to the state or generally prejudicial to the public. No indication is given, however, as to what act or omission is deemed mischievous or prejudicial to the public. This section should thus be modified so as to limit the generality of these statements and to clearly define the Government's powers ensuring that a patent is revoked only under certain specified circumstances. Furthermore, we submit that a possibility of recourse to a judicial tribunal by way of appeal against the decision of the Government should be granted to the patentee.

Section 87 and 88

These sections provide that patents relating to foods, medicines, and drugs shall automatically be endorsed with the words "Licence of Right" upon sealing and furthermore enable any person to apply to the patentee for a licence on such terms as may be mutually agreed upon or decided by the Controller, the licence under no circumstances exceeding 4 % of the net ex-factory sale price in bulk.

No principle objection is made against regulations providing for compulsory licences on fair terms if this should be in the well-defined public interest. Adequate compulsory licence conditions have, in our opinion, been clearly set out in the Paris Union. These are the conditions which are followed by a great number of countries.

Endorsing a licence in the pharmaceutical field automatically with the words "Licence of Right", constitutes a serious discrimination as compared to patents in other fields for which we fail to see compelling reasons.

The same pertains to fixing a royalty ceiling. For judging the meaning of this royalty ceiling, it must be pointed out that the ex-factory bulk price of an active ingredient in a drug can be very low as compared to the final price of the finished drug suitable for medicinal application. In such cases, the inventor would have no significant income from such royalty, particularly as such income is not tax exempt.

Section 93 (3)

This section empowers the Controller to deprive the patentee of any right which he might have as patentee to make, use, exercise or sell the invention or to grant licences under the patent as well as to revoke all existing licences in respect of the invention. In our opinion, such regulation goes far beyond any measure reasonably necessary for the safeguard of the public interest. The provision appears quite unfair to the inventor since it would deprive him of using his own invention, would destroy the existing contractual licences and would in that way put the inventor and his licencees in a position worse than any other person. As a matter of fact, he would have been better off, had he not applied for a patent at all. We therefore submit that this subclause be deleted.

Section 95 (3)

This section enables the Government to direct the Controller to authorise licencees to import the patented article or an article made by the patented process if in its opinion it is necessary to do so in the public interest. Neither the payment of any royalty nor an appeal have been provided for. This provision appears also incompatible with the ordinary principles of patent law and should therefore be deleted.

This section would furthermore appear to be against the fundamental interests of the Indian home industry as, rather than encourage the building up of this industry by requiring that manufacture be effected within the country, it competes or stifles the Indian industry by allowing importation.

It is our opinion that the Patents Bill in its present form discriminates against the inventor in favour of such parties who could reap the harvest without having contributed anything. This includes the danger that knowledge and know-how available to the inventor only would not be transmitted to other parties. The result would be that drugs manufactured with insufficient information and know-how would be substandard and possibly dangerous and unnecessarily expensive. The danger also exists that such drugs would be applied without full knowledge of their characteristics.

We believe that the quick introduction of safe, modern drugs, developed in foreign countries, is best served by fair treatment of the inventor and inducing him to transmit his full knowledge. Quite generally it may be said that the patent law was conceived as an instrument

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to encourage full disclosure of new inventions as early as possible for the benefit of the general public. Effective patent laws have fulfilled this task extremely well, while the experiences with ineffective laws have been poor, a fact already explained to the Committee in other memoranda.

It has been our impression that India is interested in foreign investments generally and of the pharmaceutical industry in particular. for such investment, inducement has to be given. The simplest, most straightforward and most widely used inducement is that of financial compensation. We regard compensation for important inventions by way of royalties as one of the most valuable inducements from any point of view. We are therefore quite concerned that India wants to deprive herself of this instrument.

We are also aware of the interest displayed by the Indian Government in building up production facilities. We believe that the Bill in its present form will discourage severely any such plans. We also are of the opinion that investments by the most productive companies doing a substantial amount of research are particularly discriminated against and that discouragement is commensurate.

It is understandable that India with its large and rapidly increasing population should desire to avail herself of drugs at the lowest possible prices. It is furthermore understandable that India will undertake all necessary efforts to achieve this goal. Undoubtedly, were this goal to be achieved by the abolition or restriction of patent protection, India would avail herself of this measure, even if this would necessitate sacrificing to a substantial extent pharmaceutical research and industrial investment in India. We are convinced, however, that the matter is not so simple and restriction or even abolishment of patent protection would not have the effect of substantially lowering the prices of drugs. If patent protection were the sole or even the major factor in keeping drug prices high, then surely the prices of all drugs would necessarily fall drastically once the relative patents have expired. The fact that this is not so, has already been shown to this Committee even for cases where patent protection expired many years ago.

Certainly the Indian Government is aware of the economic advantages of most new drugs. Antibiotics, chemotherapeutics, psychotropic drugs and many other categories are not only life-saving in part but they also reduce hospital care and the duration of other treatments drastically. The cost of such drugs is generally incomparably lower than the savings realised by their effectiveness. In concluding, we should like to substantiate our arguments by drawing attention to the course of events in the Federal Republic of Germany. You will remember the impoverished state in which Germany found herself after her defeat in World War II. Most of industry had been destroyed and there appeared to be no hope of recovery. Within the very few years which have elapsed since then, we have succeeded in reviving our economic and technological development to such an extent that it is now comparable with those countries whose industries suffered no set-backs. As a result of the lost war, German patents were expropriated in almost all foreign countries. After regaining sovereignty, it would have been very tempting to retaliate by expropriating foreign patents in Germany in order to support re-building of the destroyed industries. It was realised very soon, however, that such patent expropriation would not further this cause, but that stimulating new inventions in Germany and the use of foreign inventions would be better. Results confirm the wisdom of this decision.

On the basis of these submissions, we respectfully urge that the Joint Committee of Parliament refuse to approve the Patents Bill of 1965 in its present state as this Bill contains sections that are unique, one-sided, and far more drastic than those contained in the Patent Law of any other country.

It is our suggestion that the Committee recommend, in the interest of India, the acceptance of a Patents Law accrediting the inventor the protection due to him and not discriminating between any fields of research. Such Patent Laws have over the years proved beneficial to numerous countries, including our own, and we can say in all sincerity that it is undoubtedly an important reason that the German pharmaceutical industry has flourished.

Mannheim, May 25th, 1966.

BUNDESVERBAND DER DEUTSCHEN INDUSTRIE E.V. Die Hauptgeschäftsführung

5 KÖLN 10, den January 7th, 1966 POSTSCHLIESSFACH 107 HABSBURGER RING 2-12 FERNSPRECHER: 20-811 RA 433.10

Mr. Member of the Parliamentary Select Committee on the Patents Bill New Delhi, Parliament House

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<u>Re:</u> Bill No. 62 of 1965 - "The Patents Bill, 1965"

Dear Sir,

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The Bundesverband der Deutschen Industrie, roof organization of all central industrial associations in the Federal Republic of Germany, represents the entire German industry. German industry in all of its sectors is deeply concerned about the above mentioned Bill, because its overruling tendency is to amend the existing law by restricting patent protection in an unorthodox and farreaching manner. This tendency is considered objectionable by German industry under mainly two aspects:

1) Taking into account the underlying idea of adequate protection of inventors the proposed restrictions go away beyond what can be considered justified. The granting of patent rights is usually regarded as reward for an inventive activity, an activity based on years or even decades of research work. The results of such activity are beneficial not only to the country in which the patent is applied for and worked, but to the whole world. It is therefore in the interest of international partnership to refrain from measures which endanger inventive activity.

Too rigorous a restriction of the inventor's protection would weaken the incentive for research activity, thereby hampering technical progress. Finally, a restriction of patent protection would induce industrial enterprises to keep secret their knowledge sofar made accessible to the public by disclosure of patents and know-how, and this would counteract the

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development of research which is of the greatest importance to all nations; our experience in Western industrial nations shows, that this is a valid argument in favour of granting adequate patent protection.

2) The tendency also goes beyond what in the majority of existing petent legislations in industrialized countries as well as in the developing countries is found to be the ultimate of restrictions of the inventor's rights. The "Patents Bill, 1965" deviates essentially from the patent legislations in Western countries which have been in force for a long time and have stood the test. The Bill also deviates from recommandations contained in the draft model law recently submitted by the United International Bureau for the Protection of Intellectual Property (BIRPI). The uniform patent law of the twelve African nations united in the African-Madagascan Union - and all of them can be considered to be "developing countries" - is also based on the idea of adequate patent protection. The argument that patent protection is to be found in capitelistic economic and social structures only cannot be accepted either. In the countries of the so-celled Eastern bloc we find detailed regulations of patent law which do take into account the protection of the inventor, and the majority of these countries - the UdSSR since July 1st, 1965 - by their adherence to the International Union for the Protection of Industrial Property of March 20th, 1883 manifest their willingness to guarantee the protection of patents. Finally it should be mentioned that even the wellknown discussions within UNO as well as at the occasions of the Conference on World Trade in 1964 dating back to a recommendation of the Economic Commission of the UN General Assembly in December 1961 did not entail such broadsweeping consequences as are partly contained in the "Patents Bill, 1965".

For the German-Indian relationship in particular (and probably this will just as well be true for other countries with which India has economic relations) the following must be noted: Industrial circles furnish evidence that the readiness of German industry to invest in India will slacken considerably if industrial rights, know-how etc. which go hand in hand with investments, are not adequately secured. Thus, too strong a restriction of the patent protection would prejudice the interests of the Indian economy as well as of the Indian people. If the supporters of the Bill start from the idea that the patent rights conferred to foreigners are hampering the economic development in India, it must be stated that on the contrary it was just this transfer of industrial and technical know-how that enabled India to build up a competitive industry. Furthermore, they maintain that 90% of all Indian patents are owned by foreign enterprises; in our opinion, however, this fact does not constitute an obstacle on the way to the economic development in India.

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With progressiv research activity the percentage of Indien hold patents will rise.

Bearing in mind these considerations, we should like to express in the following paragraphs our concern with regard to a number of provisions of the "Patents Bill, 1965"; we shall confine our remarks to some provisions only and deliberately not deal with the problems of particularly concerned sectors of industry, for instance of the chemical and pharmaceutical industries. We shall concentrate exclusively on aspects interesting the German industry as a whole and which by virtue of their general importance may justify the fact that we as a foreign institution submit our views to the Indian legislator, asking him to kindly examine and consider them in his future work in this field.

1) Compulsory licencing:

The particularly conditions for the granting of compulsory licences are contained in clauses 82, 83, 90, 93 par. 3, 95 par. 3 and 96 of the Bill. The legislator starts from the principle that the non-working of patents should be prevented. It seems doubtful whether the farreaching interventions planned for such cases (in particular clauses 93 par. 3 and 95 par. 3) are justified when we consider that the nonworking is often due to factors completely outside the economic field covered by patent law. The instrument of compulsory licences should therefore in these cases be employed only with the greatest care and be restricted to cases of abuse of a monopoly right. In any case the deletion of clause 95 par. 3 seems expedient, for even indigenous patent owners cannot remain indifferent to the fact that licencees will thus be allowed to import products patented in India from countries where the same article is produced without being patented.

In connection with compulsory licencing, the regulation of the "licences of right" contained in clauses 86 - 89 is also considered very unusual indeed, since this regulation implies the automatic granting of licences in favour of a third party without any motives justifying this restriction of patent protection.

2) Use of inventions for purposes of Government:

Section 48 puts the Government in a position to infringe on the rights conferred by any patent, be it by importation of patented articles, the use of patented processes or by other measures, and any such use shall not be deemed to be an infringement of the patentee's rights. This regulation which we believe to be unprecedented in the world amounts in practice to the nullification of the patent in question. In this context, clause 99 par. 2 must in particular be taken account of: None of the measures taken under clause 48 are subject to appeal; the patentee shall receive no compensation whatsoever. Here, constitutional principles are neglected which any democratic country ought to respect and to which German industry attaches particular importance.

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3) Revocation of patent in public interest:

A revocation of patent for reasons of public interest seems justifiable only in the case of <u>abuse of patent</u> and if this abuse cannot be remedied by the granting of compulsory licences. The prerequisite quoted in clause 66 "that a patent is mischievous" lacks any definition. It seems unjustified to provide for the abolition of a patent right by mere government declaration when adequate safeguards against abuse are taken elsewhere in the Act. At any rate we maintain that the application would have to be limited and specified and that due process of law must be guaranteed.

4) Term of patent:

Clause 53 generally reduces the term of patents to 14 years and the term of patents for the process of manufacture of substances to be used as medicine ar drug to 10 years. At the international level (for instance in the UN-report "The Role of Patents in the Transfer of Technology to Underdeveloped Countries", in the patent law draft of the EEC) as well as in the majority of national patent legislations a period of 18 - 20 years from the date of filing is considered to be the most satisfactory solution.

We should welcome it if our views outlined in this letter could be taken into account in the future discussion on the Bill.

> Yours very faithfully, Bundesverband der Deutschen Industrie gez. Dr. Wagner gez. Dr. Froehlich

Copy of letter dated 15th July, 1966 from Mr. Curt Engelhorn, President, Bundesverband Der Pharmazeutischen Industrie E.V. Frankfurt Am Main (West Germany), addressed to the Chairman Joint Committee on the Patents Bill, 1965.

I would like to fulfil the request of the Joint Committee for the Patents Bill 1965 by sending a comparative list of prices as mentioned by me during the hearings and on page 64 of the transcript of these hearings.

When going over the transcrip, I found that a few points need further clarification. Permit me therefore to make the following comments:

Page 77 Question of Shri Chordia:

"The initial marketing price of chloramphenicol in India was Rs. 1500 per kg. Later on it came down to Rs. 240 per kg. So, Rs. 1360 per kg. were charged more from the consumers in India. Is it justified?"

My additional answer:

" I think it is important for you and the Committee to know the actual figures.

We started production with a volume of 10 - 12 tons per year and were able to reach a cost price of somewhat more than Rs. 400 per kg, when the plant was in full production. We have expanded production in order to more completely fill the country's needs, to about 25 tons. Due to this increase in volume, our cost price dropped recently to Rs. 308 per kg. The material had been sold at prices somewhat above Rs. 500 per kg. in bulk form and in carefully controlled quality.

We were now able to reduce this price to Rs. 410 per kg, which corresponds practically to our cost price in the past.

Our wholesale price in the form of the finished medicine, which is something quite different than the bulk material, is Rs. 4.95 per 12 capsules. Please note the corresponding price to the wholesaler in Germany of DM 10.56 per 16 capsules

This sheds some light on the significance of royalties on ex-factory bulk prices. Since the patented active ingredient in bulk accounts only for a small percentage (rarely above 20%) of the finished medicine, a royalty paid on it would be of very little practical significance. My company would in such a case probably prefer to drop it completely since such an agreement would be a royalty agreement in name only."

* During his evidence on 7th July, 1966.

Page 83 From the transcript I took that the question of Shri S.N. Mishra was as follows:

> "What are the factors in Germany which are acting as a deterrent to the inventions coming to Germany? Are there any difficulties or obstacles?"

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The answer to this question must be:

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"None. There are practically no difficulties nor obstacles. For all practical purposes there is free flow of inventions into Germany."

I had misunderstood the question and answered it in regard to foreign investments.

In case you have additional questions, I would be happy to answer them.

In closing, let me assure you that we were trying to look at the Indian patent legislation mainly from the viewpoint of best interest of India, and not from that of an individual company nor an industry.

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Comparative list of prices concerning drugs marketed both in India and in the Federal Republic of Germany as furnished by -Bundesverband der Pharmazeutischen Industrie E.V. Karlstrasse 21, 6 Frankfurt (Main) (July 16, 1966)

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I. Farbwerke Hoechst AG 623 Frankfurt-Hoechst

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(Prices before devaluation)

	India DM	Germany DM	Italy DM	USA DM
<u>Avil</u> Tbl. 50mg 100' Amp. 50mg 10 x 2 ml	7,68 5,37	21,50 11,07	10,24 5,47	-
<u>Baralgin</u> Tbl. 100' Amp. 25 x 5 ml	15,36 27,58	14,1.7 26,65	18,58 33,36	- , ``
Festal Drag. 50'	4,80	5,40	5.,44	9,80
<u>Novalgin</u> fabl. 100' Amp. 10x 2 ml 5x 5 ml	11,36 6,46 5,92	10,49 6,05 6,05	11,18 5,38 5,70	
Rastinon Tbl. 100'	14,05	25,	17,77	52,82
<u>Reverin</u> i.v. 275 mg 1'	4,99	11,85	14,46	-
Hoctacvclin 250 mg K. 100'	56,73	126,35	-	-
Knoll AG 67 Ludwigchafen	<u></u>		(Prices af	ter devaluatior
and and and and a second s	India DM	Germany	Italy DM	England DM
- <u>Cardiazol-Ampullen 1.7 r</u> Sch. m. 5 Klp. m. 100	1,64 20,67	2,50 27,80	2,96	2,08
Cardiazol liquidum 10% Gl. m. 10	- 1,64	2,25	2,73	1,,85
<u>Cardiazol Tabletten</u> R. m. 10	1,33	2,25	2,56	2,04
Cardiazol-Ephedrin Tropp Gl. m. 10 ml	<u>en</u> 2,07	2,05	2,89	1,94

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	1	2	3		
Multifungin Salbe T.m. 15 g T.m. 30 g	1,33 2,23	1,70 2,55	-	-	* · •
Multifungin Puder D.m. 30 g	2,39	3,20	-	; ∠ ,	
Multifuncin Locung Gl. M. 30 ml	2,39	3,70	-	-	
<u>Cl. m. 10 g</u>	3,05	2,45	کری د منصف هارش در هم در می مورد د	e en	
Priatan Hustensaft F1. m. 150 g	2,07	2,65	-	-	-
Priatan Tabletten R. m. 10 R. m. 20 Klp. m. 250	1,72 2,99 30,48	1,85 3,20 24,30	3,65	2,59	
Soventol Amgullen 1.1ml	4,72	× 5 , 30	-	. :: 	
Soventol Gelee T. m. 20 g T.m. 50 g	1,19 2,62	2,25 3,80	2,72	1,85	
Soventol Tabletten 50 mg P. m. 10 Klp. m. 250	1,99 42,40	2,40 36,	2,56	n 2 ₁₀₀ n - 20 N ⊒ 13 - 0 Tu	
<u>"oniazo]</u> K], m. 170 g	2,92	2,95	-	- -	ι.
Veritol (moullen Sch. m. 5	2,60	1,80	2,61	-	
I. E. Merck A 1 Darmstadt	^{معدر} به بر _{الایمی}		(Prices a	fter devaluation	n)
المجلسة المسلومات المحالية المحالية الم	India Rs. DM		German y DM	am t	·
<u>Cebion Tabl.</u> 0.5 gm 10' 100'	2,65 21,20	1,41 11,30	2,80 16,20		
Cerotion Dragees 30'	9,275	4,95	5,70		ζ
Hormo-Gorobion Lragees 30'	10,60	5,65	6,85		
<u>Ilobar Ini.</u> Glaser 10 ml	6,89	3,67	5,30		

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		······. 1 .	2	3	
	Ilvico Dragees 20'	4,876		······································	
	Neurobion Amp. 3 ml 3'	14,31	7,63	8,40 🚞	
	Polybion forte Dragées 20' 100'	5,406 25,334	2,88 13,51		n na sea an
IV.	Polvbion Ampullen 2 ml 5' 25'	6,572 27,56	3,50 14,70	5,35 18,90	
	Styptobion Tabl. 10' 50'	4,293 2 0,352	2,29 10,85	2,65 11,90	
	Ultracarbon Tabl. 0,25 gm 50'	2,968	1,58	2,50	······································
	Schering AG 1 Berlin	India DM	Germany DM	(Prices aft Italy DM	er devaluation) England DM
	Allercur 20 Dragees	1,96	-	-	2,24
	Anovlar 21	3,79	5,10	9,60	5,32
	Biligrafin 30 % 5 Amp. a 20 ml 1 Amp.	17 , 30	30,80 7,90	7,39	22,69
	Biligrafin forte 5 Amp. a 20 ml 1 Amp.	32,33	43,20 11,50	10,24	35,98
	Biloptin 5 x 6 Kapseln	13,46	32,35	-	11 ,20
	<u>Solu-Biloptin</u> 1 Fl. 5 Fl.	2,99 13,46	7.65 32,35		13,16
	$\frac{D_{uogvnon}}{20 x 1 ml}$ 2 Amp.	· 25,63	6,90	6,53	· · · · · · · · · · · · · · · · · · ·
	Duogynon forte 10 x 1 ml 1 x 1 ml	25,63	6,90	• • • • •	1 m
	$\frac{\text{Duorvnon oral}}{10 \text{ x 2 Tbl.}}$ 1 x 2 Tal.	25,63 -	4,70	- 5,95	38,22

Schering AG (Continuation)	India DM	Germany- DM	JM	England DM
Endografin 5 x 10 ml 70%	28,62	39,30		-29-,-95
Gynovlar 21	3,18	-	-	3,92
Pernexin - Elixir	3,18	3,25	7,68	an a
Primodian Dep. 3 x 1 ml 1 x 1 Amp.	14,18	18,85 7,10	7 ,87	20,02
$\frac{P_{rogvnon} D_{ep.}}{3 \times 10 \text{ mg Amp.}}$ $1 \times 1 \text{ Amp.}$	9,65	3,60	5,44	19,18
Progunon C	1,09	2,	-	2,24
Proluton 3 Amp. a. 25 mg	3,66	-	5,12	-
Frolution Depot 1 x 125 mg 3 x 125 mg 1 x 250 mg 3 x 250 mg	8,53 14,81	6 ;30 - 9 , 45	8, 6 4 12,80	19,92 29,96
<u>Testoviron</u> 3 x 25 mg Amp. 20 X 20 x 50 mg	2,84 17,30 27,32	7,40 18,65 57,35	6,14	
Testoviron Depot 50 mg 1 Amp. 3 Amp. 100 mg 1 Amp. 3 Amp. 250 mg 1 Amp. 3 Amp.	9,66 16,48 39,49	5,90 15,15 8,55 21,95 15,70 38,40	5,12 7,68 16,	15,26 27,44 63,70
Urografin 60 % $5 \times 20 \text{ ml}$ $5 \times 20 \text{ ml}$ $5 \times 20 \text{ ml}$ 1 Amp./20ml	24,19 26,84	24,05 25,80 6, 3 0	8,96	32,34 35,85

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NEO-PHARMA INDUSTRIES PRIVATE LIMITED

KASTURI BUILDINGS

JAMSHEDJI TATA ROAD

FORT, BOMBAY-1.

MEMORANDUM

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1. This memorandum sets forth how the existing Patents and Designs Act has adversely affected Neo-Pharma Industries Private Limited (hereinafter referred to as Neo-Pharma Industries), of Kasturi Buildings, Jamshedji Tata Road, Fort, Bombay-1. It also includes Neo-Pharma Industries' proposal for the amendment of the said Act.

2. The Government of India in the Ministry of Commerce and Industry had under the Industries Development & Regulations Act 1951 issued an Industrial Licence No. L/22-N-140/60 dated 8th February, 1960 to Neo-Pharma Industries for the manufacture of Chloramphenicol and its Esters of the capacity of 3.6 tons per annum in collaboration with Messra. Archifar, s.r.l. Milan, Italy. Under the said Licence, Neo-Pharma Industries was required to go into production within six months from the date thereof.

3. Just about the time of grant of the Industrial Licence, Megars. Parke Davis & Company, Detroit, Michigan, USA (hereinafter referred to as Parke Davis), the alleged holders of Indian Patents in respect of Chloramohenicol served on Neo-Pharma Industries a notice that the processes Neo-Pharma Industries propose to employ in the manufacture of Chloramohenicol would involve infringement of their Patents and that they would not condone any such infringement.

4. Anxious to implement the Industrial Licence, negotiations were then started by Neo-Pharma Industries with Parke Davis with a view to the latter's granting to Neo-Pharma Industries a Licence to use the Patents in question but without success. 5. Under the circumstances, Neo-Pharma Industries had no alternative but to submit an application to the Controller of Patents and Designs, Calcutta under Section 23cc of the Indian Patents and Designs Act 1911 for a Compulsory Licence for the employment of Parke Davis' patents in the production of Chloramphenicol in India. The application was duly submitted on 29th November, 1961 and was acted upon by the Controller who advertised it in Part III of the "Gazette of India" dated 23rd December, 1961.

6. Parke pavis opposed Neo-Pherma Industries' application for Compulsory Licence and the Controller of Patents and Designs fixed 25th June, 1962 for hearing both the sides on the matter. The hearing took place on 25th, 26th and . . 27th June, 1962 at the end of which, the Controller directed Parke Davis to file their terms of licence, should such a licence be granted to Neo-Pharma Industries under their Indian Patents. Parke Davis realising the trend of proceedings, filed a petition with the Controller praying that the Controller should first decide the question whether or not any licence should be granted and if so, only thereafter he should consider the question of the terms and conditions of any licence. On 30th June, 1962, the Controller, however, dismissed that petition and ordered that Parke Davis should submit to him within six weeks from the date of the Order (30-6-1962), their terms and conditions of the licence applied for as acceptable to them in case it was decided to grant a Compulsory Licence.

7. Parke pavis did not comply with this order of the Controller. On the other hand, they

- (a) filed a petition dated 11th August, 1962 to the Controller praying that the Controller should review his own order dated 30th June, 1962 and first determine the question of whether or not any Compulsory Licence should be granted, and if so, only thereafter he should consider the question of the terms and conditions of any licence;
- (b) followed the above petition by another petition dated 25th August, 1962 praying that in the event of the

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Controller entertaining any doubt as to possession of jurisdiction to consider or to entertain a petition for review of his own order, then an opportunity upon due notice be afforded to the parties to be heard in such connection.

8. The Controller of Patents and Designs, by his letter dated 29th August, 1962 informed Parke Davis that he cannot entertain their abovementioned two petitions for the reason that there is no provision in the Patents Act, 1911 and Rulles made thereunder empowering the Controller to review his own orders and fixed 14th September, 1962, to hear both parties in connection with the licence applied for.

9. Before 14th September, 1962, however, Parke Devis filed another petition dated 12th September, 1962, with the Controller praying that the Controller should

- (a) review his own order dated 29th August, 1962;
- (b) fix a date on due notice for hearing of the parties in relation to their petition for review; and
- (c) hold over the hearing fixed for 14th September, 1962, concerning the terms of the licence until such time as the petition dated 12th September, 1962 is heard.

10. The Controller of Patents and Designs by his letter dated 13th September, 1962 again reiterated his position that since he has no power to review his own order, he could not entertain their petition dated 12th September, 1962 and stating that in view of the said position he could not comply with their request to adjourn the hearing fixed for 14th September, 1962.

11. This was followed by submission of another petition dated 14th September, 1962 wherein Parke Davis prayed that the Controller should adjourn the hearing fixed for 14th September, 1962, for a period of 7 days to afford an opportunity for them to seek such relief, if any, as may lie in relation to the Controller's order dated 13th September, 1962.

12. On 14th September, 1962, the date fixed for hearing, Parke Davis' representatives did not attend the hearing, though Neo-Pharma Industries were

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represented. On this day, the Controller dismissed Parke Davis' petition dated 14th September, 1962 and proceeded with the consideration of the terms and conditions to which the Compulsory Licence applied for should be subject, in case it was decided to grant the Compulsory Licence. On Neo-Pharma Industries' side their submission was that they had nothing new to add to what they stated in their letter dated 29th May, 1962 addressed to Messrs. Remfry & Sons, Parke Davis' attorneys (in which Neo-Pharma Industries had stated that they would be satisfied with a Compulsory Licence on the model of the Compulsory Licence dated 30th May, 1961, granted in respect of Patent No. 51304, the royalty fixed in conformity with the recommendations of the Pharmaceutical Enquiry Committee, whose Report was published in 1954 by the Ministry of Commerce and Industry, New Delhi) and that as Parke Davis had not raised any objection to the terms and conditions proposed by Neo-Pharma Industries nor made any counter-proposals, their proposals should be accepted. Thereupon the Controller declared the hearing closed.

13. Before the Controller could pass his orders, however, Parke Davis moved before the Calcutta High Court a petition dated 26th September, 1962 for the issue of a writ of Certiorari, Mandamus and Prohibition against (1) The Deputy Controller of Patents & Designs, Calcutta, (2) Mr. B.N. Atrishi, the Deputy Controller of Patents & Designs and (3) Neo-Pharma Industries, and they succeeded in making the said High Court issue a Rule in terms of their following prayers :

- (a) That the Deputy Controller of Patents & Designs,
 Calcutta, both in his official and personal capacity
 produce his orders, dated 36th June, 1962, 29th August,
 1962 and 15th September, 1962 together with the records
 and proceedings relating thereto, so that the same may be
 quashed or set aside ;
- (b) To command the Deputy Controller of Patents and Designs, Calcutta to withdraw and cancel the orders referred to in (a) above and/or to command him to decide, after hearing the parties, to review the "petitions for review" and to5/-

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restrain him from proceeding with the Compulsory Licence proceedings without first hearing the "petitions for review" and without first deciding the question as to whether a Compulsory Licence should be granted ;

(c) To direct the Respondents to forbear from giving effect to or acting upon the orders referred to in (a) above and to forbear from proceeding with the Compulsory Licence proceedings without first deciding, after hearing the parties, the "petitions for review" and without first deciding whether a Compulsory Licence should be granted.

14. Parke Davis also succeeded in obtaining from the said Court an injunction to the effect that the Deputy Controller of Patents and Designs, Calcutta, both in his official as well as personal capacity, should not act upon or give effect to his previous orders or from proceeding with the Compulsory Licence proceedings without first hearing the parties on the "Petitions for review" and without first deciding as to whether a Compulsory Licence should be granted.

15. After the lapse of a long time the Calcutta High Court ordered that the Controller could give a re-hearing to Parke Davis. This re-hearing took place on 12th, 15th and 14th July, 1965.

16. Further dilatory tactics were adopted by Parke Davis to defer the issue of the orders by the Controller of Patents and Dasigns by filing frivolous petitions etc. which were dismissed by the Controller.

17. Finally by his order dated 23rd November, 1965 the Controller of Patents and Designs, Calcutta issued Neo-Pharma Industries a Compulsory Licence.

18. Just about the time Neo-Pharma Industries were to go ahead with the implementation of the Industrial Licence pursuant to the Compulsory Licence granted to them, Parke Davis have filed an appeal in the Calcutta High Court which inter alia contains the following prayers :

(1) Stay of Operation of the Order dated 23-11-1985 of

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(ii) Injunction restraining Neo-Pharma Industries from giving effect to the said Order dated 23-11-1965 from the Controller of Patents and Designs or from implementing the same until the disposal of the appeal.

19. Neo-Pharma Industries is not giving up the fight with Parke Davis but has opposed the said appeal and will do all that is in its power to oppose it till the very last with a view to showing its bona fides and earnestness of its intentions to implement the Industrial Licence granted to it by the Government of India.

20. The following expenses have hitherto been incurred with the sole object of implementing the Industrial Licence :

> (a) \$3,90,000/- being the cost of the land necessary for the setting up of the Industrial Undertaking (purchased in 1961)

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- (b) M.1,50,000/- by way of salaries, allowances etc. paid to the technical staff - from 1961 upto the end of March 1966 - (of whom a highly qualified chemist was also sent for specialised training abroad at the factory of our collaborators) who are still on the pay rolls.
- (c) N.50,000/- being the cost of prospecting water and drilling the bore-well on the land referred to in
 (a) above (incurred in 1966), resulting in a water supply capacity of 75,000 gellons per day.
- (d) Rs.45,000/- in the matter of litigation connected with our application for Compulsory Licence and the grant thereof - upto-date.

21. Paragraphs 6 to 18 above show how Parke Davis are trying to defeat and frustrate the very object of Section 23cc of the Indian Patents & Designs Act. But for the loop-holes in the said Act, Parke Davis would not have been able to7/-

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block and frustrate the implementation of the very Industrial Licence granted by the Government of India. Even now there is no knowing how much longer the legal proceedings will be protracted before the application is finally disposed of.

22. Section 23cc of the Indian Patents & Designs Act has not only been rendered a dead letter in achieving its objects, but has also served as a trap to entangle Neo-Pharma Industries in an increasingly heavy and vexatious litigation.

23. Neo-Pharma Industries believes that this failure of Section 23 cc is chiefly due to 2 reasons as follows : -

- The statutory procedure for the grant of a Compulsory Licence ignores the importance of granting the licence expeditiously.
- (ii) The said procedure involves proceedings akin to those involved in litigation before the Courts.
- (iii) The Appeal from the Controller's Decision lies before the High Court.

24. But there is a ray of hope in the new Patents and Designs Bill which is before the Parliament and, when enacted, the new Act should come to the aid of Neo-Pharma Industries. If the said Bill is passed without any modification of clause 53 thereof, Parke Davis' Patents said to be involved in the process of manufacture of Chloramphenicol and its Esters will be deemed to have ceased under sub-clause 2 of the said clause.

25. Besides clauses 87 and 88 of the Patents Bill 1965 provides a procedure which is not likely to give room for litigation in a Court of Law and clause 93 provides that the Appeal from the Controller's decision shall lie in the Central Government. Neo-Pharma Industries feel that these provisions of the Patents Bill will rectify the drawbacks of the existing Patents and Designs Act and therefore Neo-Pharma Industries strongly supports the proposals underlying 87, 88 and 93 of the Patents Bill. 26. Neo-Pharma Industries therefore prays that early action is taken to enact the new Patents and Designs Bill whereby an Indian Industry which

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has been duly licenced by the Government of India under the Industries Development and Regulation Act of 1951 is enabled to implement the Industrial Licence, notwithstanding the unfair actions, if any, of foreign vested interests, apart from other benefits which the new enectments may bestow upon Industries of the nature of Neo-Pharma Industries.

Bombay : Dated : May 10, 1986.

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for NEO-PHARMA INDUSTRIES PRIVATE LIMITED DIRECTOR

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MEMORANDUM

ON

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THE PATENTS BILL, 1965

HAFFKINE INSTITUTE, BOMBAY.

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HAFFKINE INSTITUTE, BOMBAY - 12

MEMORANDUM ON THE PATENTS BILL 1965

This memorandum is being presented on behalf of Haffkine Institute, one of the oldest research Institutes in the field of medical and biological research in India. Being a governmental organization, we have no personal motivation in this memorandum. The memorandum is being submitted in the best interest of people. It is based on our experience of patent law as it has operated all along.

Haffkine Institute, which is administered by the Government of Maharashtra, came into existance as a consequence of the Bubonic Plague epidemic in Bombay in the year 1896. Dr. Haffking had at that time come to India from Pasteur Institute, Paris, to prove the efficacy of cholera vaccine discovered by him. He was requested to go to Bombay and try to find out an effective vaccine against plague which he did within a short time after arrival in Bombay. This was the origin of Haffkine Institute, which since that time has been engaged constantly in epidemiological, prophylactic, curative, diagnostic and allied medical fields not only by its fundamental researches but in the practical applications in the form of making available vaccines, sera, diagnostic aids for medical profession and in teaching of medical sciences. Since the last 25 years the Institute has been also engaged in the stury of synthetic drugs and has taken out a large number of patents covering processes for the manufacture of important and life-saving drugs

and their intermediate chemicals. It has the distinction of being pioneer in creating know-how, without foreign collaboration, of modern synthetic drugs, and of manufacturing, may be on a modest scale, some of the important synthetic drugs from ' basic raw-materials. It had to face threats, litigations and other difficulties from foreign firms who alleged in some cases that they along had Patent rights in these drugs. We are sure therefore, that our experience in the matter of operation of Patent Act in India would be of great interest to the Joint Committee in appreciating the need for abrogation of Patent Act or atleast modifying it drastically so that it becomes an effective instrument in the rapid technological development and progress of the country and the well-being of its citizens.

We sincerely believe that in the matter of saving life by rescuing from the jaws of hunger, disease, pestilence and death, it is the humanitarian task that should rule supreme. There should be no scope of making undue profit in these matters concerning life and death. In developing countries, including ours, where majority of the population is not even having sufficient means to purchase their bare minimum requirements of food to ward off hunger, to sell to such population the drugs and medicine or food at prices which are exorbitant and what is worse much higher compared to the ruling prices for the same drugs in developed and

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well to do countries is a social crime that should not be allowed or pardoned. The modern miracles in medicines, surgery etc. whereby millions of victims of dreaded diseases like tuberculosis etc. are being now saved from death - against which diseases only a few decades back there was no hope of survival - are the results of selfless and devoted research workers, clinicians, surgeons, pharmacologists, and other belonging to a host of disciplines of research who have shared, shared freely their findings, results of experiments, new discoveries and made them known by publishing all the details, the know-how, without waiting for taking out patents, without expecting monetary gains. Even in United Kingdom, by tradition, inventions concerned in the medical and agricultural fields are not patentable.

PATENT LAWS NOT IN THE INTEREST OF OUR COUNTRY

A study of the patent system in India upto now shows that more than 90% of patents taken out in this country are by foreign firms for the inventions earried out abroad. What percentage of total patents taken but in our country are by Indians? Out of these, how many were subsequently patented in other countries by using the convention of reciprocatory clauses of priority among the patent convention countries ? What amount of foreign exchange by way of Toyalty etc. has been received by Indian nationals ?

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It will be seen that no advantage whatsoever has been gained by having a patent system in our country. The majority of patentees from foreign countries who have taken patents in our country have done so only to prevent anyone in this country from manufacturing the patented inventions and to prevent their import from cheaper sources so that the highest possible prices could be charged by utilizing the monopoly resulting from the Patent. Whenever they have been persuaded to take up the production in this country, often they have managed to avoid or postpone the production frombe basic starting materials and as far as possible only imported the penultimate product, which by a single or few steps could be converted into the final product calling this "Made in India". These penultimate products have been exported by their parent organisations or associates abroad at exorbitant prices. In this way they have been able to circumvent the restrictions on the amount of royalty imposed by Government of India and remitted to their countries moneys far in execss in what would amount to overinvoicing, involving drain on foreign exchange resources. When it is known that even finished products, whose international prices could be easily ascertained are imported by the patentees at prices several times that of the ruling prices of that item in the world market, as revealed already during the discussions of Patent Bill 1965 in Lok Sabha, it can be readily appreciated how difficult it would be to check the actual and

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reasonable price of any penultimate product (which is not an item of commerce whose price could be ascertained) imported by the Patentee or his collaborator for the so called manufacture of the patented invention in India. This way they not only collect unduly higher prices, but manage to avoid bringing to this country the technology involved in the manufacture of the product from the basic raw-materials.

Even in the cases of independent processes, patented by the Indian nationals, the provisions of Patent system have been utilized to prevent the manufacture, sale or licensing of the patent, by foreign patentees even when their patents on the strength of which they have been threatening the Indian patentees or their licensees - have been proved in the court of laws in other countries to be invalid and thereby already revoked.

The efforts of the Güvernment in trying to meet the urgent life-saving requirements of drugs and medicines by taking up the manufacture in the country have been obstructed and delayed by the foreign patentees utilizing the existing Patent Act.

The provisions of the compulsory license and other measures introduced after independence to the compulsory licences expeditiously.

PATENTS FOR PRODUCT PER SE SHOULD NOT BE GRANTED

It is argued in some quarters, particularly by the foreign patentees and their collaborators that PRODUCT PER SE must be allowed because the patent for processes only do not give the patentees adequate protection and returns. They naievely suggesty that inventions be directed towards discovery of newer drugs rather than to new processes for making already known drugs.

We beg to submit that having found a drug for any disease in itself is of no utility unless **in** the technology of its economic manufacture resulting in it being available in adequate quantities and at reasonable prices, within the reach of the majority of public in need of such drugs is effected. Any number of examples could be given to show that it is the attempt to find cheaper and better methods of producing a known effective drug that have contributed to the development of newer technologies and to bring down the prices of the drugs within the reach of the common man.

OUR EXPERIENCES IN THE OPERATION OF PATENT ACT

The following instances of our experiences will be found useful in deciding the modification of the Patent Act.

1. SULPHATHIAZOLE

As early as in 1939 while synthesising and testing newer organic substances against Plague, one of the compounds - now known as Sulphathiazole was found to be highly effective against experimental plague infection of laboratory animals, whereas pregious to this there was no drug available to be so effective for the plague infection. Sufficient quantities of this drug was prepared in the Institute for clinical field trials in the plague epidemic areas. The actual trials on Bubonic Plague patients showed that this drug could save **80%** of the plague victims.

To prepare small quantities of any synthetic substance in test-tubes is not very difficult and any competant organic chemist could do, but to prepare sufficient quantities for actual clinical trials requires an advanced knowledge of technology, chemical engineering, material handling, designing of equipment etc. All these know-how were worked out in the Institute without any foreign collaboration and sufficient quantities were produced and supplied for clinical trials.

As plague epidemics were raging in different parts of India, it was necessary to make this drug available urgently. Although we were informed that a Patent application was pending covering a large number of compounds in which this substance

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was also included, this product was not available in the country. The patentees had not carried out any work on the suitability or efficacy of the patented products on plague. Since this drug was not available in the country, attempts were made to get a compulsory license according to the provisions of the Patent Act existing then for the use of Government. The Patentees frustrated the attempts at manufacture in the country and making it available cheaply on the grounds that Haffkind Institute was not capable of manufacturing the drug due to lack of adequate facilities; This shows how the efforts to save millions of lives by taking up the manufacture at a critical time were brought to naught. The drug was later(imported from U.K.) conce) made available in the country in limited quantities at a price of Rs 250/- or near about per 1b. by the foreign patentee, whereas our eost of manufacture on a very modest scale which is normally much more costlier than the large-scale production, was found to be about R 20/- per 1b. The same drug could have been imported from U.S.A. at that time at a landed cost of Rs 39/- per 1b. because in U.S.A., there were several patented processes for the manufacture of this product and in absence of monopoly, the prices could come to reasonable levels. Unfortunately this drug could not be imported from U.S.A. because the Patentees under the Indian Patents Act had the exclusive monopoly of import, sales, manufacture, licensing others to manufacture etc. So it happened that Indians for

years went on paying at exorbitant rate charged by the Patentee for sulphathiazole.

In U.K., later on this Patentee was challenged in the court for having claimed too much territory, and other grounds, which are the grounds sufficient to revoke a patent. The patent was revoked. As a result the prices of this drug even from U.K. came down to a small fraction of the original high prices.

2. PROGUANIL HYDROCHLORIDE (An Antimalarial drug),

In order to take up a full scale anti-malarial campaign, the Government was in need of large quantities of an antimalarial Arug called Proguanil. A number of processes for the manufacture of this drug were patented in this country by a U.K. firm. Even at the concessional price of Rs 95/- per 1b. offered by this firm, it was beyond the means of the Government to purchase enough quantities of its requirements. The Institute worked out the know-how, technology etc. to produce this item indigenously at a cost of around Rs 30/- per 1b. An application for the grant of compulsory license was made to the Controller of Petent (as per amendment introduced in the Patent Act after Independence). In response to the notice served on Patentees, this firm suggested that they were willing to give license voluntarily by negotiations. The negotiations lasted several years in the matter of fixation of royalties to be paid, which finally came down to 10% of the bulk sale

price from the initial royalty of 25% demanded by them.

Unless a license is officially obtained from the Patentee, by entering into agreement duly signed, it is illegal to manufacture a patented invention, under the existing Patent Act. It has therefore, been suggested by us that in the consideration of the proposed Patent Bill, suitable and adequate provisions should be incorporated to eliminate delays in the matter of licensing.

3. TOLBUTAMIDE (An antidiabetic drug)

It is well known that Diabetes is a condition in which the medicine - whether insulin injections or the oral tablets introduced in recent times such as Tolbutamide, Chlorpropamide, DBI etc. - has to be taken day in and day out throughout the life time of a diabetic patient. Because of this continuous requirement of drug, the cost of treatment is very important. If the medicine is beyond the purchasing power of the patient, he faces the risk of gangrene following even minor wounds, diabetic come and vascular changes leading to early death.

During our research work on orally acting antidiabetic substances, newer processes for the manufacture of <u>T</u>olbutamide and Chlorpropamide were worked out and Patented by our Institute. These processes

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eliminated the use of hazardous chemicals, complicated equipment and had the advantage of making available the drug at very low prices that could be within the reach of even a person of modest income. Processes for this product were patented in this country by a foreign firm that was importing this drug at a very high cost. Later on the said firm took upon itself to "manufacture" by importing the penultimate products and converting by a single step into the final product.

The same drug was available in other parts of the world at a small fraction of the price charged by the firm for its importation, so a number of Indian Pharmaceutical firms imported the product and began selling the tablets at a cost substantially lower than that charged by this firm. The foreign patentee filed suits for infringement of its patent rights on all the Indian firms and compelled them to stop the import or sale of the said oral antidiabetic preparation.

The Institute invited offers for the licensing of its patent to manufacture and sell this product. The foreign firm in question sent circulars and notices threatening that action will be taken against anyone manufacturing the product as they alone had the exclusive patent rights. One of the Indian firms who had taken the license to manufacture Tolbutamide

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by our patented process, was repeatedly threatened to stop the manufacture and sale of Tolbutamide and finally an injunction was sought in the court in 1962, trying to restrain them from manufacture and sale, pending disposal of the suit on the validity of patent. Our licensee submitted evidences that it has taken a license to manufacture the product by a different process duly patented, which is quite different and in no way infringing the processes covered by the foreign firm. On the other hand, to show that the foreign firm's patent was defective, covering as it did much more than what was really invented, making false and vague claims etc., it also filed a counter-suit for the revocation of the patent held by the foreign firm. The case has yet to come for hearing after a period of 3 - 4 years. In the meanwhile, the drug is being sold by the foreign patentee at their exorbitant price. Thus, even if we have a valid patent, we are rendered helpless in helping the country from being exploited.

It would be interesting to know that the foreign patentee who had also taken out the same patent in Canada and had threatened a firm that dared to sell the product lost not only the case k in the Exchequer Court of Canada but the patent was revoked on the same or similar grounds that have been given by our licensee for the revocation of the patent in India also.

This case illustrates how the patent Act as it exists today is being used to prevent the setting up

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of industries, rapid development of newer technologies and making available the drugs at reasonable prices to the common man.

Nearly twenty tonnes of oral antidiabetic drugs are being sold annually at very high prices and the estimated requirement of the country is in the heighbourhood of 40 tonnes annually.

Threats and litigations have held up the working of this process for the 8 years since it was patented as it is beyond the means of any Indian industry to stand such long delays, and heavy drain the foreign its meagre resources in opposition the foreign for giant firms with unlimited resources and funds. The foreign firms can well afford to adopt these delaying techniques to such an extent that the Indian manufacturer could be held at bay almost for the entire period of patent protection which at present is 16 years.

Under the circumstances, the provision of the frocedures Patent Act and the legal proceeding aconnected therewith, can give a monopoly to a so called patentee and prevent the indégenous manufacturer from manufacturing the patented article irrespective of whether the patent in question is really valid or not. Could anyone under these circumstances consider the Patent Act as in the interest of the country and its industrial progress ?

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These bitter experiences compelies to submit the following suggestions in the interest of industrial and technical development of the country and well-being of the citizen for the favourable consideration of the Committee.

OUR SUGGESTIONS

1. PATENT LAW SHOULD BE TOTALLY ABROGATED

Our experience and that of all other Indian manufacturers who have been struggling to create know-how for indigenous manufacture of important and essential life-saving medicines, drugs etc. would convince anyone prepared to take an impartial and unprejudiced view that the continuance of the Patent Law is not in the interest of the country. Under the circumstances, we suggest that the Patent Law be abrogated totally.

2. NO PATENTS SHOULD BE GRANTED TO PRODUCTS AND PROCESSES COVERING MANUFACTURE OF FOOD. DRUGS, MEDICINE AND CHEMICAL INTERMEDIATES:

If for any reasons whatsoever, it is decided not to abrogate the Patent Laws totally, then we suggest that atleast no patents should be granted for products or processes covering the manufacture of food, drugs, medicine and chemical intermediates used in the manufacture of drugs & medicine. If the next best course suggested as above is also ruled out, then,"-

- No patents for products <u>per se</u>.
 Patents should be granted for processes for the manufacture and <u>net</u> for the product <u>per se</u>.
- (2) All Patents covering the processes for the manufacture of food, drugs, medicine and chemical intermediates related thereto should be endersed as "PATENT OF ALGHT"
- (3) Period of validity of all Patents covering the processes for the manufacture of food, drugs, medicines etc. to be not more than 7 years from the date of filing of complete specifications with no provision for any extension.

If the period of this 7 years suggested is to be considered from the date of scaling instead of the date of filing the specifications, as suggested and represented by some interests, then, protection to the patentee should also commence only after the date of scaling the patent. The Patentee cannot under these circumstances, claim any damages or any other redress from others, using or operating the patented invention prior to the date of scaling.

(4) The patent granted should give protection in so far as the invention is practiged in this country and no right should accrue to the patentee

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with regards to importation of patented invention as his exclusive right.

(5) The use of "Patent of Right" by any one desirous of operating the same to be made expeditious by simplification of procedure. Anyone desirous of operating or using a Patent of Right, can simply inform the Controller of Patents of his intention to do so, along with remittance of a modest fee and then start the manufacture. The delays due to procedural technicalities, objections from patentees discretionary powers. of Controller of Patents in the matter of financial ability, Technical competancy, doubting about the quality of product etc. should be eliminated. The financial ability, technical competancy and quality of the product (Drugs) and being looked after by other Government Agencies already existing. Royalty in no case should exceed 2% of ex-factory bulk price.

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SOCIÉTÉ DES USINES CHIMIQUES

SOCIÉTÉ ANONYME AU CAPITAL DE F 450.000.000

SIÈGE SOCIAL: 22, AVENUE MONTAIGNE, PARIS 89

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PARIS, May 18, 1966

To the Secretary, Lok Sabha Secretariat, Parliament House, Agrahayana 20, 1887, <u>New Delhi</u>, India

Subject : Joint Parliamentary Committee for consideration of the Patents Bill, 1965.-

Dear Sir,

EC0454

Having been urged by many Colleagues in different industrial countries to take part to the worldwide inquiry conducted by your Government with respect to the patonts Bill, 1965, I respectfully ask for the permission to submit a memorandum on this field for consideration of the Joint Parliamentary Committee. I an also prepared to give evidence before this Committee for which I am at your disposal any time at your convenience when the Committee reconvenes early next July.

I have been for thirty seven years in charge of the patents of Société des Usines Chimiques RHONE-POULENC in Paris, one of the biggest companies in France, the activities of which are mostly in chemicals, pharmaceuticals and artificial textiles. I have been for twenty four years a member of the Advisory Council to the French Government for Industrial Property Rights and the official reporter to this Council of the French Bill enacted later as the Law on the Special Patents for Medicaments.

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CONDITIONS Générales de VENTE. Les incendies inondations bris de machines, grêves guerres a tous autres occidents qui empêchent ou réduisent les fabrications sont considérés comme cas de force mojeure a déchargent la Société des Usines Chimiques RNOME-Pouleaux de l'obligation de livrer. Toutes nos marchandises, qu'elles soient expédiées ou livrees directement par nos surses succursales agent tous not ensidérées comme prises dans nos maganises sont propubles à Paris. Elles voyagent toujours et périls du destinataire (art 100 du Code de Commerce : qu'elles soient expédiées en port du, ou port payé pour le compte du destinatoire ou franco de port. Dans toutes contestations ou litiges sons exception les Tribunaux de la Seine sont seuls compétents. La crobion de troites ou lacception de dréglement n'impliquent ni novation ni dérogation à cette clause attributive de juricition. I am also a member of the International Chamber of Commerce and in this capacity I attended its Congress in New Delhi in February 1965. A this occasion, with a small group of industrialists and patent specialists of major industrial countries, I visited Mr. Ranganathan, then Secretary of the Ministry of Industry. This was an opportunity kindly granted to us by your Authorities of expressing our views on the general lines of the Indian Patent Bill then in the process of drafting.

With my long experience in Patents, specially in chemical and pharmaceutical patents, and also with my participation in the development of the French legislation for the last thirty years plus, I believe that I am in a position to help the Joint Parliamentary Committee with valuable information on the adjustment of Patent legislation to fostering the development of industry for the welfare and to the benefit of the consumers.

I should be extremely grateful of your giving me an opportunity of being heard and I shall send you shortly a memorandum on the subject.

Yours respectfully,

J. MONNET Director Société des Usines Chimiques RHONE-POULENC Statement relating to Bill 62 of 1965 (Patents Bill 1965) presented to the Joint Committee of the Indian Parliament

by J.F. Monnet

Director at the Société des Usines Chimiques RHONE-POULENC, France, in charge of International Relations based on industrial property rights.

Among the several ways of encouraging the establishment of novel industries in their countries, Government all over the world have adopted the patent system as the fairest and the most efficient. By granting inventors as temporary exclusivity they simultaneously gave their nationals a stimulus to exert their skill and creative imagination and provoked the establishment in their respective countries of new industrial manufactures of foreign origin. The national consumers were to benefit from it by an increase in new products put at their disposal and by a drop of the prices they had to pay for products manufactured in their own country under the most economical processes. Such goals were actually those of the Indian patent law of 1911, but it is stated in the 1965 bill that they have not been reached as a consequence of misuse or abuse of their rights by the patent owners.

It is perfectly understandable that provisions should be introduced in the law for achieving its purpose to the largest extend. Such remedies should not however take so much out of the hands of the inventors that they put in jeopardy the whole design of the law. Our experience with the French patent law appears to be a dazzling illustration of the research for a balance between the incentive to industrialisation by privileges granted to the inventors and the necessary advantages the consumer should enjoy.

The French patent law dating back to 1844 provided for the patentability of chemical products and excluded any patent protection for pharmaceuticals. My purpose is to show what influence these provisions had on the development of French industry, and what measures were taken to improve the law when it was found that it affected detrimentally the harmonious progressive development of the industries concerned and the satisfaction of the consumers.

Chemical products

It has been strongly debated at the time of the first world war and some years later whether the patentability of chemical products had not hampered the development in France of the chemical industry ; it was particularly pointed out that in Germany chemical industry had flourished under a less protective Patent system. Before our Parliament several bills were introduced aiming at a modified French patent law more in line with that of Germany. Such proposals never ended up in a law. Yet, since the first world war the chemical industry has developed in France very successfully indeed through the working of licensed patents of foreign origin and through the increase of domestic patented inventions. As a result the call for the limitation of the patent protection to the processes for the manufacture of chemical products has completely subsided and France is now one of the strongest supporters of the patent protection for chemical products in the draft bill for European patents currently worked out under the patronage of the E.E.C. •/•

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Authority. By the same token the French Government does not contemplate any modification of the French patent law in this respect.

Pharmaceuticals

For what concerns pharmaceuticals, as long as these found their origin in natural products and were produced by extraction, the French patent law had practically no influence on the development of the French pharmaceutical industry.

When synthetic pharmaceuticals started their whopping career, the question seriously arose whether patent protection if any was possible in this field. It was felt that if French pharmaceutical industry was to live up to its foreign competitors, patent protection for its manufactures was of necessity. The French Patent Office granted then patents for the manufacturing processes, even though doctrinal authors expressed serious doubts on their validity. Interested companies of ethical standing felt it, however, improper to try and invalidate such patents. They accepted to acknowledge the work of the patentees by paying them royalties at the rate on patented products usually practiced in countries where patent protection was undoubtedly admitted for pharmaceutical products. They refrained from court actions lest a decision adverse to the inventors! interests should come down, which would not only be unfair but also would dramatically affect their own researches.

In 1944, the French Government legalised this behaviour by modifying the Patent law correspondingly. From then on, undisputedly valid patents were granted covering processes for the preparation of pharmaceuticals, the products themselves being excluded from patent protection. This put the French law exactly in line with the German law.

With the further development of chemical science, leading to a multiplication of chemical methods applicable to the preparation of any chemical, the system became more and more objectionable. When considering that the true invention of a pharmaceutical lies much more in the discovery of new compound and of its therapeutic properties than in the process to make it, it became obvious that the true inventor could easily be frustrated of the due reward to his effort and imagination. Any interested industrialist having enough scholarly skilled chemists could find out a process which had not been specifically patented by the original author of the invention and benefit freely from all the costly and essential work done by him in the biological and clinical field. In the interest of the inventor, the Special Patent on Medicaments was then created which was ruled by a Decree dating back to the end of May 1960.

From the standpoint of economics, it might have been feared that the exclusivity thus granted to the first inventor of a pharmaceutical would lead to abuses, mainly to prices of pharmaceuticals at unreasonable and intolerable heights.

It is far from being proven that the multiplication of manufacturers of the same pharmaceutical should bring down prices to the lowest possible level. Competition between many manufacturers entails several productions on a small scale Société des Usines Chimiques RHONE-POULENC

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with high cost prices ; it means also very high promotion and propaganda expenses to keep abreast of each other. It is also to be emphasized that the great number on the market of similar products of different origins with different trade names is a serious embarrassment to the medical profession.

Finally, the increasing number of controls to which new patented pharmaceuticals have to be submitted in order to give the patient the highest possible safety in its use, very rapidly comes out of reach of small manufacturers. A great danger to the Public Health may be the threatening answer to wild competition.

The experience in France with the Special Patent on Medicaments shows that prices of pharmaceuticals have been kept down very reasonably and that the consumers, i.e. the patients have benefited of the best possible quality and safety of the products when made by the patentees or with their technical help.

As a sanction against the patentees taking excessive advantage of their dominant position, provisions have been introduced in the French law for immediate compulsory licence when the needs of the consumers are not satisfied in quantity or in quality or when prices are unreasonably high. No court action has ever been initiated by prospective manufacturers. This shows that the mere threat of a possible request under such provisions has kept back the inventors from over-taxing the consumers.

M B M O R A N D U M

ON

THE PATENTS BILL

Dr. T.R. Govindachari, Director, CIBA Research Centre, Bombay 62. It is important that in considering such a vital issue as the law governing patents on drugs, approaches based on politics or dogma should not influence our judgement; on the other hand, considerations of the best national interest should be the sole criterion. In the field of drugs, the national interest can be classified as factors affecting:

- i) use of indigenous scientific talent
- ii) the growth of the Indian pharmaceutical industry
- iii) the need for easy and ready accessibility to the average Indian of good drugs at reasonable prices.

Given below are some reflections on how the proposed patent law modifications will adversely affect Indian interests, and to what extent, if at all, some changes can be made in the existing situation without detriment to these interests.

1. <u>Pharmaceutical Research in India</u>: The rapid advances made in pharmaceuticals by

Western countries, with beneficial results to humanity need not be emphasized. But what can bear any amount of reiteration is the fact that we are doing very little comparable to the pharmaceutical research abroad and that it is high time we gave adequate attention to the problem. We simply cannot rest with buying formulae developed abroad or the know-how on patent-expired drugs. To say the least, this would be a short-sighted policy which would deny the Indian public the fruits of the latest research in pharmaceuticals. It follows then that our pharmaceutical industry must be encouraged to invest in research in India. It is well-known that this country has a large number of highly

qualified chemists and biologists for the job. As the opportunities under the present set-up are inadequate, we have suffered from a brain-drain, which can be avoided, if more opportunities are provided by increased investment in India for pharmaceutical research. The investment can be wholly Indian; on the other hand, collaboration from a reputed foreign pharmaceutical firm with adequate safeguards for national interest should not be unwelcome. The fruits of such an investment would be realizable in a short time and would be tangible. With the discovery of each new drug, we can cut down imports, saving valuable foreign exchange. By creating an export market, we would be also in a position to earn valuable foreign exchange. However, this can happen only if our drugs are suitably protected abroad. Thus, we have to ensure that our patent laws conform more or less to those of the countries in which we plan to sell our drugs.

For example, the Regional Research Laboratories at Hyderabad have a synthetic drug, RRL 1421, with sedative-tranquillizing activity. If it proves superior to the existing ones, and if properly exploited all over the world, this can earn foreign exchange worth several millions of rupees. This would of course require that our compound is protected adequately abroad.

Patent No. 1004071 taken out by C.S.I.R. in U.K. is another case, which if useful, would emphasize the advantages to our national economy arising from the patent system.

2. <u>Cost of Pharmaceutical Research</u>: We have seen before, the need for research in this field, and the benefits therefrom to the national economy. We must now consider the cost of such research. It is possible that this is not too well-realized by people who would like to modify the present patent laws. A drug is the end point of the collec-. tive research effort of several people belonging to various disciplines of science over a long period of time, as much as 6-7 years. There has to be a minimum set-up, and a minimum investment below which, it would be futile to expect results. The birth of a drug may be briefly described as follows:

An organic chemist prepares a new compound; it may be from natural sources; on the other hand, as it is the case most often, it may be purely synthetic, made because it has some resemblance to some existing drug of known activity or because it is a novel type of compound whose biological properties are unknown. The new compound is then examined by a team of biologists for macro and microbiological activities. Sometimes one such compound may have some interesting activity, let us say, stimulation of the central nervous system. The chemist then makes a number of analogous compounds and these are tested biologically. Very often the best compound of the series may not be active enough to be worth pursuing. But once in a while it is; then it is compared with known drugs in the market to see what advantages it has to offer; the compound is then fed to animals for a month, at the end of which the animals are examined for symptoms of 'subacute toxicity'. If the compound proves safe, with the Government's permission, it is subjected to a limited clinical trial on human volunteers under the control of expert doctors. At this stage if the compound proves efficacious on the one hand, and negligibly toxic on the other, it goes back to the laboratory, where it undergoes a chronic toxicity test in animals, for a period of six months. After clearance from this test, the compound is subjected to an expanded clinical trial. If the results are successful, it has a fair chance of becoming a drug.

Statistically, it has been found in the Pharmaceutical Industry that one in three thousand compounds has a chance of becoming a drug. It should also be noted that a viable research unit should have at least 5-10 senior chemists and ten senior biologists, with a large number of assistants and several ancillary services and that the average expenditure per scientist in such a unit is about R.150,000/- to R.250,000/-. It should also be emphasized that the cost of research is not significantly less in India than in advanced Western countries like the United States and Switzerland.

In describing the birth of a drug, we noted that once the biologists find a new compound interesting, a number of analogues are made to find out the best compound and its utility. It is at this stage a patent application is filed so that having discovered a usefully active compound, the scientists can proceed with its further examination without fear of competition. The ultimate utility naturally is the possibility of selling it as a drug and we saw that 6 years of investigation would be needed to show that it can become a drug, and another two years would be needed to establish it as one.

Under the existing patent rules, the discoverer would have the time to recover from the sales of the drug, not only a reasonable return for the investment, but also money for further research. There would be also a considerable impetus for competitors to come out with similar, sometimes better products of the same type. All this would go to build up the economy of the country.

On the other hand, according to the provisions of the new bill, the lifetime of a patent is only ten years. Since almost seven to eight years would be gone from the time of filing a patent to the successful introduction of a new drug, there would be barely two years for the discoverer to recover the investments. It is pertinent to note that in practically every major country of the world, a patent is granted for a minimum of 15 years and even in the few countries, where the lifetime is less, a provision for extension exists. It would therefore be in the interest of the national economy which ultimately depends on a healthy industry that the proposed curtailment of the validity period of a patent be abandoned.

.4.

Equally crippling to the economy and harmful for the national interest would be the proposed provision for the compulsory licensing of any applicant by the discoverer for payment of 4% of the bulk price of the patented product. The return is meager but more than that, the system would leave the field open to manufacturers who do not have established reputation for the maintenance of standards. Much damage will be thus done to the patenter as well as to the public. It is necessary therefore that this amendment be abandoned. On the other hand, if it is going to be passed in any form, the least the Parliament could do would be to ensure that applications for licences would be scrutinized by an independent board of scientific experts, with respect to the credentials of the applicants, their past record, standards of their current products, etc.

3. <u>The role of patents in world economy</u>: An argument commonly advanced for abolition or restriction of the patent system is that several advanced countries do not have this system and that drugs are cheaper in such countries. It has been well-established that such countries do not have cheaper drugs. It is more interesting to note that the countries that were quoted as examples have in fact embraced the patent system realizing its advantages and the undoubtedly useful role it plays in the economy of advanced countries. U.S.S.R., Italy, Hungary, Czechoelovakia and Poland are some of the countries that have lately adopted patent laws. It is also worthwhile to point out that the socialist countries have realized the inevitability of the need for incentives and are slowly readjusting their

4. <u>The cost of drugs</u>: It is fallacious to argue that the patent laws as they exist encourage monopoly and consequently high prices for drugs; for one has only to think of the cost of the several nonpatented or patent-expired drugs in Indian to realise that the causes must lie elsewhere. When thinking

thinking and methods to subserve this end.

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of the cost of drugs in India, relative to the standard of living, we must consider besides overheads like research which is common to the pharmaceutical industry all over the world, the following factors:

- i) cost of raw materials
- ii) heavy taxes on import of starting materials or intermediates
- iii) uneconomic production.

The recent law placing a ceiling on expenses that may be incurred for promotional advertisement must undoubtedly result in some reduction in overheads. There is a lot of scope for reduction in the cost in terms of the three factors mentioned above. Anyhow it would not be difficult to realize that the patent system does not contribute significantly to the cost of drugs in India.

5. <u>The need for a product patent</u>: A very serious feature of the proposed amendment to our

patent laws is the abolition of the patentability of products; instead it is proposed that patents may be given only for processes. The apparent justification for such a change is that a competitor may come out with a more economical process for the same product, which will be useful for the public in that the drug may be available cheaper. With a little thought, it would be easy to recognise that the reasoning is wrong. Firstly, in the marketing of a drug, enormous money is spent, not only in discovering a process, but also testing the drug through various costly, time-consuming stages. Naturally, the discoverer would not like to leave the field open to a competitor, who has merely to claim he has a cheaper process to acquire the right to sell the drug. The original discoverer would therefore, to safeguard his own interest, like to work out all possible processes for the manufacture of the compound. The outlay accordingly would become enormous, which naturally would have to be reflected in the price of the drug. But it would be a criminal waste of our resources to fritter them away on such a totally unnecessary endeavour; for theoretically a large number of processes for a single drug are possible but it would not be humanly possible to exhaust them, nor would it be necessary; as often only one or two processes would be economically feasible. Now, if only process patents are granted, a competitor may claim a new process which in reality may be much inferior. He acquires the right to market this drug, ostensibly by his process; but he may manufacture the drug only by the original process, without anybody being aware of it. Thus there is a premium on dishonesty.

Very often the actual cost of production of a drug is only a fraction of the cost of the drug. Thus by working out an alternate process, even granting it to be cheaper, there would be some saving in the cost of production, but its effect on the price of the drug will be only marginal.

Since granting of a process patent only would encourage dishonesty and would not help bring prices down, the present laws for patenting products should continue.

6. <u>The role of the Government</u>: In a democratic country the Government has undeniably the duty to safeguard the health of the citizens, and for this reason, ensure that life-saving, health-giving drugs are accessible to one and all alike. There are several ways open to a democratic government, to see to it that the prices of drugs have a bearing to the standard of living. Some of the measures would be:

- i) to lower the excise on imports
- ii) to encourage indigenous manufacture of raw materials for pharmaceuticals

iii) to encourage increased investment by industry in pharmaceutical research in the form of corporate tax exemption, etc. with results outlined earlier.

On the other hand, for reasons pointed out before, any abridgement of the present patent laws will certainly not achieve the aim; prices of drugs will not come down; private Indian and foreign investment will dwindle, but most important, the quality of drugs is likely to suffer in the hands of unscrupulous manufacturers. The price in human terms may be much too great.

7. <u>Conclusion</u>: The Indian Economy has gained considerably by the co-existence of public and private enterprise. Just as other sections of private enterprise enjoy patent protection to the advantages of all concerned, it is imperative that the same measure of patent protection should be available to the drug industry if it should continue in its growth and play a useful role in the economy. THE ALL INDIA DRUGS & PHANMACEUTICAL MANUFACTURERS' CONSULTATIVE

COMMITTEE.

(Under the auspices of THE ALL_INDIA MANUFACTURERS' ORGANIZATION)

> Jeevan Sahak**ar**, Sir Pherozshah Meht**a** Road, Fort, Bombay 1.

Confidential.

JANUARY 15, 1966

The Chairman, Joint Committee of Parliament on the Patents Bill, 1965, Lok Sabha Secretariat, MAN DELHI.

Dear Sir,

Sub: Patents Bill, 1965.

The All-India Drugs & Pharmaceutical Manufacturers' Consultative Committee having gone through various amendments introduced by the Bill to the Indian Patents and Designs Act, 1911, relating to patents, I have been directed to : address you as follows:-

I would hovever, before going into the subject matter of the Bill give a brief history of coming into being the Consultative Committee.

The All-India Manufacturers: Organization under its auspices and with close and active co-operation of Association of Indian Tharmaceutical Manufacturers, Calcutta, The Chemical & Pharmaceutical Manufacturers: Association, Delhi, Federation of Manufacturers of A yurvedic and Siddha Medicines, Delhi, The Indian Drug Manufacturers: Inspectation, Bombay, Indian Pharmacists: Association, Bombay, Northern India Pharmaceutical Manufacturers & Distributors Association, Delhi, and Tharmaceutical, Chemical & Allied Manufacturers! Association of South India, Madras, organized the First All-India Drugs & Pharma-

ceutical Manufacturers Conference on the 30th April, 1965, in New Delhi, under the presidentship of Lala Hansraj Gupta, the Chairman of the Organization. The Conference was inaugurated by Prof. Humayun Kabir, the Union Minister for Petroleum and Chemicals. It was at the directive of this Conference a Consultative Committee was formed representing important personages connected with the industry and representatives of the co-operative associations with the objective of working for the interest of the Indian Pharmaceutical Industry.

Having given a brief history of the Consultative Committee, I now proceed to place before your Committee, the considered opinion of my Consultative Committee.

My Committee welcome the much awaited Patents Bill which seeks to ensure that patent rights are not misused to the detriment of national interest. There is no doubt in the minds of my Committee that the Indian Patent System prevailing upto now has failed in its main purpose, namely to stimulate invention amongst Indians and to encourage the development and exploitation of new inventions for industrial purposes in India, so as to secure the benefit thereof to the largest section of the public. Further, the patents that are registered in India by foreign companies have been taken out mainly with the purpose of securing their economic interest and not the in terest of the national economy of the country giving protection to these patents.

A study of the subject would reveal that the majority of the foreignorss who have taken out patents did not manufacture their p_atented products in this country. It looks as if that the patents registered in this country was only with a view to prevent

the Indian manufacturers from going into the production of these products.

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In view of this my Committee welcome the main objective of the new legislation i.e. to ensure that patents are put to the greatest possible use for the purpose of industrial production in the country. The provision that have been incorporated in the Bill for the compulsory licensing of patents and for the revocation of patents if they are not put to use within a reasonable period of time is welcomed to my Committee.

With these p_reliminary remarks I proceed to set out views on various clauses of the Bill as follows:-

Clause 27.

Under this clause, the Controller may, wit hout opposition, refuse to grant the patent if at any time after the acceptance of the complete satisfaction of an application for a patent and before granting of a patent thereon it comes to the notice of the Controller, otherwise than in consequence of proceedings in opposition to the grant under section 25 of the Bill as to the publication in India or any other country before the priority date of the claim.

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The clause is very wide and the C_0 ntroller may refuse the patent unless the complete specification is amended to his satisfaction within such time as may be prescribed by him. My Committee find that under this clause, the applicant has no opportunity to contest the information received by the C_0 ntroller. My Committee, therefore, suggest that applicant should be given an opportunity to show cause why his application should not be rejected.

Clause 48.

This clause provides that Patent rights shall not be deemed to be infringed when the paten_ted article or the product made by the patented process is imported by or on behalf of the Government for use of the Government or any other dispensary, hospital or other medical institutions maintained by the Government or any hospital or medical institution, which may be specified by the Government, by rotification in the Official Gazette.

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In the opinion of my Committee, this clause grants unlimited powers to the Government, which would to against the interest of other local industry, and is likely to hamper any local industrial progress. It militates against the basic objectives behind the grant of patent as set out in Clause 83.

No doubt the Covernment have got the right to acquire the patent for the general public interest; but the inventor needs to be protected, whereby Government can also be restricted from taking undue advantage of the provision set out in this clause.

My Committee, therefore, suggest that Government should take advantage of this Clause only in those cases where the patent is not worked for producing sufficient quantity to meet the requirements of the country.

Clause 53.

This Clause limits the period for which the patent is to remain in force. This Clause provides that any inventor claiming a process for the manufacture of food, medicines or Drug (including all Chemical substances used as intermediates in the manufacture of medicine or drug) the term of a patent shall be 10 years from the date of patent and in respect of any other inventions by 14 years from the date of the patent.

My Committee is of the firm view that this peridd of 10 years from the period of granting of the patents is quite sufficient for all products for the inventor to get a reasonable benefit from the invention made out by him, and under no circumstances should this period be allowed to be extended.

Clause 64.

The clause deals with the revocation of patents. The patent, whether granted before or after the commencement of this Act, may, on the petition of any person interested or of the Central Government, be revoked by the High Court in various grounds. My Committee (more)

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particularly refer to the grounds relating to (e) and (f) of this clause --

- (e) that the intention so far as claimed in any claim of the complete specification is not new, having regard to what was known or used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in section 13;
- (f) that the invention so far as claimed in any claim of the complete satisfaction is obvious or does not involve any inventive step, having regard to what was known or used in India or what was published in India or elsewhere before the priority date of the claim.

Further, for the purpose of clause (e) and (f) of sub clause (i) of this clause 64, according to sub-clause (ii) of this clause 64 states that -

- "(a) no account shall be taken of secret use; and
- (b) where the patent is for a process or for a product as made by a process described or claimed, the importation into India, of the produce made abroad by that process shall constitute knowledge or use in India of the invention on the date of the importation."

My Committee feel that the importation of the product would be considered as prior knowledge and becomes a ground for revocation. Before such a patented produce is manufactured in India, it may be necessary to carry out experimental tests to find out its usefulness in this country for which purpose a token import will be required. My Committee, therefore, feel this relevant provision of this clause 64 should not effect a product thus imported for the purpose of tests or experiments only.

Clause 82.

This clause provides two special definitions for the purpose _ of chapter XVI of the Bill, and as such they are supposed to supercede the general definition given in clause (n) and (o) of subclause (1) of clause 2 of the Bill.

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The word "Process" is not .defined in this clause. According of to the accepted Canons /construction of statutes when the word is not defined in the Statute the meaning to be ascribed to it is its natural and grammatical meaning. According to the Oxford Concise Dictionary "Process" means course of action, Proceeding, a special method of operation in manufacture etc.

My Committee feel it necessary that the word "Process" is defined under this clause so as to restrict the patentee fromregistering all permutations and combinations of processes, which were not experimental by him in his own laboratory.

Clause 83.

This Clause lays down general principle applicable to the working of patented invention namely (a) that patents are granted to encourage invention and to secure that inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay, and (b) and that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.

My Committee are of the opinion that there is a necessity for such a provision in the Bill as the patent system in India upto now prevailing has failed in its main purpose, namely to stimulate invention among Indians and to encourage the development and exploitation of new invention for industrial purposes in the country, so as to secure the benefit thereof to a large section of the public. In view of this, this Clause is welcomed.

Clause 84.

This Clause provides for the issueance of a compulsory licence. The Sub-Clause (2) and (3) talks about the ability of the applicant and the capacity of the applicant for licence to undertake the risk. In the opinion of my Committee the provisions under this clause are satisfactory.

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Clause 85.

This Clause sets out matters to be taken into consideration by the Controller while granting Compulsory Licence they are:

- (i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licencee to make full use of the invention;
- (ii) the ability of the applicant to work the invention to the public advantage.
- (iii) where the invention relate to a scheduled industry within the meaning of the Industries (Development' and Regulation) Act, 1951, whether the applicant would be granted permission to work the invention if a licence were granted.
 - (iv) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted.

In the opinion of my Committee that while these clauses are welcome, it is necessary to provide against possible cartelisation with a view to defeating the objectives of the amendment to the Act. My Committee, therefore, suggest the insertion of a sub-clause by which the controller may be allowed to examine the possibility of cartelisation before insuing orders on the application for compulsory licence. The consequencial changes in clause 87 may also be incorporated to make the suggestion made herein above effective.

Clause 87.

This clause relates to certain patents deemed to be endorsed with the words "licences of right". According to this clause 87, every patent in force at the commencement of this Act relates. to inventions of items such as food, medicines or drug and the process for their manufacture, and also processes for the manufacture of or production of chemical substances (including alloys, optical glass, semi-conductors, inter-metallic compounds) will be deemed to be endorsed with the words "licences of right". It is noted that in respect of every patent granted after the commencement of this Act in respect of any invention referred to above, shall (more) also be deemed to be endorsed from the date of sealing of the patent under clause 87. It is found that patents in respect of substance such as requirements of food, medicines or drug, is deemed to be endorsed with the words "Licences of Right" from the commencement of this Act for patents already in force and from the date of the sealing of the product in regard to patents granted after the com encement of the Act. Further, in regard to patents relating to other articles clause 86 provides for grant of "Licences of Right" after the expiry of 3 years from the date of sealing of patented invention because the reasonable requirements of the public have not been satisfied.

My Committee feel that distinction between endorsement of the words "Licences of Right" and compliance with certain conditions under clause 86 in regard to patent relating to other articles appears to be not justified. Further, my Committee are of the view that clause 87 would affect adver sely the drugs and pharmaceutical industry in the sense that even before a patentee can work out the patent, any person would be able to apply to the patentee to grant him a licence for exploiting the patent. This, according to my Committee, goes against the basic principle of granting a putent. My Committee, therefore, suggest the deletion of clause 87and that clause 86 should govern the patents relating to drugs and medicines, etc. My Committee further suggest that consequential changes should be made in other clauses of the Bill.

Clause 88.

Clause 88 seeks to fix a cealing on royalty. This Clause also provides that where an endorsement of "licence of right" has been made by any proon who is interested in working out the patented invention in India may call upon the patentee to grant him a licence on terms to be mutually agreed upon and in default of such agreement on terms, it shall be decided by the Controller on application after making such enquiry as he deems fit. The royalty and other remuneration payable under licence to a patentee in respect of patent in the field of food, medicine or drug, shall not exceed 4% of the net ex-factory sale price in bulk of the prtented (more

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article exclusive of tax and commission determined in the prescribed manner according to the rules which will be framed hereafter. In the opinion of my Committee the cealing of 4% royalty and other remuneration reserved to the patentee is reasonable and should not be increased under any circumstances.

Clause 90

This Clause spells out in greater detail the circumstances in which reasonable requirements of the public shall be deemed not to have been satisfied --

(a) If by reason of the default of the patentee to manufacture in India to an adequate extent and supply on reasonable terms the patented article or a part of the patented article which is necessary for its efficient working or if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, etc.

The reference to the default of the patentee in this clause, it is feared, may be used to the prejudice of an applicant for compulsory licence by contending that there was no default on part of the Patentee. If the working of a patent in India, is to (be looked upon as an essential obligation on the part of the patentee, the very fact that the patentee has not cared to manufacture in India the patented article, should be sufficient to conclude that reasonable requirements of the public, is not satisfied.

My Committee therefore suggest deletion of the first line starting from "if and ending with "Manufacture" and insert the words "if the patentee has not manufactured".

The Clause amended will reas as follows:

(A) If the patentee has not manufactured in India to an adequate extent and supply on reasorable terms for any justifiable reasons, the patented articles or a part of the patented articles which is necessary for its efficient working or if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms.

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Clause 92

This Clause lays down the procedure for application under clause 84, 86 or 89, that is compulsory licence, licence of right and revocation. The procedure outlined is specially to be elaborated in the Rules. The existing Rules are defective. In that they do not make it clear that the application must be accompanied by all the evidence relied upon by the applicant and the same should he put on oath. The present Rules do not make any provision for evidence in reply by the applicant, which defect should be removed either by the eleboration of the present clause or by Rules that would be formed under this Clause.

Clause 93.0

This Clauss spells out the power of the Controller in Granting compulsory licences. It also lays down in sub-clause (6) that.his decision shall be subject to appeal to the Central Government.

In the original Act the appeal was to the High Court of Calcutta . It was noticed that the appeal to the High Court of Calcutta was time consuming. This might have prompted the Government to effect change of forum for the appeal.

My Committee have however reason to feel that an appeal to the Central Government is likely to be governed by non-judicial considerations.

My Committee therefore suggest the constitution of an independent tribunal for such appeals which could have its.sittings by rotation in important cities to dispose of appeal cases.

Clause 96.

This Clause deals with the licensing of related patents. ... In the case of patent for addition, it would be impossible to work it without the licence of the parent patent. The working for... some patents may require starting materials which themselves are subject matters of patents. Therefore, in the opinion of my Committee (more) the provision of the clause is essential and therefore, is welcomed.

Clase 97.

This clause lays down special provisions for compulsory licences on notification by Central Government.

For a compulsory licence application the applicant has to wait for three years after the sealing of the patent. However, cases may arise wherein the interest of the public it may be necessary to exploit the patent before the expiry period of three years from the date of sealing.

In the opinion of my Committee this Clause is essential and should remain without any modification.

Clause 98.

This Clause provides that any order for grant of licence to. . operate would be of the nature of a deed between parties concerned.

Clause No.99, 100 and 102.

Clause 99 defines "use of invention for the purposes of Government", and Clause 100 gives powers to the Central Government to use an invention for the purposes of the Government . It also empowers any prison authorised in writing by the Central Government to use the invention for the purposes of Government.

In the opinion of my Committee this clause is very wide. in scope and confers on the Government unrestricted powers to use patented invention without due processes of law.

If at all it is felt that these provisions are necessary,my Committee suggest that they should apply only so long as the _ patent is not worked by any party and the production is not undertaken in sufficient quantity to meet the requirements of the country.

Clause 102 gives powers to the Central Government to acquire an invention for public purposes by notifying its intention in that behalf. After such notification is issued, the patent and all rights in respect of the invention shall vast with the Government . The clause provides for a notice of an acquisition being given to the $\frac{1}{4}$ applicant for a patent and the patentes. Compensation for such acquisition is to be determined in such manner as may be agreed and in default by reference to the High Court.

In the opinion of my Committee that in view of the ample means provided for in the Bill, there is no legitimate reason . for such complete expropriation of industrial property rights. In any case it is submitted that the acquisition of an invention should be limited to certain specified public purposes, such as for defence, in case of an epidemic or for similar emergent public purposes.

It is also necessary that the compensation that is determined such cases should not be less than the royalty provided in clause No.88.

My Committee hope that your Joint Committee would give due consideration to the various suggestions made here-in-above.

My Committee would be pleased to render oral evidence before the Committee for elucidating any of the points made in this memorandum or any other points related to the subject.

(R. K. Dhote Chairman

DS:chR.



The All-India Manufacturers' Organization

JEEVAN SAHAKAR SIR PHIROZSHAH MEHTA ROAD BOMBAY-I

256552

FILE No

REF. No.

JANUARY 5,1966

COMPTDENTIAL

The Chairman, Joint Committe of Parliament on the Patents Bill, 1965, Lok Sabha Secretariat, NEV DELHI.

Dear ,Sir,

Sub: PATENTS BILL, 1965.

The Vorking Committee of the Organization having gone through the various amendments introduced by the Bill to the Indian Patents and Designs Act, 1911, relating to patents, I have been directed to address you as follows:-

My Committee welcome the much awaited Patents Bill which seeks to ensure that patent rights are not misuced to the detriment of national interest. There is no doubt in the minds of my Committee that the Indian Patent System prevailing upto now has failed in its main purpose, namely to stimulate invention amongst Indians and to encourage the development and exploitation of new inventions for industrial purposes in India, so as to secure the benefit thereof to the largest section of the public. Further, the patents that are registered in India by foreign companies have been taken out mainly with the purpose of securing their economic interest and not the interest of the national economy of the country giving protection to these patents.

A study of the subject would reveal that the majority of the foreigners who have taken out patents in India never intended to manufacture their patented products in our country; thus the patents have been registered in this country to prevent Indian manufacturers from Loing into the production of these products.

Having convinced themselves of the various shortcomings of the Act, and the unfair advantage taken by foreigners to abuse. the provisions of the Act, the Organization had as far back as 1953 made a few suggestions to amend the Patents Act, and had advocated a reduction in the period of validity of drug patents and giving protection to processes only.

My Committee, therefore, welcome the provisions made in this connection in the Bill.

My Committee note that the main objective of the new legislation is to ensure that patents are put to the greatest possible use for the purpose of industrial production in the country. My Committee, therefore, welcome the provisions that have been incorporated in the Bill for the compulsory licensing of patents and for the revocation of patents if they are not put to use within a reasonable period of time.

With these preliminary remarks, my Committee proceeds to. Live their opinion on various clauses of the Bill as follows:-

Clause 27.

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Under this clause, the Controller may, without opposition, refuse to grant the patent if at any time after the acceptance of the complete satisfaction of an application for a patent and before granting of a patent thereon it comes to the notice of the C_0 ntroller, otherwise than in consequence of proceedings in opposition to the grant under section 25 of the Bill as to the publication in India or any other country before the priority date of the claim.

The clause is very wide and the Controller may refuse the patent unless the complete specification is amended to his satisfaction within such time as may be prescribed by him. My Committee find that under this clause, the applicant has no

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opportunity to contest the information received by the C_ntroller. My Committee, therefore, suggest that applicant should be given an opportunity to show cause why his application should not be rejected.

Clause 48.

This clause provides that Patent rights shall not be deemed to be infringed when the patented article or the product made by the patented process is imported by or on behalf of the Government for use of the Government or any other dispensary, hospital or other medical institutions maintained by the Government or any hospital or medical institution, which may be specified by the Government, by notification in the Official Gazette.

In the opinion of my Committee, this clause grants unlimited powers to the Government, which would go against the interest of other local industry, and is likely to hamper any local industrial progress and research initiative. It militates against the basic objectives behind the grant of patent as set out in Clause 83.

No doubt the Government have got the right to acquire the patent for the general public interest; but the inventor needs to be protected, whereby Government can also be restricted from taking undue advantage of the provision set out in this clause.

My Committee, therefore, suggest that Government should take advantage of this clause only in those cases where the patent is not worked for producing sufficient quantity to meet the requirements of the country.

Clause 53.

This Clause limits the period for which the patent is to remain in force. This Clause provides that any inventor claiming

My Committee is of the firm view that this period of 10 years from the period of granting of the patents is quite sufficient for all products for the inventor to get a reasonable benefit from the invention made out by him, and under no circumstances should this period be allowed to be extended. However, my Committee feel that it is proved and found necessary then a provision for extending the period **not** exceeding four years in deserving and

appropriate cases may be made.

Clause 64.

The clause deals with the revocation of patents. The patent, whether granted before or after the commencement of this Act, may, on the petition of any person interested or of the Central Government, be revoked by the High Court in various grounds. My Committee particularly refer to the grounds relating to (e) and (f) of this rclause --

- (e) that the intention so far as claimed in any claim of the complete specification is not new, having regard to what was known or used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in section 13;
- (f) that the invention so far as claimed in any claim of the complete satisfaction is obvious or does not involve any inventive step, having regard to what was known or used in India or what was published in India or elsewhere before the priority date of the claim.

Further, for the purpose of clause (e) and (f) of subclause (i) of this clause 64, according to sub-clause (ii) of this clause 64 states that -

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"(a) no account shall be taken of secret use; and (b) where the patent is for a process or for a product as made by a process described or claimed, the importation into India, of the produce made abroad by that process shall constitute knowledge or use in India of the invention on the date of the importation.".

My Committee feel that the importation of the product would be considered as prior knowledge and becomes a ground for revocation. Before such a patented produce is manufactured in India, it may be necessary to carry out experimental tests to find out its usefulness in this country for which purpose a token import will be required. My Committee, therefore, feel this relevant provision of this clause 64 should not affect a product thus imported for the purpose of tests or experiments only.

Clause 82.

This clause provides two special definitions for the purpose of chapter XVI of the Bill, and as such they are supposed to supercede the general definition given in clause (n) and (o) of sub-clause (1) of Clause 2 of the Bill.

The word "Process" is not defined in this clause. According to the accepted Cannons construction of statutes when the word is not defined in the Statute the meaning to be ascribed to it is its natural and grammatical meaning. According to the . Oxford Concise Dictionary "Process" means course of action, . Proceeding, a special method of operation in manufacture etc.

My Committee feel it necessary that the word "Process" is defined under this clause so as to restrict the patentee from registering all permutations and combinations of processes, which were not experimental by him in his own laboratory.

Clause 83.

This Clause lays down general principle applicable to the working of patented invention namely (a) that patents are granted to encourage invention and to secure that inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay, and (b) and that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.

My Committee are of the opinion that there is a necessity for such a provision in the Bill as the patent system in India up to now prevailing has failed in its main purpose, namely to stimulate invention among Indians and to emcourage the development and exploitation of new invention for industrial purposes in the country, so as to secure the benefit thereof to a larger section of the public. In view of this, this Clause is velcomed.

Clause 84.

This Clause provides for the issueance of a compulsory licence. The Sub-clause (2) and (3) talks about the ability of the applicant and the capacity of the applicant for licence to undertake the risk. In the opinion of my Committee the provisions under this clause are satisfactory.

Clause 85.

This Clause sets out matters to be taken into consideration by the Controller while granting Compulsory Licence they are:

 (i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;

- (ii) the ability of the applicant. to work the invention to the public advantage.
- (iii) where the invention relate to a scheduled industry within the meaning of the Industries (Development and Regulation) Act, 1951, whether the applicant would be granted permission to work the invention if a licence were granted.
 - (iv) the capacity of the applicant to undertake the risk in providing capital and torking the invention, if the applicationswere granted.

In the opinion of my Committee that while these clauses are welcome, it is necessary to provide against possible of cartelisation with a view to defeating the objectives of the amendment to the Act. My Committee, therefore, suggested the insertion of a sub-clause by which the controller may be allowed to examine the possibility of cartelisation before issuing orders on the application for compulsory licence.

Clause 87.

This clause relates to certain patents deemed to be endorsed with the words "licences of right". According to this clause 87, every patent in force at the commencement of this Act relates to inventions of items such as food, medicines or drug and the process for their manufacture, and also processes for the manufacture of or production of chemical substances (including alloys, optical glass, semi-conductors, inter-metallic compounds) will be deemed to be endorsed with the words "licences of right". It is noted that in respect of every patent granted after the commencement of this Act in respect of any invention referred to above, shall also be deemed to be endorsed from the date of sealing of the patent under clause 87. It is found that patents in respect of substance such as requirements of food. medicines or drug, is deemed to be endorsed with the words "Licences of Right" from the commencement of this Act for patents already in force and from the date of the sealing of the product (more)

in regard to patents granted after the commencement of the Act. Further, in regard to patents relating to other articles clause 86 provides for grant of "Licences of Right" after the expiry of 3 years from the date of sealing of patented invention because the reasonable requirements of the public have not been satisfied.

My Committee feel that distinction between endorsement of the words "Licences of Right" and compliance with certain conditions under clause 86 in regard to patent relating to other articles appears to be not justified. Further, my Committee are of the view that clause 87 would affect adversely the drugs and pharm ceutical industry in the sense that even before a patentee. can work out the patent, any person would be able to apply to the patentee to grant him a licence for exploiting the patent. This, according to my Committee, goes against the basic principle of granting a patent. My Committee, therefore, suggest the deletion of clause 87 and that clause 86 should govern the patents relating to drugs and medicines, etc. My Committee further suggest that consequential changes should be made in other clauses of the Bill.

Clause 88.

Clause 88 seeks the about fixing of a sealing on royalty. This Clause also provides that where an endorsement of "licence of right" has been made by any person who is interested in working out the patented invention in India may call upon the patentee to grant him a licence on terms to be mutually agreed upon and in default of such agreement on terms, it shall be decided by the Controller on application after making such enquiry as he deems fit. The royalty and other remuneration, payable under licence to a patentee in respect of patent in the field of food, medicine or drug, shall not exceed 4% of the net ex-factory sale price in bulk of the patented article exclusive of tax and commission determined in the prescribed manner according to the rules which will be framed hcreafter.

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Clause 90

This Clause spells out in greater detail the circumstances in which reasonable requirements of the public shall be deemed not to have been satisfied ---

 (a) If by reason of the default of the patentee to manufacture in India to an adequate extent and supply on reasonable terms the patented article or a part of the patented article which is necessary for its efficient working or if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, etc.

The reference to the default of the patentee in this clause, it is feared, may be used to the prejudice of an applicant for compulsory licence by contending that there was no default on part of the Patentee. If the working of a patent in India, is to be looked upon as an essential obligation on the part of the patentee, the very fact that the patentee has not cared to manufacture in India the patented article, should be sufficient to conclude that reasonable requirements of the public, is not satisfied.

My Committee therefore suggest deletion of the first line starting from "if and ending with "Manufacture" and insert the words "if the patentee has not manufactured".

The Clause amended will read as follows: -

(A) If the patentee has not manufactured in India to an adequate extent and supply on reasonable terms for any justifiable reasons, the patented articles or a part of the patented articles which is necessary for its efficient working or if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms.

Clause 92

This clause lays down the procedure for application under clause 84, 86 or 89, that is compulsory licence, licence

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of right and revocation. The procedure outlined is specially to be elaborated in the Rules. The existing Rules are defective. In that they do not make it clear that the application must be accompanied by all the evidence relied upon by the applicant and the same should be put on oath. The present Rules do not make any provision for evidence in reply by the applicant, which defect should be removed either by the elaboration of the present clause or by Rules that would be formed under this Clause.

Clause 93:

This Clause spells out the power of the Controller in granting compulsory licences. It also lays down in sub-clause (6) that his decision shall be subject to appeal to the Central Government.

In the original Act the appeal was to the High Court of Calcutta. It was noticed that the appeal to the High Court of Calcutta was time consuming. This might have prompted the Government to effect change of forum for the appeal.

My Committee have however reason to feel that an appeal to the Central.Government is likely to be governed by non-judicial considerations.

My Committee therefore suggest the constitution of an independent tribunal for such appeals which could have its . sittings by rotation in important cities to dispose of appeal cases.

Clause 96:

This Clause deals with the licensing of related patents. In the case of patent for addition, it would be impossible to work it without the licence of the parent patent. The working for some patents may require starting materials which themselves are subject matters of patents. Therefore, in the opinion of my Committee the provision of the clause is essential and therefore, is welcomed.

Clause 97:

This clause lays down special provisions for compulsory licences on .notification by Central Government.

For a compulsory licence application the applicant has to wait for three years after the sealing of the patent. However, cases may arise wherein the interest of the public it may be necessary to exploit the patent before the expiry period of three years from the date of sealing.

In the opinion of my Committee this clause is essential and should remain without any modification.

Clause 98:

This Clause provides that any order for grant of licence to . operate would be of the nature of a deed between parties concerned.

There are cases in the past where the patentee refused to co-operate with the Controller. Such clauses are, therefore, absolutely necessary in the interest of the applicant or licensee. My Committee, therefore, welcome this clause. Clause No.99, 100 and 102.

Clause 99 defines "use of invention for the purposes of Government", and Clause 100 gives powers to the Central Government to use an invention for the purposes of the Government. It also empowers any person authorised in writing by the Central Government to use the invention for the purposes of Government.

In the opinion of my Committee this clause is very wide in scope and confers on the Government unrestricted powers to use patented invention without due processes of law.

If at all it is felt that these provisions are necessary, my Committee suggest that they should apply only so long as the patent is not worked by any party and the production is not undertaken in sufficient quantity to meet the requirements of the country.

This Clause giv es powers to the Central Government to acquire an invention for public purposes by notifying its intention in that behalf. After such notification is issued, the patent and all rights in respect: of the invention shall vast with the Government. The clause provides for a notice of anacquisition being given to the applicant for a patent and the patentee. Compensation for such acquisition is to be determined in in such manner as may be agreed and in default by reference to the High Count

High Court.

In the opinion of my Committee that in view of the ample means provided for in the Bill, there is no legitimate reason for such complete expropriation of industrial property rights. In any case it is submitted that the acquisition of an invention should be limited to certain specified public purposes, such as for defence, in case of an epidemic or for similar emergent public purposes.

It is also necessary that the compensation that is determined in such cases should not be less than the royalty provided in clause No.88.

My Committee hope that your Joint Committee_would give due consideration to the various suggestions made here-in-above.

My Committee would be pleased to render oral evidence before the Committee for elucidating any of the points made in this memorandum or any other points related to the subject.

> Yours faithfully, <u>PLBadami</u> (P.L.Badami) Secretary

PLB: chr.



The All-India Manufacturers'

IEEVAN SAHAKAR SIR PHIROZSHAH MEHTA ROAD BOMBAY-I

Organization

FILE No

JANUARY 5,1966

CONFIDENTIAL

REF. No.

The Chairman, Joint Committe of Parliament on the Patents Bill, 1965, Lok Sabha Secretariat, NEV DELHI.

Dear Sir,

Sub: PATENTS BILL, 1965.

The Working Committee of the Organization having gone through the various amendments introduced by the Bill to the Indian Patents and Designs Act, 1911, relating to patents, I have been directed to address you as follows:-

My Committee welcome the much awaited Patents Bill which seeks to ensure that patent rights are not misused to the detriment of national interest. There is no doubt in the minds of my Committee that the Indian Patent System prevailing up to now has failed in its main purpose, namely to stimulate invention amongst Indians and to encourage the development and exploitation of new inventions for industrial purposes in India, so as to secure the benefit thereof to the largest section of the public. Further, the patents that are registered in India by foreign companies have been taken out mainly with the purpose of securing their economic interest and not the interest of the national economy of the country giving protection to these patents.

A study of the subject would reveal that the majority of the foreigners who have taken out patents in India never intended to manufacture their patented products in our country; thus the patents have been registered in this country to prevent Indian manufacturers from going into the production of these products.

Having convinced themselves of the various shortcomings of the Act, and the unfair advantage taken by foreigners to abuse the provisions of the Act, the Organization had as far back as 1953 made a few suggestions to amend the Patents Act, and had advocated a reduction in the period of validity of drug patents and giving protection to processes only.

My Committee, therefore, welcome the provisions made in this connection in the Bill.

My Committee note that the main objective of the new legislation is to ensure that patents are put to the greatest possible use for the purpose of industrial production in the country. My Committee, therefore, welcome the provisions that have been incorporated in the Bill for the compulsory licensing of patents and for the revocation of patents if they are not put to use within a reasonable period of time.

Clause 27.

Under this clause, the Controller may, without opposition, refuse to grant the patent if at any time after the acceptance of the complete satisfaction of an application for a patent and before granting of a patent thereon it comes to the notice of the C_0 ntroller, otherwise than in consequence of proceedings in opposition to the grant under section 25 of the Bill as to the publication in India or any other country before the priority date of the claim.

The clause is very wide and the Controller may refuse the patent unless the complete specification is amended to his satisfaction within such time as may be prescribed by him. My Committee find that under this clause, the applicent has no

opportunity to contest the information received by the C_ntroller. My Committee, therefore, suggest that applicant should be given an opportunity to show cause why his application should not be rejected.

Clause 48.

This clause provides that Patent rights shall not be deemed to be infringed when the patented article or the product made by the patented process is imported by or on behalf of the Government for use of the Government or any other dispensary, hospital or other medical institutions maintained by the Government or any hospital or medical institution, which may be specified by the Government, by notification in the Official Gazette.

In the opinion of my Committee, this clause grants unlimited powers to the Government, which would go against the interest of other local industry, and is likely to hamper any local industrial progress and research initiative. It militates against the basic objectives behind the grant of patent as set out in Clause 83.

No doubt the Government have got the right to acquire the patent for the general public interest; but the inventor needs to be protected, whereby Government can also be restricted . from taking undue advantage of the provision set out in this clause.

My Committee, therefore, suggest that Government should take advantage of this clause only in those cases where the patent is not worked for producing sufficient quantity to meet the requirements of the country.

Clause 53.

This Clause limits the period for which the patent is to remain in force. This Clause provides that any inventor claiming

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a process for the manufacture of food, medicines or Drug (including all Chemical substances used as intermediates in the manufacture of medicine or drug) the term of a patent shall be 10 years from the date of patent and in respect of any other inventions by 14 years from the date of the patent.

My Committee is of the firm view that this period of 10 years from the period of granting of the patents is quite sufficient for all products for the inventor to get a reasonable benefit from the invention made out by him, and under no circumstances should this period be allowed to be extended. However, my Committee feel that it is proved and found necessary then a provision for extending the period **not** exceeding 1002 years in deserving and

appropriate cases may be made.

Clause 64.

The clause deals with the revocation of patents. The patent, whether granted before or after the commencement of this Act, may, on the petition of any person interested or of the Central Government, be revoked by the High Court in various grounds. My Committee particularly refer to the grounds relating to (e) and (f) of this clause --

- (e) that the intention so far as claimed in any claim of the complete specification is not new, having regard to what was known or used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in section 13;
- (f) that the invention so far as claimed in any claim of the complete satisfaction is obvious or does not involve any inventive step, having regard to what was known or used in India or what was published in India or elsewhere before the priority date of the claim.

Further, for the purpose of clause (e) and (f) of subclause (i) of this clause 64, according to sub-clause (ii) of this clause 64 states that -

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"(a) no account shall be taken of secret use; and (b) where the patent is for a process or for a product as made by a process described or claimed, the importation into India, of the produce made abroad by that process shall constitute knowledge or use in India of the invention on the date of the importation.".

My Committee feel that the importation of the product would be considered as prior knowledge and becomes a ground for revocation. Before such a patented produce is manufactured in India, it may be necessary to carry out experimental tests to find out its usefulness in this country for which purpose a token import will be required. My Committee, therefore, feel this relevant provision of this clause 64 should not affect a product thus imported for the purpose of tests or experiments only.

Clause 82.

This clause provides two special definitions for the purpose of chapter XVI of the Bill, and as such they are supposed to supercede the general definition given in clause (n) and (o) of sub-clause (1) of Clause 2 of the Bill.

The word "Process" is not defined in this clause. According to the accepted Cannons construction of statutes when the word is not defined in the Statute the meaning to be ascribed to it is its natural and grammatical meaning. According to the . Oxford Concise Dictionary "Process" means course of action, . Proceeding, a special method of operation in manufacture etc.

My Committee feel it necessary that the word "Process" is defined under this clause so as to restrict the patentee from registering all permutations and combinations of processes, which were not experimental by him in his own laboratory.

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This Clause lays down general principle applicable to the working of patented invention namely (a) that patents are granted to encourage invention and to secure that inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay, and (b) and that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.

My Committee are of the opinion that there is a necessity for such a provision in the Bill as the patent system in India up to now prevailing has failed in its main purpose, namely to stimulate invention among Indians and to emcourage the development and exploitation of new invention for industrial purposes in the country, so as to secure the benefit thereof to a larger section of the public. In view of this, this Clause is velcomed.

<u>Clause 84.</u>

This Clause provides for the issueance of a compulsory licence. The Sub-clause (2) and (3) talks about the ability of the applicant and the capacity of the applicant for licence to undertake the risk. In the opinion of my Committee the provisions under this clause are satisfactory..

Clause 85.

This Clause sets out matters to be taken into consideration by the Controller while granting Compulsory Licence they are:

 (i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;

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- (ii) the ability of the applicant.to work the invention to the public advantage,
- (iii) where the invention relate to a scheduled industry within the meaning of the Industries (Development and Regulation) Act, 1951, whether the applicant would be granted permission to work the invention if a licence were granted.
 - (iv) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the applicationswere granted.

In the opinion of my Committee that while these clauses are welcome, it is necessary to provide against possible c oartelisation with a view to defeating the objectives of the amendment to the Act. My Committee, therefore, suggested the insertion of a sub-clause by which the controller may be allowed to examine the possibility of cartelisation before issuing orders on the application for compulsory licence.

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This clause relates to certain patents deemed to be endorsed with the words "licences of right". According to this clause 87, every patent in force at the commencement of this Act relates to inventions of items such as food, medicines or drug and the process for their manufacture, and also processes for the manufacture of or production of chemical substances (including alloys, optical glass, semi-conductors, inter-metallic compounds, will be deemed to be endorsed with the words "licences of right". It is noted that in respect of every patent granted after the commencement of this Act in respect of any invention referred to above, shall also be deemed to be endorsed from the date of sealing of the patent under clause 87. It is found that patents in respect of substance such as requirements of food. medicines or drug, is deemed to be endorsed with the vords "Licences of Right" from the commencement of this Act for patents already in force and from the date of the sealing of the product (more)

in regard to patents granted after the commencement of the Act. Further, in regard to patents relating to other articles clause 86 provides for grant of "Licences of Right" after the expiry of 3 years from the date of sealing of patented invention because the reasonable requirements of the public have not been satisfied.

My Committee feel that distinction between endorsement of the words "Licences of Right" and compliance with certain conditions under clause 86 in regard to patent relating to other articles appears to be not justified. Further, my Committee are of the view that clause 87 would affect adversely the drugs and pharm.ceutical industry in the sense that even before a patentee. can work out the patent, any person would be able to apply to the patentee to grant him a licence for exploiting the patent. This, according to my Committee, goes against the basic principle of granting a patent. My Committee, therefore, suggest the deletion of clause 87 and that clause 86 should govern the patents relating to drugs and medicines, etc. My Committee further suggest that consequential changes should be made in other clauses of the Bill.

Clause 88.

Clause 88 seeks the about fixing of a sealing on royalty. This Clause also provides that where an endorsement of "licence of right" has been made by any person who is interested in working out the patented invention in India may call upon the patentee to grant him a licence on terms to be mutually agreed upon and in default of such agreement on terms, it shall be decided by the Controller on application after making such enquiry as he deems fit. The royalty and other remuneration payable under licence to a patentee in respect of patent in the field of food, medicine or drug, shall not exceed 4% of the net ex-factory sale price in bulk of the patented article exclusive of tax and commission determined in the prescribed manner according to the rules which will be framed hereafter.

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(8)

Clause 90

This Clause spells out in greater detail the circumstances in which reasonable requirements of the public shall be deemed not to have been satisfied --

 (a) If by reason of the default of the patentee to manufacture in India to an adequate extent and supply on reasonable terms the patented article or a part of the patented article which is necessary for its efficient working or if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, etc.

The reference to the default of the patentee in this clause, it is feared, may be used to the prejudice of an applicant for compulsory licence by contending that there was no default on part of the Patentee. If the working of a patent in India, is to be looked upon as an essential obligation on the part of the patentee, the very fact that the patentee has not cared to manufacture in India the patented article, should be sufficient to conclude that reasonable requirements of the public, is not satisfied.

My Committee therefore suggest deletion of the first line starting from "if and ending with "Manufacture" and insert the words "if the patentee has not manufactured".

The Clause amended will read as follows:-

(A) If the patentee has not manufactured in India to an adequate extent and supply on reasonable terms for any justifiable reasons, the patented articles or a part of the patented articles which is necessary for its efficient working or if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms.

Clause 92

This clause lays down the procedure for application under clause 84, 86 or 89, that is compulsory licence, licence (more)

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of right and revocation. The procedure outlined is specially to be elaborated in the Rules. The existing Rules are defective. In that they do not make it clear that the application must be accompanied by all the evidence relied upon by the applicant and the same should be put on oath. The present Rules do not make any provision for evidence in reply by the applicant, which defect should be removed either by the elaboration of the present clause or by Rules that would be formed under this Clause.

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This Clause spells out the power of the Controller in granting compulsory licences. It also lays down in sub-clause (6) that his decision shall be subject to appeal to the Central Government.

In the original Act the appeal was to the High Court of Calcutta. It was noticed that the appeal to the High Court of Calcutta was time consuming. This might have prompted the Government to effect change of forum for the appeal.

My; Committee have however reason to feel that an appeal to the Central Government is likely to be governed by non-judicial considerations.

My Committee therefole suggest the constitution of an independent tribunal for such appeals which could have its sittings by rotation in important cities to dispose of appeal cases.

Clause 96:

This Clause deals with the licensing of related patents. In the case of patent for addition, it would be impossible to work it without the licence of the parent patent. The working for some patents may require starting materials which themselves are subject matters of patents. Therefore, in the opinion of my. Committee the provision of the clause is essential and therefore, is welcomed.

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This clause lays down special provisions for compulsory licences on . notification by Central Government.

For a compulsory licence application the applicant has to wait for three years after the sealing of the patent. However, cases may arise wherein the interest of the public it may be necessary to exploit the patent before the expiry period of three years from the date of sealing.

In the opinion of my Committee this clause is essential and should remain without any modification.

Clause 98:

This Clause provides that any order for grant of licence to . operate would be of the nature of a deed between parties concerned.

There are cases in the past where the patentee refused to co-operate with the Controller. Such clauses are, therefore, absolutely necessary in the interest of the applicant or licensee. My Committee, therefore, welcome this clause. Clause No.99, 100 and 102.

Clause 99 defines "use of invention for the purposes of Government", and Clause 100 gives powers to the Central Government to use an invention for the purposes of the Government. It also empowers any person authorised in writing by the Central Government to use the invention for the purposes of Government.

In the opinion of my Committee this clause is very wide in scope and confers on the Government unrestricted powers to use patented invention without due processes of law.

(more)

(12)

If at all it is felt that these provisions are necessary, my Committee suggest that they should apply only so long as the patent is not worked by any party and the production is not undertaken in sufficient quantity to meet the requirements of the country.

This Clause giv es powers to the Central Government to acquire an invention for public purposes by notifying its intention in that behalf. After such notification is issued, the patent and all rights in respect: of the invention shall vast with the Government. The clause provides for a notice of anacquisition being given to the applicant for a patent and the patentee. Compensation for such acquisition is to be determined to in such manner as may be agreed and in default by reference to the

High Court.

In the opinion of my Committee that in view of the ample means provided for in the Bill, there is no legitimate reason for such complete expropriation of industrial property rights. In any case it is submitted that the acquisition of an invention should be limited to certain specified public purposes, such as for defence, in case of an epidemic or for similar emergent public purposes.

It is also necessary that the compensation that is determined in such cases should not be less than the royalty provided in clause No.88.

My Committee hope that your Joint Committee_would give due consideration to the various suggestions made here-in-above.

My Committee would be pleased to render oral evidence before the Committee for elucidating any of the points made in this memorandum or any other points related to the Subject.

> Yours faithfully, <u>PLBadami</u> (P.L.Badami) Secretary

PLB: chr.

The Chairman & The Members Of The Joint Select Committee of Parliament on Patents Bill, 1965, Lok Sabha Secretariat, New Delhi,

Dear Sir,

The present Patents Bill was moved before the Parliament on 22/11/1965 for referring to the Joint Select Committee consisting of members of the Lok Sabha and Rajya Sabha by the Hon. Minister for Industry and Supply Shri T. N. Singh.

The Patents Bill as it is, is the most desirable move to encourage the inventors and reward them and, though at Present Indian inventors have not been able to get a good share in the benefits of the system with increasing emphasis on technical education and the number and quality of Research Institutes have been established in the country together with the rapid industrialization that is proceeding, we may look forward to the time when the Indian Research Worker and Inventor will be able to take fullest advantage of the Patent Law.

As regards the bill is concerned it is quite comprehensive and to a certain extent meets the requirements of the country and it will be to a greater extent help to give the needed incentive and encouragement to the Indian Scientists and Technicians to come forward and show their abilities. If I may say so, this bill has been discussed at the cabinet level many times and many prominent people from the country as well as outside have expressed their views and also discussed the clauses particularly in respect of the food and medicines.

As far as the Patent Registration is concerned today the Drugs and Food Industry, it has been already reported by eminent parliamentarians who said that 90% of the patents are at present held by foreign nationalists – which goes to prove that hardly about 10% of them have been held by Indian nationals and, therefore, it is high time that the Government of India and the Ministry concerned should do something to stimulate inventors especially among Indian nationals.

It is a fact that in the present law of 1911 many of the foreign firms as well as foreign collaborated firms whose parent bodies are holding patents under this act have been threatening the indigenous manufacturers that if they put such products in the market, legal steps may be taken up against them. This

factor has been always one of the most important point for the higher prices of the drugs and medicines in our country today. As it appeared sometime ago that 'Librium' a tranquilliser introduced in the Indian market by a Swiss firm who was importing the same during 1963 - 64 at about Rs. 5,555/- per kilogram C.I.F. - the same material is said to have been imported by a firm in Delhi at C.I.F. price of about Rs. 312/- per kilogram.

There are similiar other examples of this kind where another firm established in India who has been charging in this country for Vitamin B12 at Rs. 230/- per gram. whereas everyone in the Industry knows and is aware that the international price at which it is obtainable in other countries is between Rs. 90/- to Rs. 100/per gram. Similarly another foreign firm who are the patent holders of "Dexamathazone" were having a price of this product of Rs. 60,000 per kilogram and at the pressure and threats from the Import Controller, who threatened them that if they are going to charge this unconscionable price, he would have to stop the import gradually and get the material from other sources. Within 11 year's time this firm reduced the price of Dexamethazone from Rs. 60,000 to the present rate of Rs. 16,000/-. This is the kind of things has been going on with the Patent Holders in India! There is another case which may be cited here that very recently the Bombay High Court has issued an injunction against the Haffkine Institute, which is one of the Research Institutes of this country. This was issued for what they have invented - a process to make Tolbutamide indigenously, whose patent holders in India are a German firm; and if the Haffkine Institute starts processing and making this product, the patent product concerned may loose the market for that product. This has happened only because of the Patent Law as it exists at present, which give them that monopolistic opportunity. The Haffkine Institute has been directed by the Court not to proceed further with this process of making this product.

Considering the present state of the National emergency the availability of nutritious food to common man, we have to go a very long way in making the country self-sufficient and whether it is Food, Medicine, Housing or even clothing, to cover the body. We have been facing a grave situation especially in the foreign exchange and, it is the duty of every individual or a firm or even a ministry concerned to see that every paisa in foreign exchange spent with utmost care and, from examples cited above, it will be known that the Patent Holders under the shelter of the Patent rules have been enjoying the monopolies to the maximum possible extent which is certainly against the national interest.

It is really gratifying that Hon. Minister has appointed a Jt. Committee to go into further details and we hope that the committee will work on the responsibilities entrusted with all the due care while submitting their recommendations for the finalisation of this law.

The change in the present Patents Bill is ennumerated today, would help the Govt. in checking such high prices charged by such firms whose parent bodies are having the patent production. No doubt it is admitted by all concerned that there is no harm in agreeing for these inventions are the Industrial property and should have reasonable safeguard. By giving this protection to the Inventor or to such property holder, one should not neglect the national interest which should also be looked after and should not be allowed to be exploited unreasonably and unduly.

It will not be out of place to quote here from "Michel" – Principal National Patent Systems, Vol. I., Page 15 that "Patent Systems are not created in the interest of the inventor but, in the interest of the National Economy". Further it could be observed in Para. 23 of Mr. Justice N. R. Ayyangar's Report, 1959 that "the patented invention must be worked in India which grants the patent".

Indian Patent system has failed in its main purpose, namely to stimulate invention among the Indians and to encourage the development and exploitation of new inventions for Industrial purposes in India, so as to secure the benefit thereof to the largest section of the public (page 165 of the Interim Report of the Patents Enquiry Committee).

In the United Kingdom the Patent System had its origin in the prerogative of the Crown to regulate commerce and industry. The Crown used to grant charters under its Great Seal to grade guilds and corporation. This prerogative was much misused by the Crown for it's own purposes by granting letters Patent to foreigners to practice their craft and trade to the detriment of the British subjects. While originally designed to import new industries into England, the system deteriorated into farming out the Crown's favours. The abuses of the Patent System became so scandalous that in the reign of James I a statute entitled "Statute of Monopolies" had to be passed to regulate the system to promote national interest.

In our country unfortunately the Patent System was introduced by the British Government to protect their own commercial interest. They were not so much afraid of the Indian inventors

and businessmen as of the foreign inventors and manufacturers, particularly German. Before the First World War England found itself very much in the same predicament as we find ourselves today. There was a tremendous outcry against German patentees for exploiting the British public by importing patented articles and preventing the British manufacturer from manufacturing them by reason of patent protection obtained by Letters Patent issued to them in the United Kingdom. One has only to look at the Parliamentary debates of the period to judge the measure of the outcry of the British manufacturer against the German exploitation.

The Objects and Reasons to the Patents and Designs Ammendment Bill 1919 set out the British complaint in clear terms: "The object of granting patents for new invention is to benefit the trade or industry of the United Kingdom. For this purpose it is not enough to reward the inventor; but it is also necessary to secure that the new inventions be brought into commercial use without delay."

If a proper study is made on this subject, we will be able to find out that the majority of patents taken by the foreigners have not yet started the manufacture of their patented products in our country.

A foreigner taking out a patent for an invention in India enjoys its hospitality and by not using it here except by importation he abuses his privilege. It is an implied obligation of a patentee to work his invention in the country which grants him the patent.

The reason advanced by such holders are that because of the market being very limited and the prohibitive cost of manufacture owing to the local conditions they do not desire to take up the manufacture. But if the proper scrutiny is made one will come to the conclusion that such cases are very very rare and they cannot prevent general beneficial provision from being enacted under the present bill.

The Pharmaceutical industry in India is most dependent on imports of fundamental substances and the scope of compulsory licences of pharmaceuticals patents is very limited today. A large majority of infringement actions filed in India are confined to imports from non patent countries of Europe. There have been a very meagre number of cases of infringement of a pharmaceutical patent manufacture. It is of considerable importance to the Pharmaceutical industry of India at its present stage of

development that imports of fundamental substance should be permitted without fear of infringement where the patentee is following a policy of exploitation by reason his patent monopoly.

The definition of 'patented article' is the same as the one in section 22(4) of the Indian Patents and Designs Act, 1911. According to this definition, "patented article" iucludes any article made by a patented process. The expression "patented process" in this definition is defined in clause 2(1) (n) of the bill as a process in respect of which a patent is in force. The meaning of the expression "patented article" is, therefore, an article made by a process in respect of which a patent is in force. The meaning of the expression "patented article" is, in the ultimate analysis, dependent on the meaning of the word "process" which is not defined in the Bill.

According to the accepted canons of construction of Statutes, when a work is not defined in the Statute, the meaning to be ascribed to it is it's natural and grammatical meaning. According to the Oxford Concise Dictionary, "process" means course of action, proceeding, especially method of operation in manufacture etc. There is no reported patent case wherein the word "process" came before a court of law for interpretation. However, in the case of G.E.C's application (60 RPC 1) Romer J. regarded a process as a manner of manufacture if it (a) resulted in the production of vendible article, or (b) improved or restored to it's former condition a vendible product, or (c) had the effect of preserving from deterioration some vendible product to which it was applied. The etymological meaning of the word "process" is "the act of going forward." In the patent law, a process is a means of converting certain known integers into a new and useful product or result.

The Bill is concerned with processes which amount to inventions as defined by clause 2(1) (j). The definition of "invention" in clause 2(1) (j) combines the definitions in sub-sections (8) and (10) of Section 2 of the Act. According to the definition in clause 2(1) (j), a process would amount to an invention if it was new and useful. There is nothing new in this definition of "invention" as novelty and utility have always been regarded as tests of inventive steps in the patent law.

Clause 53:

Clause 53 limits the period of the patent to remain in force, providing that any inventor claiming the process for manufacture of Food, Medicine or Drug (including all substances used as

intermediaries in the manufacture of medicine or drug) the term is very necessary to be of a period of 10 years from the date of filing the complete specification for all the Industries. This period of 10 years is very essential for the inventor to get a reasonable benefit for the invention carried out by him and in no case this period should be allowed to be further extended.

Clause 82(b) gives an extended definition of the word "patentee" by including in its meaning an exclusive licensee who would not be included in the general definition given in clause 2(1) (c). An exclusive licensee does not necessarily exclude the patentee from operating the patent but by contract the patentee can do so in which case the exclusive licensee is in the same position as an assignee. That is the reason behind this somewhat anomalouse definition.

Clause 83:

This clause lays down the general principles applicable to the patented inventions. A clause of this kind is generally more mischievous than beneficial because it puts a constraint on the normal rules of interpretation of Statutes. It is supposed to induce a benevolent construction of the provisions to which it applies but at the same time it circumscribes the scope of interpretation by providing an exhaustive list of circumstances.

In order to understand this clause, it is necessary to understand the economics of a patent system and its historical origin in United Kingdom from where we have borrowed it.

"The theory upon which the patent system is based is that the opportunity of acquiring exclusive rights in an invention stimulates technical progress in four ways: First it encourages research and invention; second that it induces an inventor to disclose his discoveries instead of keeping them as a trade secret; third, that it offers a reward for the expenses of developing inventions to the stage at which they are commercially practicable; and fourth, that it provides an inducement to invest capital in new lines of production which might not appear profitable if many competing producers embarked on them simultaneously. (Paragraph 9 of the Second Interim Report by the Swan Committee).

The advantage accruing to a nation's economy from rewarding inventors with the grant of exclusive privileges for a limited time are dependent on two main factors: (2) The country must be technologically advanced to maintain the rate of invention which is brought forth by the promise of the reward, This in it's turn would be dependent upon (a) the degree of diffusion of scientific



and technological education and the number of persons reaching high proficiency by such education; (b) a massive industrial production which could absorb the products of the education and develop the instinct for research and direct it to useful and productive channels; (c) the amount of speculative capital which is forthcoming for being risked in investment in new ventures and for profitable utilisation in such industries. The patented invention must be worked in the country which grants the patent. (para-23 of Mr. Justice N.R. Ayyangar's Report, 1959).

The clause as worded is not sufficiently definitive of the object behind the provisions of compulsory licences. It should make a clear provision that working of the patent was an essential condition of the grant. An argument is sometimes advanced that the working of some inventions in India would not be profitable to a patentee either because of the limited market or because of the prohibitive cost of manufacture owing to local conditions. Such cases may be possible but are bound to be very rare and they cannot prevent a general beneficial provision from being enacted.

Clause 90 elaborately sets out the circumstances in which reasonable requirements of the public are to be deemed not satisfied. In sub-clause (a), the reference to the default of the patentee is mischievous because it gives a scope to the patentee to contend that there was no default on his part. If the working of a patent in India is to be looked upon an essential obligation on the patentee, there can be no such contenion.

Clause 91 gives power to the Controller to adjourn applications for compulsory licences in appropriate cases where the patentee has used his best endeavours to operate the patent in India and has proceeded to use his invention to some extent at least. The case of genuine difficulties of patentee in the implentation of his invention in India are thus covered by clause 91.

Although the marginal note speaks of reasonable requirements of the public, the reference to the public is singularly absent in the section itself except in the preamble to the clause. The object of every invention ought to be the supply of patented article of material to the public at reasonable price in adequate quantities. The clause lays emphasis only on the industrial development patentee can equally well be played by an Indian patentee for commercial gain by maintaining high prices through limited production.

The menning of the words "Person Interested" requires to be explained. Normally it must mean any person interested in the

manufacture of the article patented. In all cases of application for compulsory licences, the patentee has invariably contended that the applicant is not a person interested. Sub-clause (3) which corresponds to section 23D(1) requires the applicant to set out in the application his interest. The expression "Person interested" is intended to give locus standi to the applicant and therefore, must be defined with some precision. While it is necessary to keep a sheer opportunist out of the benefit of the clause, it is equally important that a genuine manufacturer should not be excluded from its benefits. An interested person must necessarily have a commercial capability to work the invention and that must involve financial and technical capability as well.

Clause 85:

This clause follows section 23C(2) of the Act. Subclauses (iii) and (iv) are new. The consideration of (iii) would bring in official intereference and administrative matter inaquasi-judicial inquiry.

There have been in the past frivolous applications for compulsory licences as a possible defence to an infringement action. It is necessary to guard against such applications. It is therefore, necessary that the applicant should give a guarantee to the Controller to work the patent in the event of his being granted a licence so that he can be proceeded against in the event of his application turning out to be frivolous. This can be safeguarded by making the applicant give a guarantee in a specified sum.

The last lines require omission of the words "be required to make the provision more effective."

Clause 86:

The provision for "Licences of rights" is more attractive than useful. It is intended to do away with the elaborate procedure of an application for compulsory licence.

Claus 87:

Barring the United States of America, there are few countries in the world that do not have special provisions as regards the patentability of inventions in respect of articles of food and medicines or as to the licensing and working of patents falling in this class. Clause 5 of Bill prohibits product claims in patents for food and medicine. Clause 87 puts further restrictions on these patents by providing for compulsory endorsement of licences of rights. The procedure of clause 85 is therefore, not necessary in the case of patents for medicines and articles of food



The procedure of clause 84 for compulsory licences has to be initiated by a person interested and therefore its applicability is limited. Clause 86 is wider in its application because the procedure outlined in it has to be initiated by the Government itself. Clause 87 is still wider in its application in as much as it required no action at all to make the patents capable of being licenced.

Clause 88:

The distinction between compulsory licences and or rights is that while in the former case it is possible to the patentee to show cause why the licence should not be granted, in the latter case he has no option but to grant the licence and the controller is approached only when the parties cannot agree on the terms of the licence. No doubt the licence would be given only to a person interested.

The reference to taxes in this clause requires a clarification. They must be taxes on sale or transport like the sales-tax and octroi. An upper limit must prescribed for the commissions.

It is not very clear whether this ceiling is applicable in case the terms are settled by the controller or even in case where the settlement is affected mutually. It is therefore, necessary to make it clear that the celing of royalty and other remunerations, fixed by this clause, is applicable in both the cases.

The clause states that the royalty will be computed on the net ex-factory sale price in bulk of the patented article. In general parlance the words "Ex-factory sale price" is not used. It is therefore, suggested that the usual terminology as used in commercial parlance, "Selling price" may be used so as to remove any ambiguity in the term.

In the opinion 4% royalty and other remunerations reserved to the patentee is reasonable and should not be increased under any circumstances. It is necessary, however, to make it clear that the "other remuneration" includes fees towards technicalknow-how, service charges etc.

Clause 89:

This clause deals with revocation of patents by the controller in certain circumstaces and is intended to be deterrent against an unwilling patentee to disclose completely the method of manufacture.

Although a complete specification is supposed to describe and ascertain the manner of manufacture, it rarely does so. Even the man best versed in the art would not be able to practice the invention by following the steps indicated in the complete specification. In actual practice of an invention, quantities, physical conditions and to'erances play an important part and in these matters a patent is generally silent. These are generally comprised in the term "know-how". The power given in this clause would normally be utilised against a recalcitrant patentee who refused to give the licensee all the required know how for the practice of the invention.

A mere licence will not serve the purpose of the licencee.

The Bill nowhere provides for the sale of know-how by the patentee. The provisions of clause 88 (5) would be easily defeated by a patentee by charging a fabulous royalty for the know-how. The Bill must provide for the sale of know-how by the patentee and fix the maximum royalty for it.

Clause 93:

Sub-clause 4 and clause 96(1) must be noted. The former applies when the same patentee holds related patents whereas the latter applies where the related patents are not necessarily held by the same patentee. Sub-clause 3 would be applicable to a case where there is a collusion between the patentee and his licencee to operate the patent to detriment of the public e.g. when the patentee and his licencee are likely to act in unfair competition with the applicant for compulsory licence.

I strongly feel that as regards the appeal provisions on appeal to the Central Government is likely to be governed by non-judicial considerations. I suggest the appointment if Independent Tribunal for such, appeals which could have its sittings by rotation in important cities to dispose of appeal cases.

Clause 94:

This clause lays down the general purposes that should be obtained by granting compulsory licence. The factors that are laid under this clause, are (a) that patented invention are worked on a commercial scale in India without undue delay and to the fullest extent that is reasonably practicable; (b) that the interests of any person for the time being working or developing an invention in India under the protection of a patent are not unfairly prejudiced. The reference to the interest of the community that inventions are worked in the country within a

short time and on ample scale and at reasonable prices is not touched by this clause. In fact such a factor should have a paramount place in this clause. I therefore suggest that suitable sub-clause may be inserted under this clause to safeguard the interest of the community of having items of food and drug in sufficient quantity and at reasonable prices.

Clause 95:

Sub-Clause (1) (i) lays down an accepted formula for computation of royalty. In the case of a pharmaceutical patent, the maximum royalty is fixed by clause 88(5) at 4% of ex-factory sales price. Sub-clause 2 is intended to prevent substitution of the licensee in place of the patentee by bogus or collusive licensing arrangements. The provision aims at prevention of non-genuine licensing arrangments by the patentee setting up a bogus compulsory licence applicant.

Clause 97:

In this clause special provisions have been laid down for compulsory licences on inventors by the Central Government. Under this clause for a compulsory licence application the applicant has to wait for 3 years after the sealing of the patent. It is quite likely that cases might arise wherein the interests of the public, it is necessary to exploit the patent before the expiry of 3 years from the date of sealing. By this clause is given power to the Government to notify such patents and thereafter the Controller can proceed to grant licences before the expiry of the 3 years from the date of sealing. Considering the importance of this clause is really essential and should remain without modification.

Referring to clause 99 and 100 about the use of inventions for the purpose of Government and also informing the Central Government to use inventions for purpose of their convenience, it also empower any person authorised in writing to the Central Government to use the invention for the Government purpose. This clause is very wide in scope and confers on the Government. unrestricted powers to use any patent invention without due processing of law. If at all it is felt that these provisions are essential, it should only apply so long as the patent is not worked and the production is not undertaken in sufficient quantity to meet the entire requirements or only in the case of emergencies or situations like droughts, epedemics etc.

In conclusion it will not be out of place to mention here that Jt. Committee appointed by the Ministry should while submitting

their reports on this bill take into consideration all the facts as well as the prevailing situations in the country and while finalising the bill it should be ensured that no legal loop holes are left out which can prove in the court of law a benefit or a trumpcard for the people enjoying the benefits of the existing patent law. As the entire industrial development and encouragement especially to the Indian Inventors is involved and ultimately it will work upon our national interest for which everyone in the country is anxious today.

Yours truly,

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Im. Panich

(G. M. PARIKH) Bombay: 7-1-1966

Partner: JUGATRAM & CO. Managing Agents to: ZANDU PHARMACEUTICAL WORKS LTD., Bombay 28.

INDIAN CHAMBER OF COMMERCE, CALCUTTA

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INDIA EXCHANGE, INDIA EXCHANGE PLACE CALCUTTA-I

- 8 JAN 1855

The Chairman, Joint Conmittee of Parliement on the Tatents Bill, Lok Sebhe Secretariat, Parliement House, New Delhi.

Dear Sir,

Sub: Patents Bill 1965.

I am directed by the Committee of the Chamber to forward to you this Memorandum setting forth the Committee's views on the various provisions contained in the Patents Bill, 1965. As notified by the Joint Committee, 65 copies of this Memorandum are being forwarded to the Secretary of the Lok Sabha Secretariat, by separate registered packet. In view of the importance of the subject to which this Bill relates, the Committee would also like to depute 3 or 4 representatives of the Chamber to tender oral evidence before the Joint Committee and elaborate the points made out in this Memorandum.

At the outset the Committee of the Chamber would like to state that in this Memorandum only some major provisions of the Bill involving important matters of principles or policies affecting Industry and Trade are dealt with, and the Chamber would like to leave it to the Industrial Associations and other affected interests to deal with other matters including matters of procedure.

The Committee of the Chamber wish to state that having regard to the requirements of the country for development in the industrial and technological fields in the present economic conditions, it is desirable that emendments to the Patents Law be made with great caution and circumspection, and it be ensured that the changes do not prove an impediment to foreign investment in India, and to the availability of know-how for industrial undertakings. The Chamber would suggest that it would be desirable to proceed further with the present Bill only after taking into account the comments and suggestions of all affected intorests, including manufacturers in the United States, the United Kingdom, France, West Germeny, Japan, and other countries with which India has industrial collaborations, to whom sufficient opportunity should be given to forward their comments and suggestions.

The Committee understand that in 1961 the United Nations passed a resolution that its Secretary-General should report on the existing petents systems in developing countries and the role of patents in the transfer of technology from developed to developing countries. The United Nations, the International Society for the Protection of Industrial Property (A.I.P.P.I.), the United International Bureaux for the Protection of Intellectual Property (BIRPI) are, it appears, giving active consideration to these matters. BIRPT it is understood, has drafted a Model Patents Law for developing countries, which is to be discussed in February 1966 at Colombo at an Asian Seminar on Industrial Property. The same draft law is also to be discussed at the A.I.P.P.I Conference in Tokyo in April 1966. In view of this proposed harmonization of Patents Law for developing countries, it will be in the interest of our country if the present draft Bill is considered after the February and ipril conferences referred to above have been held, and the United Nations has considered the Model Patents Law in the context of the 1961 resolution of the U.N.General Assembly.

Subject to the above observations, the Committee of the Chamber make the following suggestions for modification of the Patents Bill:-

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This cleuse makes a significant depar-Clause 5: ture from the existing position in regard to patents in the field of chemicals and drugs. According to this clause only inventions relating to processes would be patentable in this field but products would not be patentable. The Committee of the Chamber are of view that it would not be desirable to abolish patenting of products. It is felt that if this clause becomes law, it may considerably affect the availability of know-how. If protection is not extended to the product made by the process, the effect would be that inventors would prefer to work the invention secretly. In regard to drugs and medicines, it is the kncw-how relating to the manufacture that is more important. That is why although the composition of every medicine is given in the package, yet the public prefer to make their purchases of drugs / those menufactured by reputed If it is felt that the patenting of products has manufacturers. led to high prices or other advorse results, the remedy does not lie in abrogating patents in respect of arugs and medicines, but in liberalising the licensing policy and allowing a number of menufacturing units to obtain licences so that by force of competition the prices of patented drugs can reach their proper level. It is suggested that this clause may be suitably modified so that products also may be patented. The Patent Laws of the United Kingdom, the United States and many other countries provide for the patenting of products.

<u>Clause 21:</u> Under the existing Patents Law, a patent has to be accepted within a period of 18 to 21 months. In the Patents Bill no period is prescribed in this regard. Delay in the grant of patents will not only discourage the inventors, but will also delay the exploitation of the invention which may be of use to the public. The delay in the development of an invention may also affect other related industries. It is, therefore,

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important that the time for acceptance of applications by the Controller should be specified in the Bill, and this should not exceed 2 to $2\frac{1}{2}$ years. For this purpose, the Bill should prescribe in Clause 13 the time within which the Examiner should give his first report: and in Clause 21 the time within which the Controller should report the objections should also be specified.

<u>Clause 45:</u> In view of even the existing limitation on the tenure of patents, it is desirable that the date of the patent should be the date of the grant of the patent. Correspondingly, it is also desirable that the time for granting the patent, after the application has been filed, should be specified in Clause 43.

Clause 48: This clause provides, among other things, that the import of medicines or drugs by Government for its own purposes or for distribution in any dispensary, hospital or other medical institution maintained by Government or notified by Government shall not be deened to denstitute an infringement of patent rights. This has to be read with Clause 99 which specifie 8 that no royal ty will be payable in such cases. The Chamber feels that payment of reasonable compensation for a patentee for such user should also be provided in the Statute, as otherwise it will amount to expropriation of rights and will discourage for eign investment. A large proportion of the entire output of the pharmaceutical industry is utilised by Government and Government's health services, and the loss of patents protection over such a wide field is not desirable, without reasonable compensation being ensured by the Statute. In other countries of the world Government does not have the right to use the petents free of royalty.

<u>Clause 53:</u> One of the major features of the Bill is to reduce the tenure of patents, and that is effected by this clause. This clause provides that for inventions claiming a

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process for the manufacture of food, medicines or drugs the term of patent shall be 10 years, and that in respect of any other class of inventions the term will be 14 years. Under the existing law the term for all patents is 16 years, and there is also a · provision for extension for a further term of five to ten years. In the Bill there is no provision for extension of the term. The Committee of the Chamber are of the view that any reduction in the term of patents will be undesirable. With the complex nature of new technology, the time for putting an invention in the market on a commercial scale is generally large. Our country's procedural and administrative requirments make this time factor . even larger. The general experience is that it takes about 5 to 6 years from the date of the patent before it can be commercially exploited. Taking the case of drugs for instance, after obtaining the patent and studying the potentialities of the market for commercial exploitation of the product (which itself takes considerable time), further time is involved in the following processes .- Permission has to be obtained from the Central Drugs Controller for the manufacture of the product. Then a licence to manufacture the product has to be obtained under the Industries (Development and Regulation) Lct. Then licences have to be obtained for import of the machinery, spares, components and raw materials. After obtaining import licences, the actual import has to be arranged, which involves further time. Then the machinery has to be installed, and thereafter some further time is lost before production can actually commence. ...bout 5 to 6 years is lost in this way between the date of the patent and the commencement of production. It will be appreciated from this that reduction of the tenure of a patent to 10 years in the case of drugs, medicines and food products, and 14 years in other cases will leave an insufficient time for the patent holder to market the product and receive a fair return on the heavy expenditure incurred by him over research

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experimentation and studies before the cormercial development of the product. The Committee of the Charber are therefore of the view that the existing term for patents should not be reduced.

In foreign countries, the tenure is longer: it is 17 years in the United States, 16 years in the United Kingdom, 18 years in West Germany and 20 years in France, to quote a few instances.

Further, by reducing the term of petents as proposed in the Bill, the Indian Patent Law will not be in hermony with the Patent Laws of the world. The Model Patent Law for developing countries prepared by the United International Bureaux for the Protection of Intellectual Property (comprising 69 countries including India) provides for a term of 20 years for patents, at the same time allowing any country, if it so wishes, to shorten the duration to 16 to 18 years. But they observed that it is in the general interest that the rules concerning duration should be fairly uniform throughout the world so that the protection of a given invention will and approximately lat the same time in all countries: this would eliminate the inconvenience which might otherwise be caused to industry and trade by the fact thar an invention already free in some countries is still protected in others.

In the light of these considerations, the Committee of the Chamber hope that the existing period of 16 years for the term of p atents will be retained.

<u>Clause 84:</u> This clause enables the Controller to grant compulsory licences to work patented inventions. Under clause 92 where the Controller is satisfied that a prime facie case has been made out for making the order, provision is made to notify the patentee about the application for compulsory licensing, and the patentee is to be given an opportunity to oppose the application. In order that these, provisions may not prove to be -7-

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a disincentive to foreign interests, it is suggested that similarly as in clause 91, under clause 92 also a provision should be made to the effect that the Controller should issue a notice to the within patentee whether \angle a period to be specified by the Controller (after taking all circumstances into account) the patentee himself will effect manufacture in India, and only if the patentee declined to do so should a compulsory licence be issued.

Clauses 87 & 88: These clauses are new and provide that petents in the field of drugs, medicines, and beby and invalid foods, and chemical inventions shall be deened to be endorsed with the words 'licences of right'. Where such an endorsement is made, any, interested person may ask for a licence on terms to be mutually agreed upon between the patentee and himself, or failing such agreement, on terms to be settled by the Controller. Further, in no case is the royalty and other remuneration reserved to the patentee in respect of such patents, to exceed 4% of the net ex-factory sale price in bulk of the patented article (exclusive of all taxes, and of any commissions payable). These are drastic provisions and the Committee of the Chember feel that if they are placed on the Statute Book it may have serious adverse repercussion on research: for, there will be no incentive to maintain expensive research laboratories required for experimentation and development of new products, because these clauses provide easy accessability for new products developed by the research efforts of others. Again, because of the diminution of the patent protection resulting from these clauses, the tendency for inventors will be to work an invention secretly, and thus transfer of technology to under-developed countries like India will be prevented. Then again, a patent by itself is not of much use without the know-how acquired by the patentee in developing the invention: and, if several people not having the proper know-how are allowed to work the invention freely (which will be the result of Clause 88), the public may receive products of indifferent and inferior quality from some of the manufacturers,

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and the whole benefit of new developments will thus be lost to the public. The ceiling on royalty will not also stimulate inventions: the 4% royalty may in many cases be found insufficient to compensate the patentee for the huge expenses that he may have incurred over research and development of the new product: it has to be remembered that before one successful product is achieved there are numerous experimental failures, many of which are costly. The Chember feels that royalty terms should not be rigidly fixed by Statute. The royalty term will vary according to the nature of the invention and it will not be possible to lay down a rigid and uniform law in this regard. Every licence, before it is sanctioned, is screened by Government, and the quantum of the royalty can be negotiated at that stage.

The Committed of the Chamber therefore feel that Clauses ¹⁰ 87 and 88 should be dropped. The present law contained in Sections 23A, 23B and 23CC sufficiently provide for these matters. Under Section 23A, the Contral Government may at any time after three years from the date of sealing of a patent apply to the Controller for endorsement of that patent with the words 'licences of right' on the ground that by the refusel of the patentee to grant a licence on reasonable terms the establishment or development of commercial or industrial activities in India, is unfairly prejudied, or that the development of an industry the control of which is expedient in the public interest is being prevented or hind **ered**. When the Controller rakes such an endorsement, any on such terms person is entitled as of right to a licence/as may be agreed upon between him and the patentee, or in default of such agreement on terms to be settled by the Controller, and in exercising his right the Controller has to ensure that the inventor receives reasonable remuneration having regard to the nature of the invention. The Committee of the Chamber feel that these provisions are adequete to meet the public interest, and the drastic proposals contained in Clauses 87 and 88 of the Bill are not necessary.

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Clauses 99 and 100: Under clause 99 reed with clause 100, private patents may be used by Government undertakings free of any royalty or other renuneration to the patentee, and such use will not be deemed to be an infringener; of the patent, so long as it is done by an order of the Central Government or any person authorised by it. Apart from the discouraging effect it will have on the inflow of foreign capital because of the expropriation of the rights of the patentee, the Committee wish to point out that this provision will result also in discrimination as between companies under private enterprise and Government companies, for whereas Goverment companies could use the patents without having to pay royalty or any other remuneration, companies in the private sector cannot use these patents at all unless they get a licence from the person who has obtained the patent and that too only on payment of the agreed royalty. The Committee, therefore, suggest that the provisions of these two clauses be reconsidered. The specific suggestions that the Committee would like to make in this connection are:- (i) that Government companies be kept out of the purview of clauses 99 and 100; (ii) that with a view to protect the interests of the industry and ensure that the rights of patentees are not unfairly prejudiced, the right of Government to use inventions under these clauses be limited to certain specific purposes such as for purposes of defence, for prevention of epidemics and for other public purposes of like nature; (iii) that a provision be included in these clauses that before exercising the right under these clauses Government shall give the Patentee an opportunity to be heard; (iv) that it be made clear that Government's use of patents shall be subject to payment of royalty; and (v) that in view of the drastic curtailment of rights involved, the Patentee should have the right to appeal to the High Court against any expropriatory orders passed by Government under these clauses.

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Clause 115: While the Cornittee are glad to note that the right of appeal to the High Court is retained under this cleuse, it is found that there are two significant omissions in the list of Controller's orders against which appeals may be made to the High Court. Under clause '4(7), when the Controller orders compulsory licensing, an appeal will lie only to the Centrel Government and not to the High Court. Again, under clause 93 certain otherwise, discretionary powers are vested in the Controller in the matter of compulsory licensing: and against any decisions of the Controller in this regard, an appeal will lie to the Central Government only and not to the High Court. It has been represented to the Charber that in the United States also there is a system of Administrative Tribunals, but the experience has been unsatisfactory. When appeals are heard by judicial bodies it inspires confidence in the parties. Taking all things into account, the Chamber would suggest that wherever High Court's jurisdiction is taken away, the appeals should be decided by a quasi-judicial body with powers of summary procedures. The President of this Body shuld be a serving or retired High Court Judge, and there may be two Officers one from the Ministry of Law and the other from the concerned Ministry. Such a Body would give to the contending parties the adventages of a judicial consideration of the matters in dispute, and at the same time expeditious disposal.

In conclusion the Chember would like to observe that some of the issues involved in the Patents Bill are of a fundamentel nature, and may have a profound effect on the inflow of much needed foreign capital to India; on the transfer of technology to India from the industrially advanced countries; and on the future industrial development, and of industrial research, in our country. The Committee of the Chember have made the above suggestions for -11modification of the Bill bearing in mind these paramount considerations. The Charber therefore hopes that the various suggestions contained in this Henorendum on the Bill will receive the Joint Select Committee's sympathetic consideration. Thanking you,

ours faithfully,

(C.S.Pande) Secretary-General.

The Associated Chambers of Commerce & Industry of India

BENGAL CHAMBER OF COMMERCE AND INDUSTRY BOMBAY CHAMBER OF COMMERCE AND INDUSTRY CALICUT CHAMBER OF COMMERCE AND INDUSTRY

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THE FATENTS BILL, 1965

The Associated Chambers desire to comment only on a few of the major features in the Patents Bill which, in their opinion, are likely in their present form to prove particularly damaging to the country's industrial economy and which therefore require amendment. They would also like to preface their comments on specific clauses in the Bill with the following general remarks.

At the outset they would observe that patents are statutory grants which is return for the disclosure of an invention confer on the inventor for a limited period the exclusive privilege of working an invention, selling the invented product, and authorising others to do so. The main purpose behind the recognition of patents is to stimulate invention and thereby achieve technical progress. It is, therefore, in the national interest to have a system of protection by patents.

The Chambers are not convinced however that the radical changes in the law provided for in the bill will stimulate the inventive spirit in India and hasten industrial progress. On the contrary, they believe that, while the Bill will preserve the semblance of a legal patent structure, many of the changes which it seeks to introduce - notably, the issue of Licences of Right, the reductions in the life of patents, and the very wide exemption of Government from the need to honour the protection granted by patents - will in fact take away much of the incentive for an inventor to obtain patent protection for his invention. This will undoubtedly lead to a situation where inventors keep their inventions secret and do not seek patent protection, and such a retrograde step into the secrecy of the past can only have the most adverse effects on research and on technological and industrial development.

Since scientific research and industrial development are international A to a star in Struger in their scope, it is important too, that the changes contemplated by the Bill should be properly viewed in their international context. Most countries in the Sam and G world recognise patents, and the exchange of patented products in international markets underscores the need to observe fairly uniform legal practices. It is not desirable that India should be too far out of step with the general trend of patent legislation in other countries, for wide variations in national laws only tend to subject the international movement of goods to difficulty and hazard. The general trend among many countries to extend patent protection for longer periods is a factor of particular relevance at a time when India is engaged in developing export markets for her manufactured products. It is noteworthy also that countries which have hitherto refused to grant patent protection, or have granted only limited patent protection, have now taken steps to remedy the position. Italy is to introduce a law to grant patent protection in the field of drugs and medicines. Russia has recently joined the Paris Convention, indicative of the importance she attaches to patent protection in the field of international commerce.

Similarly, on the international plane, the effect of the Bill on foreign inventment should be most carefully assessed. Hitherto, India's policy has been to encourage a steady flow of foreign capital and know-how, and the special efforts made in this direction have been strongthened by the prospects of a vast and growing market, and a stable political and legal system that recognises the sanctity of property rights. The present measure, by reducing the term of patent protection, curtailing patent rights in respect of existing patents with retroactive effect, and authorising widespread infringement of these rights, can only have a most serious adverse effect on the climate of investment. The psychological impact is not confined to industries engaged in the production of food, medicines and drugs; the prospect of possible interference with the enjoyment of property rights as represented by a system of patents protection has caused serious apprehension among all industrial investors from overseas.

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The cost of modern research calls for the investment of large amounts of money in equipment and talent qualified to undertake the work. Large scale expenditure on research cannot be expected to materialise if it is denied the inducement of continued protection for the products in which it results, the promise of reasonable rewards and a guarantee that property rights now conferred by law - and potents are a species of intangible property - will continue to be respected.

The Chambers would now offer the following comments on specific clauses in the Bill :

Clause 25

It seems probable that this clause, when read in conjunction with Clause 8, will provide opportunities for vexatious opposition where, for example, information on competitive applications in other countries is not readily forthcoming.

Clause 48

This clause takes out from the sphere of infringement of patents rights a wide variety of operations if they are done by or on behalf of the Government. If the clause were enacted it would be open to the Government, which is a major consumer of many products, to import are use patented machines, apparatus or articles. While it is certainly the duty of every Government to ensure that the laws of a country pay due regard to the interests of the national economy, the provisions of clause 48 are cast in such wide terms as to confer almost unlimited powers on the Government to infringe patent rights. Clause 83 of the present bill, which refers to the general principles applicable to the working of patented inventions, states that patents are granted to encourage inventions and to secure that they are worked in India on a commercial scale and to the fullest extent. It is submitted that if clause 48 were enacted it would subject indigenous industry to the loss of patent protection over a wide field. It would lay the way open to the invasion of property rights, of which patents are an intangible species, at the hands of the Government, witnout reasonable compensation or due process of law. As for as is known, the provisions

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of this clause do not find a parallel in the patent laws of other countries, and it is respectfully urged that it be deleted.

Clause 53.

Existing patent law in India provides that the term of all patents shall be 16 years, and there is provision for the term of a patent to be extended by a further term of 5 or even 10 years if the Government is satisfied that the patent has not been sufficiently remunerative.

Clouse 53 seeks to determine the term of different classes of patent, and provides that for inventions claiming a process for the manufacture of food, medicine or drug the term of a patent shall be 10 years from the date of filing of the complete specification; in respect of any other invention, 14 years. It is further provided that the term of all existing patents relating to a food, medicine or drug will be 10 years from the date of the patent; in respect of other inventions, 14 years. In the case of a patent, duration is of the essence, and if the period of patent protection is too short for remunerative exploitation such a circumstance would substantially diminish the attractiveness that a potent would have for industrial investment. It is submitted as a broad proposition commanding general acceptance that too great a departure from accepted normal terms of putent protection would not be to the advantage of any country. Viewed in this light it should be noted that there is hardly any country in the world which provides for a term as short as 10 years without making adequate provision for extension of this term. In the case of drugs and medicines, the trend in all countries, particularly after the Tholidomine tragedy, is to prescribe for extensive and elaborate trials before clearing a drug for general use. In India too the procedures that have to be completed before commercial manufacture of a new drug is possible, involve such a timelag that the potent will in many cases have expired before the holder has derived any reasonable return for the expense which he has incurred on research trials and development. If the term of a patent is reduced to 10 years it would in effect be as good as the abrogation of patents in the field of drugs and medicines.

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It is in the general interest that the rules concerning the duration of a patent should be fairly uniform throughout the world and the protection of a given invention should end at approximately the same time in all countries. Reduction in the term of a patent to 10 years would not only put India out of step with the general trend of patent legislation in other countries, where the tendency has been to increase rather than curtail the term of patents, but might seriously curtail the flow into India of know-how from other countries. In brief, a serious impairment of confidence is likely to result with, so far as can be gauged, no componsatory benefits to off-set this.

Clauses 87 and 88 - "Licences of Right" and "Effect of endorsement of patent with the words 'Licence of Right' "

The existing law empowers the Controller on application being made to him under Section 23 A at any time after the expiration of 3 years from the date of secting of a patent to endorse a patent with the words "Licences of right" on the ground that by the refusal of the patentee to grant a licence on reasonable terms industrial development is being prejudiced. In such cases the inventor is to receive reasonable remuneration having regard the nature of the invention. In so far as food and medicine are concerned, the Controller is obliged in terms of Section 23CC on application made to him by a person interested to order the grant of a licence on such terms as he thinks fit, unless it appears to him that there are good grounds for refusing the application.

Clauses 87 and 88 of the Bill wark a radical departure from the existing law. Every existing patent relating to articles of food, medicine or drug, as also processes for the manufacture of chemical substances (including alloys, optical glass, semi-conductors and inter-metallic compounds) is to be deemed to be endorsed with the words "Licences of right" from the commencement of the Act. Clause 88 provides that where a patent has been endorsed with the words "Licences of right" any person who is interested in working the patented invention in India Law require the patentee to grant him a licence on such terms as may be mutually agreed upon, failing which either of them may apply to the Controller to settle the terms and the Controller after due notice shall decide the terms on which the licence shall be granted by

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the patentee. It is further provided that in respect of every patent deemed to be endorsed with the words "Licences of right" the royalty and other remuneration reserved to the patentee under a licence granted to any person shall in no case exceed 4 per cent of the net ex-factory sale price in bulk of the patented article. No appeal is provided for against the decisions of the Controller.

These provisions go far beyond the conditions governing compulsory licensing under clause 84 and, basically, their main result will be to deprive the inventor of protection for his invention and of reward for his efforts. Moreover, they are likely to lead to a situation where a plethora of applicants become entitled to a licence of right, irrespective of their financial standing or technical ability. A blanket ceiling of 4 per cent fixed for royalties without regard to the nature of the invention or the sums spent on developing it, if passed into law, would be a unique provision, almost confiscatory in some cases in its effect. If the objection to the legislation of 1911 is that it has failed to stimulate invention in India, one would expect that the present bill would be designed to achieve more effectively that desirable purpose. However, if clauses 87 and 88 were enacted as they stand it would be more profitable for industry in India to copy foreign invention thom to undertake original research. Such a development, at a time when India stands on the threshold of technical advance, and its own inventions will in future have to be safeguarded, can only be regarded as retrograde.

Clause 96.

The intention of this clause is obscure, but it might well enable marginal patents to be used as a lover for obtaining licences under major patents if other means failed. It is suggested therefore that the clause needs clarification and the incorporation of some safeguard against this danger.

Clause 116 - Appeals

A serious defect of the Bill is that it mokes no satisfactory provision for appeals. In terms of clause 116 no appeal lies against any decision, order or direction made by the Central Government under the Act, or

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from any act or order of the Controller for the purpose of giving effect to any such decision, order or direction. In other specified cases an appeal shall lie to a High Court from any decision, order or direction of the Controller. Apart from such appeals, it will of course be open to an Indian company, firm or person to appeal under Article 226 of the Constitution against an unfair or improper order of the Controller; but, since a constitutional appeal of this kind is not available to a non-Indian holder of an Indian patent, the appeal procedure will discriminate unfairly against foreign companies. Presumably the object in enacting clause 116 is to obviate the delays commonly experienced in ' all matters of judicial determination. If such be the case, it is respectfully urged that a more satisfactory remedy could be devised. The Chambers believe that the provisions of the U.K. Patents Act, 1949 which provide for appeal to a Patents Appeal Tribunal, comprising a single judge of the High Court, might usefully be incorporated in the proposed legislation. The Chambers understand that these provisions for appeals to a Patents Appeal Tribunal are not only working effectively, but are regarded in that country as an improvement on previous legislation on the subject.

MP:PCG 10.1.66

- From : Sri P. K. Guha, Hony. Secretary, All India Federation of C. & D., & Bengal Chemists & Druggists Association, 10, Bonfield Lane, Calcutta-1.
- To: Hon'ble Members of the Joint Committee on Patent Bills, Lok Sabha.

Dear Sir,

I have the honour to submit to you the following for your kind consideration :-

The pharmaceutical industry of India, has just passed its infancy from mere bottlers to processors. While during the earlier part of this century the medical profession had to depend solely on imported drugs, during the 1st and the 2nd Great War period necessity added fillip to this industry and at the present moment this industry employs about 50,000 people.

It is universally accepted that the cost of labour in this country is cheaper compared to the same in the other parts of the world and the indegenous resources are quite encouraging.

In spite of these facts, the prices of drugs and medicines are costlier in this country compared to the same in other parts of the world.

So far as the patent law in India is concerned it may justly be termed as a gift with the transfer of power which aimed at preserving the interest of the patent-holders who were mostly British firms. It needs no mention that indigenous enterprises had little opportunity to develop under the foreign rule and the tentacles of patent system acted as a discouraging factor. But those days are gone. India is now free and choosing her own way of development independent of any foreign directives. Then, why she should continue to safeguard the interest of only a few foreign concerns at the cost of our own national interest is a serious question which deserves careful and sympathetic consideration.

The protagonists of patent system argue that the "patent" has nothing to do with the higher cost of medicines in this country and put up the various reasons that affect the price structure, including of course, the higher prices of imported raw materials, prices of indigenously obtained raw materials, solvent losses oving to high temperatures, duties, taxes, etc. etc. Hon'ble sirs, you will certainly understand that excepting the argument relating to the prices of indigenously obtained raw materials, the other factors are common every where in the world with little variations.

It is argued that the abolition of patent will retard the development and research in this country. You will certainly agree that this argument is fantastic. If anything it amounts to, that is, it east aspersions to the genius of the inventors, who had dedicated their lives for the welfare of the human being. Right from the early days of physician Galen of 200 A.D. till the present day, there is not a single reference, to prove that the mind of an inventor of remedy was pre-occupied with the idea of a patent on discovery or that any invention or discovery was made on prior assurance.

The patent system or in other word the "exclusive privilege" is nothing but a gurantee of profit assured to the commercial burgainer of an invention covering all its processes. In a country like India, where the per capita income is low and the per capita consumption of pharmaceuticals is as low as Rs.2/- per annum the continuation of adding premium on the cost of treatment, is certainly hard to bear.

The problem again, is not that there is any dearth in talent for research, or shortage of entrepreneurs, which could establish a fair competition in the drug industry for the benefit of the people but it is due to the blockade created by the execlusive privilege granted to the owners of patents that the progress of the pharmaceutical industry has been largely checked. The licensing system again, is no remedy of the evil. It is a known fact that throughout the world, where the patent system is prevailing, the industry is mostly controlled by interests controlling the patents and the licencees can make negligible efforts in relieving the cost problem

Italy is a country with no patent system and has made definite progress in the pharmaceutical trade, in as much as, her foreign trade in this sphere has added to its exchequer. And if the "standard" is the question, it has definitely established its efficiency. The name of Japan can also be cited as a rapid developing country having no patent law before the World War II and in fact, the absence of patent law in that country did never stand in the way of her tremendous progress in the sphere of industry. These two countries had to bear the brunt of the last Great war most severely but as a matter of fact the development of their industries after the war did hardly suffer for the absence of any patent law.

Then comes Russia, where the Drug research is entirely controlled by the State. The development of Medical Science in that country, needs no mention here. The progagonists of pat nt system have, of course, without any reliable evidence referred to the failure of that country, in inventing any new drug worth mentioning. It is clear enoughfrom their views reproduced in the Pandal bulletin, that the real pain thes with the fear of State control - or in other words the "Nationalisation terror". Sirs, if there is a choice between the monopolistic ring" created by the so-called India Private Limited concerns protected by patents and the State control, the latter is definitely beneficial to this country and its poor masses.

It cannot be defied that the patentees in Drug industry form a privileged nonopoly group, not only in this country, but in developed countries too. And its impact are quite well felt. The public reaction to the heavy burden on the National Health Service Scheme in U.K. imposed by the Drug industry is too well known, and that perhaps, prompted the Labour party to include drug industry in the list of of "Nationalisation". The effect of the patent syst with r is easily understandable, although not apparently express Q.

The American Drug Manufacturers contribution on this score is also worth mentioning. The "Pregress through alliance" deal of the Drug manufacturers in the matter of aid to South America, is a glaning example, which initiated an investigation by the American Senate. A little study of these facts will reveal the unfortunate system of capitalising on human ailment.

B Podia praise and support are always accorded to better efforts and the Drug Manufacturers here have the best opportunity of exploiting a market bigger than that of the whole of Europe taken together and earn greater profit through free and fair competition and without resorting to unwarranted protection of patent system. The pharmacopoeal non-patented drugs are best examples.

In the conclusion, Sirs, India and its people, having in view the Socialistic system, can hardly afford to pay any unwarranted extra premium for the treatment of the sick and suffering population. It is suggested, therefore, that, for the interest of the millions of people, India should do without the patent protection for the benefit of a few. Should any doubt, as to the feasibility of doing without patent, cause to cloud your minds, let us try at least for 20 years or so without patents to have the matter tested.

Thanking you, Sirs,

Yours faithfully, MGdaue

P.K.Guha.

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So far as the patent law in India is concerned it may justly be termed as a gift with the transfer of power which aimed at preserving the interest of the patent-holders who were mostly British firms. It needs no mention that indigenous enterprises had little opportunity to develop under the foreign rule and the tentacles of patent system acted as a discouraging factor. But those days are gone. India is now free and choosing her own way of development independent of any foreign directives. Then, why she should continue to safeguard the interest of only a few foreign concerns at the cost of our own national interest is a serious question which deserves careful and sympathetic consideration.

The protagonists of patent system argue that the "patent" has nothing to do with the higher cost of medicines in this country and put up the various reasons that affect the price structure, including of course, the higher prices of imported raw materials, prices of indigenously obtained raw materials, solvent losses oving to high temperatures, duties, taxes, etc. etc. Hon'ble Sirs, you will certainly understand that excepting the argument relating to the prices of indigenously obtained raw materials, the other factors are common every where in the world with little variations.

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The problem again, is not that there is any dearth in talent for research, or shortage of entrepreneurs, which could establish a fair competition in the drug industry for the benefit of the people but it is due to the blockade created by the execlusive privilege granted to the owners of patents that the progress of the pharmaceutical industry has been largely checked. The licensing system again, is no remedy of the evil. It is a known fact that throughout the world, where the patent system is prevailing, the industry is mostly controlled by interests controlling the patents and the licencees can make negligible efforts in relieving the cost problem

Italy is a country with no patent system and has made definite progress in the pharmaccutical trade, in as much as, her foreign trade in this sphere has added to it exchequer. And if the "standard" is the question, it has definitely established its efficiency. The name of Japan can also be cited as a rapid developing country having no patent law before the World War II and in fact, the absence of patent law in that country did never stand in the way of her tremendous progress in the sphere of industry. These two countries had to bear the brunt of the last Great war most severely but as a matter of fact the development of their industries after the war did hardly suffer for the absence of any patent law.

Then comes Russia, where the Drug research is entirely controlled by the State. The development of Medical Science in that country, needs no mention here. The progagonists of pat nt system have, of course, without any reliable evidence referred to the failure of that country, in inventing any new drug worth mentioning. It is clear enoughfrom their views reproduced in the Pandal bulletin, that the real pain thes with the fear of State control - or in other words the "Nationalisation terror". Sirs, if there is a choice between the nonopolistic ring" created by the so-called India Private Limited concerns protected by patents and the State control, the latter is definitely beneficial to this country and its poor masses.

It cannot be denied that the patentees in Drug industry form a privileged monopoly group, not only in this country, but in developed countries too. And its impact are quite well felt. The public reaction to the heavy burden on the National Health Service Scheme in U.K. imposed by the Drug industry is too well known, and that perhaps, prompted the Labour party to include drug industry in the list of of "Nationalisation". The effect of the putcht systematics is easily understandable, although not apparently war as 5.

The American Drug Manufacturers coals it is a contribuscore is also worth mentioning. The "Programs it wash while one" deal of the Drug manufacturers in the matter of aid to South America, is a glaning example, which initiated an investigation by the American Senate. A little study of these facts will reveal the unfortunate system of capitalising on human ailment.

India praise and support are always accorded to bester efforts and the Drug Manufacturers here have the best opportunity of exploiting a market bigger than that of the whole of Europe taken together and earn greater profit through free and fair competition and without resorting to unwarranted protection of patent system. The pharmacopoeal non-patented drugs are best examples.

In the conclusion, Sirs, India and its people, having in view the Socialistic system, can hardly afford to pay any unwarranted extra premium for the treatment of the sick and suffering population. It is suggested, therefore, that, for the interest of the millions of people, India should do without the patent protection for the benefit of a few. Should any doubt, as to the feasibility of doing without patent, cause to cloud your minds, let us try at least for 20 years or so without patents to have the matter tested.

Thanking you, Sirs,

Yours faithfully, P.K.Guhn.

pkg:kd.

MEMORANDUM

ON

THE PATENTS BILL 1965

T. DURAIRAJAN

4

TELEGRAMS : { '' HADENSA ''
'' TEDCOY ''

T. DURAIRAJAN THE DOLLAR COMPANY

MERCHANTS AND AGENTS

TELEPHONE: OFF: 23456, 23868 LAB, 51674 ANDHRA INSURANCE BUILDINGS 337, THAMBU CHETTY STREET MADRAS-1 (South India)

15th January 1966

The Secretary, LOK SABHA Lok Sabha Secretariat NEW DELHI

Sir,

PATENTS BILL 1965

I beg to enclose my memorandum, in response to your notification in the Press recently, asking persons interested in the above Bill to forward their comments to you, on or before 12th January 1966. I regret, that there has been some delay in getting the copies printed, as the manuscript copy prepared by me earlier and given to the printer was mislaid, and thereafter holidays intervened here between 11th to 16th instant. I am, therefore, enclosing a typed copy, and will be forwarding to you 65 printed copies within the next few days, and would request you to pardon me for the delay. I am submitting this memorandum as an individual, from the experience and knowledge I have gained during the past two decades, mainly as importer and wholesaler of Pharmaceutical Drugs and latterly as a small manufacturer of proprietory medicines, tablets, etc.

I am in agreement with the sponsors of the Bill, as I realise the necessity for granting necessary protection and recognising patents, which affords a return for the inventor for a limited period, for his invention and thereby gives an incentive for further research and also investment on further large expenditure. In other words while such products as for example ASPIRIN were invented or discovered by individuals in small sized laboratories, modern inventions as hormones, steriods, antibiotics, tranquilizers, etc. have been discovered or identified only by large sized companies, with a team of scientists, biologists, assayers, and wider clinical trials.

I would, however, mention that although Patent laws are recognised in most of the civilised countries in the World, yet, a majority of the inventions relating to drug and medicine have been confined only to a few countries as U. K., Germany, France, Switzerland, Sweden, U. S. A. and recently Mexico, where the cortesteroid under the generic name Prednisone was discovered. In point of fact over 90% of the Patents in the field of drug and medicine in our country are held by foreigners. It is only quite recently we hear about discoveries as Hamycin and Dermostatin developed by the scientists at the research department of Hindustan antibiotics, Pimpri, but having regard to the various or similar antibiotics, I do not know if countries outside India will evince any interest in the same, or for that matter, I am not very sure if these two products will have any sales worth mentioning in our Country.

The United States which has granted full patent protection i. e both for product and process since 1790, and with all their resources, the very large purchasing power, and their currency being free, yet, had not developed an important drug industry of its own, with any patents to their credit in the past, and it was only during the recent 20/25 years, that several important discoveries in the line of drugs have been made in U. S. A. and patents obtained. The demarkation period appears to have been occasioned by the British, due to conditions during the second World War being unable to devote time and energy on research, resorted to laboratories and manufacturers in U.S.A. to explore the possibilities of mass production of "Penicillin" by fermentation process, which was readily available with them. This in fact really laid the foundation for further research and discovery of new drugs. It was actually a Czech refugee Dr. Frank M. Berger that had discovered a muscle relaxant Mephenesin in U. K. but went to the U. S. A and succeeded in patenting a closely related product (DRUG) Meprobamate, sold under the trade names of Miltown and Equanil, perhaps having the largest sale as a tranquilizer. Sometime thereafter a research team in a comparatively small manufacturing firm in U. K. have been able to evolve an entirely different process for the manufacture of Meprobanite and I understand the owners of the patent in U.S.A. Carter Wallace did make abortive attempts to purchase the same.

I have set out the above facts only with a view to illustrate that by merely granting Product and Process protection, it will not stimulate research or afford an incentive. Let me again amplify this further. If a product patent (i.e. product and process) is granted for say a new "Tranquilizer" in which the reported yield from the starting material is say 10% or less, and for the sake of argument another scientist or a small manufacturer is able to produce the identical product by an entirely different process from a different starting material of lesser cost, or with the same raw material with a yield of say 25% or more, this latter firm will be helpless, unless the product patent holder grants him a licence, and it is only thereafter that he would be able to obtain a patent for his process. Also, in view of the relatively lower yield in reference to the original product patent holder the cost to the consumer would be relatively high, and the benefits arising from the latter process will not be available both to the country and the consumer. There will thus be a definite incentive or encouragement on the part of others to evolve different or other economical methods or processes of manufacturing the patented drug or substance, including the patentee if the rights are restricted only to "process patent".

In this context, I wish to bring to the notice of the members two instances where the patentee's of the drug have endeavoured to exploit their patent rights to the detriment of this Country and perhaps due to lack of necessary provisions in our patent system as the present Bill, suitable action could not be taken.

(i) The Swiss firm Hoffmann La-Roche hold the patent in this Country for "CHLORDIAZEPOXIDE" a tranquilizer sold by them in tablet form under the trade name "LIBRIUM". Since the substance is not manufactured by them in India, though they have an associate Company Roche Products of India, in which they have a majority holding, the Indian Company have been importing the drug at a price of around Rs. 5.500/- per kilo, and then processing and selling the same in the form of tablets, again with a very large profit. As however, the same drug is available in Italy, exporters purchasing from manufacturers are able to offer the same pround Rs. 300 / 350 per kilo. It was only when this came to the notice of the authorities, the maximum price at which the above drug would be allowed import was gazetted, and I believe the Roche People also are now obliged to import the drug at this level.

(ii) A patent was granted to Messrs. May and Baker No. 26513 in India for Sulphathiazole. A similar Patent was also granted to them ln U. K. As however, the invention was considered 'WIDE' as the specification was capable of nearly 9 million derivatives, Boots another British firm therefore filed a petition for revocation of the patent in U. K. and the matter was pending in the Courts there. As Boots have an Indian Company and had imported Sulphathiazole, May and Baker filed an action against Boots in the Calcutta High Court for infringement of their Indian Patent, which was naturally resisted by Boots on the same lines as in U. K. While the proceedings against the judgement in the Chancery division of the High Court, (Jenkins J) allowing the petition of Boots and granting the revocation, was pending in the House of Lords, in the Calcutta High Court in Suit No. 890 of 1946 both the parties compromised the same in March 1949 and allowed the patent in favour of May and Baker to be affirmed. Shortly thereafter early in 1950, the House of Lords, by a majority judgement of Lord Simonds dismissed the appeal of May and Baker, and the patent was thus revoked. Inspite of this May and Baker continued to advertise in the Indian Press as under between 1952 / 55 :---

> "May and Baker Limited of Daganham, England, owners of Indian Letters Patent No. 26513 relating to processes for the manufacture of Sulphathiazole, have from time to time warned the trade of the consequences of importing Sulphathiazole into india in infringement of their patent rights.

> They have endeavoured to avoid a restrictive policy, and have in many cases been able to avoid loss to their friends in the trade who have inadvertently, or through ignorance of the trade position rendered themselves liable to legal action. Nevertheless, they believe that despite their wish to avoid unnessary litigation certain importers have continued to offer this material for sale .n infringement of Letters Patent 26513 and it is, therefore, necessary for the patentees to take stronger measures for the enforcement of their legitimate commercial interests As from the 1st July 1952 therefore, May and Baker Limited will cease their practice of warning infringers of their patent, and will take immediate action in all cases of infringement which are brought to their notice. If however, any importer or dealer who is still in possession of offending material or who is committed financilaly in connection with the importation of further consignments, will submit before the date of 31st July 1952 a true account of his stocks or liabilities to the patentee's associated company at one of their addresses, negotiations will be started "without prejudice" to arrange the disposal of the material without causing a financial hardship. No such sympathetic consideration will be given to dealers who continue wilfuily to infringe May and Baker Limited's patent rights after that date.

Most members of the trade will, ofcourse, be aware that certain other firms are licensed to sell Sulphathiazole in India under the above Letters Patent.

Supplies sold under these llcenses are only available through the accredited agents of the licensees who are as follows :

Licensees :	Accredited agents or Representatives
Ciba Limited, Basle, Switzerland.	Ciba Pharma Limited.
Boots Pure Drug Company Ltd. Nottingham, England	Boots Pure Drug Company (India) Limited.
E. R. Squibb and Sons, New York, U. S. A.	Sarabhai Chemicals Limited.
Eli Lilly and Company Inc. Indianapolis, U.S.A.	Eli Lilly and Company (I) Limited.

warning importers from obtaining supplies of Sulphathiazole and continuing to benefit from the compromise. It was only when May and Baker filed an action for alleged infringement of their Patent against a firm in Madras in C. S. No. 34 of 1953 of the Madras High Court that Justice Rajagopala Iyengar who tried the suit held that there was no infringement, and thereafter the drug was being freely imported.

I have mentioned these only to show that while under the earlier Act there were no specific provisions to deal with such malpractices with the provisions in the present Bill, it will be possible to deal with such abuses effectively.

I would also submit that we have to consider the various clauses in the Bill, from conditions existing in India, and not with those in advanced countries, especially in view of the present acute foreign exchange position, which I am afraid will continue for the next 5 to 10 years.

I am appending below an extract from "Administered Prices – Drugs " - Senator Kefauver committee report (at page 42).

"Chas Pfizer and Company: for example conducts more extensive foreign operations than any other U. S. Manufacturer approximately 45% of the Company's 1959 sales of 253 million dollars, were made in foreign markets. Yet its foreign markets were more profitable than the domestic market.

The following question was put :

Senator Kefauver: How can you make more money abroad on less sales in the United States.

In reply the President of Chas Pfizer and Company said :

Mr. KcKeen: Senator, with your permission, I would like to keep that as a trade secret. "

In a majority of the cases, the foreign manufacturing firms in India have endeavoured to import the substance or intermediary from their parent Company at prices far in excess of world prices the reason behind being obvious. As however, these products after processing are being sold under their trade name enabling them to have sufficient profits, it is to their advantage to have larger amounts remitted to their parent Company. Although under the provisions of this Bill, the authorities do not have the necessary powers to check such malpractices, if a committee is appointed to investigate such imports during the past say 20 years, it would probably be a revelation. as to the large amount of foreign exchange that has been drained from this country. In view of all this, I welcome the various provisions of the proposed Bill, and trust the members of the Joint Select Committee will consider the same objectively and recommend that with such minor amendments or alternations as are whereever considered necessary, they would recommend the passing of the same.

I shall be grateful for favour of on acknowledgment, and remain,

Yours faithfully,

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(T. DURAIRAJAN)

Encl. 1

Memorandum from:

T. DURAIRAJAN, c/o The Dollar Company, Andhra Insurance Buildings, 337, Thambu Chetty Street. Madras-1.

Clause 2 (g)

Definition of Food: Although this is not either in the patents Bill 1953, or in the report of Justice Rajagopala Iyengar, I am glad that the framers of the Bill have thought it necessary to give the Central Government wide powers, which I trust would be exercised in the larger interests of the country as and when circumstances or necessities arise; otherwise the definition as mentioned is in order.

Clause 2 (h)

In order to discover a new chemical substance or drug or to isolate the active ingredient from a herb, which has been known to have some therapeutic value, apart from a well equipped laboratory what is mainly required is a large team of scientists and assayers, which is lacking in our country. Although it may appear to be in the nature of taking away the rights granted to a patentee, in actual practice as commercial exploitation requires an entirely different set up, it will not be so. The definition, therefore, does not require any change.

Clause 2 (I)

Medicine or Drug: I presume that this has been put in this form in order, that after the grant of a patent for a chemical substance, which can be used in the manufacture of only chemical substances or chemicals and not as a medicine or drug, if the same chemical substance later on can be used as an intermediary in the manufacture of a medicine or drug, there should not be any lacuna in the act and create legal difficulties. Also, in the process or processes involved in the manufacture of a patented drug, requiring the use of various chemical substances, and or catalytic agents, it is necessary to have the above protection in order to work the patent satisfactorily for medicines or drugs as otherwise the use of any chemical substance in such manufacture is likely to amount to an infringement of the patent. I. therefore, feel that the definition in the above form though may appear wide would be in the larger interests of our country, and should stand.

Perhaps it may be useful to illustrate my submission. 'X' is a patented chemical substance and not used as a medicine or drug. 'Y' is a patented medicine in substance form. In order to manufacture 'Y' the chemical substance 'X' is required. In the absence of the above definition, a licensee in India for 'Y' will not be able to manufacture the same; or in other words the grant of such a license itself will be incapable of performance.

e.g. I. N. H. | GAMA PICCOLINE

Clause 3

While I am in agreement with all the sub-sections, I am afraid that Clause (d) is likely to act as a deterrent in the case of any novel product, produced by known processes, and known substances. For example if a combination of known drugs prepared in a particular method is tested and found effective for a disease for which no remedy has been found or discovered so far under this sub-Clause it cannot be patented. Liwould, therefore, suggest that it may be suitably amended by the addition of "except in the case of product or products produced by process or processes which are novel".

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Clause 5

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This provides a necessary amendment that has been lacking in our patent system which has been hitherto granting patents both for the process as also the product. I may mention that in such an advanced country like West Germany, responsible for several inventions the protection is granted only for the process and not for the product. Also, Switzerland, France-Sweden and Mexico grant protection only for the processes and not for the product. In view of my general comments, I strongly recommend that no amendments should be made, and the Clause in the present form should stand.

The only question that will arise will be with regard to infringement and the onus of proof with regard to process of manufacture, whether by the patented process or processes or by a separate process. According to the Indian Evidence Act, the burden of proof will be on the Patentee to establish that the infringed product had been manufactured according to one of more of the processes claimed, and if the product was manufactured in a country outside India and imported, the patentee or the Court may not have any access or means to ascertain such details. Also from the end product it will be difficult to establish the process adopted in the manufacture. In order to get over this anamoly I would recommend that a suitable provision should be made in this Clause providing that subject to the patentee establishing that he has covered all economic processes of manufacture in the absence of any evidence from the other manufacturer to the contrary it shall be presumed that the imported product alleged to infringe the Patent is or has been made according to the process or processes claimed in the Patent.

Clause 25

This clause should provide an exception in the case of imports made by the applicant for the grant of the patent for research, clinical trials and evaluation purposes; otherwise it is in order.

Clause 47

In view of my remarks under Clause 5, this "product-by-process" protection under this Clause in the case of drug or medicine would be quite adequate.

Clause 48

This is very commendable. I might refer to the recent case of Pfizer Limited Vs The Crown in U. K. where the House of Lords held that the import into U. K. by a private firm of a patented substance "Oxytetracycline" from Italy, and supplied to the Government for use and distribution including numerous chemists in the country dispensing prescriptions under the National Health Services was held to be 'for the use of the Crown' under the U. K. Act. and that there was, therefore no infringement of the patent. The provisions in the Bill under Clause 100 confer only very limited powers for the use of a patent or invention by the Government, and the above clause is, therefore, just and necessary. I have no doubt that the Central Government will exercise due and diligent care in the exercise of their discretion before notifying in the official gazette to prevent any abuse.

Clause 53

The ten year period should be from the date of acceptance by the patent office While in countries like U.S.A. where the Federal Drug Administration have laid down elaborate procedural details to be followed before a new drug or medicine is allowed to be marketed, in our country, permission from The Central Drug Control administration is obtained within a very short time, in many cases within 2 to 3 weeks. There is, therefore, no need to reckon the delay that is occasioned in other countries. In view of the fact that many drugs or substances are replaced by new discoveries and the patented products are sold only as ethical products through the medical profession, under a distinct, trade mark, even after the term of expiry of the patent, the patentee continues to derive profits on a much larger scale, due to the medical profession continuing to prescribe under the trade name and not under the common name. The peried of 10 years will, therefore, be adequate. I would, howver, suggest that a provision can be made that in special cases where the patentee is able to satisfy that it had not been possible to obtain sufficient reward in relation to the amount expended on research in discovering the product, extension can be granted and such period may be for a maximum period of 2 to 3 years.

Clause 64

In view of my general comments that provision should be made while granting a licence for working a patent in India, for "Compulsory licensing of know-how" under Clauses 87, 88 mainly on the ground that the technological advance in our country and facilities for scientific research are far behind other countries, the provisions under this Clause are quite essential. It may appear that there is an admission on the part of the authorities by the mention of 'average skill and 'average knowledge' of the Act as relating to our country under sub-section (h) to the above effect, but until such time that we are able to come up to the standards in the other advanced countries I feel there is nothing wrong in such an admission.

Clause 66

Perfectly in order, especially in view of the facts cited by me in regard to Patent No. 26513 relating to Sulphathiazole in the earlier part of this memorandum. The only comment I will make is whether under our Constitution, we can take away the right of the patentee to apply to a judicial tribunal of the High Court against the decision of the Central Government. Perhaps it will be useful to examine this aspect and see if a suitable amendment can be made providing for appeal to a proper judicial authority or Court.

Clauses 87, 88

While the concept of compulsory licensing of Drug Patent is commendable it must be apprecisted that the mere grant of a 'patent licence' in most instances would be of very little or no use, unless it is accompanied by disclosure of 'know-how', including plant designs, specification and recipes. This practice is now being considered, seriously in some of the countries and I understand that the authorities in Belgium are proposing to introduce legislation to this effect. In some of the under developed countries like Turkey, Greece and Isarel, I gather that such a procedure is likely to be adopted. There seems to be no point in our comparing with conditions existing in such advanced countries like U.S.A., U.K., Germany, etc. and consider compulsory licensing without "technical know-how". The paymet of any royalty would only be justifiable if the quality of the product produced in India; exactly corresponds to the original in all respects I, therefore, submit that "compulsory know-how" should be made a pre-requisite for any such licensing and remittance of royalty. As regards the percentage of royalty, since in many of the agreements for setting up factories with foreign collaboration, royalties have been provided as and for "technical know-how", I recommend that instead of a maximum of 4% that is fixed in the Bill, the same may be increased to a maximum of $7\frac{1}{4}$ % on the bulk Ex-Factory price. I would strongly stress that there should be compulsory disclosure of "Know-how", and should be made a pre-requisite for licensing of any patent, in order to insure that there will not be any delay in the manufacture of the product by the licensee in this country and the quality would compare with those obtaining in other countries. Then only payment of royalty would be justifiable. In this connection it may not be out of place to mention that if the patentee himself works the patent in India and is able to offer the product at reasonable prices and is able to meet the entire demand of the country both to the consumer and for other smaller factories, the chances of others applying for compulsory licensing will be remote. The above provision will, therefore, certainly act as a deterrent, in that the patentee would be compelled to keep down the prices of the product at a reasonably low level.

As regards the persons mentioned under Clause 88, there should be sufficient safeguards that the person applying should have the necessary machinery, equipment and technical personnel or undertakes to do so, before the licence is granted to him. Ref: Page 233 of Justice Rajagopala Iyengar's report:

It may also be useful to append paragrach 156, at page 66 of Justice Rajagopala Iyengar's report :---

Know-how

156. The third reason assigned by the Swan Committee for the paucity of applications for compulsory licences was that few inventions could be worked or worked commercially with the description and instruction contained in the patent specification, without the knowledge of the technical "know-how" and as the patentees were not inclined and could not be compelled to impart the "know-how" the compulsory licensing provisions were rendered inefficitive without the co-operation of the patentees. This [factor is obviously of greater significance in this country than in the U. K. because here, owing to the comparatively less technological knowledge, licensees are less able to devise methods by themselves for working an invention. Speaking of the role of know-how in rendering ineffective provision regarding compulsory licences; Penrose observes :—

"** It is alleged that without the "know-how" many patents could not be worked. If this latter allegation is true, it must mean that the disclosure of the invention (which is legally required in order to obtain a patent and is supposed to be sufficient to enable others to apply the new invention) has been insufficient. Stricter laws regarding disclosure may be desirable, even providing, perhaps, that to obtain a patent a patentee must be prepared to instruct a licensee in the use of the invention if necessary." (page 197)"

Clause 89 and 90

I have no doubt the framers of the Bill have introduced these provisions having regard to the reluctance on the part of manufacturers of drugs under their patents or under licence from ¹heir parent companies to set up manufacture in India without delay and even after doing so offer a part of their production in substance form to other smaller manufacturers for processing and sale. Also, as mentioned in my general comments, there have been innumerable cases where the patentee, or the licensee in India has always adopted the practice of importing the substance or intermediaries at prices very much higher than what their parent companies have charged to other markets, or pay for intermediaries themselves, so that the total foreign exchange remitted from this country is free of Indian Income-Tax and becomes wholly available to their parent company. I trust I have made myself clear, and these two clauses are, therefore, necessary.

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Clause 95 (3)

In view of the example relating to "CHLORDIAZEPOXIDE" sold under the trade name "LIBRIUM" by the Roche people cited by me, this clause will, in public interest be a safeguard and I welcome the same.

As, however, it may take some time before a "Licensee" as defined, sets up manufacture, it may be he would endeavour to import the product, subject ofcourse to the present import restrictions. It would also be unfair to allow the licensee to import the product after he has set up manufacture in the country. I would, therefore, suggest that the persons or firms applying for the licence should be screened by the authorities i.e. the Central Government and after satisfying themselves that the person or firm applying for the licence is in a position to set up manufacture of the product, grant the license.

I would also recommend that if any person or firm requires the patented product for the use of the Government Departments, i.e. for supply against a Government Tender, he should be able to import though he may not be a licensee under the Act. and as held in the recent judgement of The House of the Lords in the "Pfizer's case," this would not amount to an infringement of the patent.

Clause %

I would recommend that instead of the the decision of the Controller being subject to appeal to the Central Government, it should be to a Judicial tribunal or a Court. This will be in conformity with the recommendations of Justice Rajagopala Iyengar in his report at page 110, Also, persons who interpret the law should not be allowed to sit in judgement over their own decision or of their subordinate, which as at present will be final.

Clause 126

This Clause in effect means in order to qualify for functioning as a patent agent, the person should be a scientist as well as an advocate. It is common knowledge that persons who have handled some of the important or leading patent cases, in the High Courts have been those who have been practising as lawyers without any scientific background. While, therefore. a minimum number of years of practice of say 5 to 10 years as lawyers can be fixed, this Clause should be so amended as to include lawyears, barristers, solicitors, who have had the minimum number of years practice at the bar, and such persons who possess such scientific or technical qualification as the Central Government may specify in this behalf.

In regard to the existing patent agents they will be duly protected under sub-Clause C (iii).

In regard to the other provisions of the Bill, I have no comments to offer at present, as I have confined my self with regard to such provisions as are directly applicable to Medicines and Drugs.

If, ofcourse, I am called upon to tender any evidence before the Joint Select Committee, and any further points occur to me I shall be only too pleased to apprise them.

(T. DURAIRAJAN)

1. Judgement of the House of Lords :

House of Lords.

INVENTION OF DRUG: CLAIM TO PATENT FOR AMENDED SPECIFICATION

May and Baker Ltd., and others Vs Boots Pure Drug Company Ltd.,

Lord Simonds, Lord Normand, Lord Morton, Lord Mcdermott, and Lord Reid 9th Feb 1950

• Appeal from the court of appeal :

Certain letters patent were granted to the appellants May & Baker Ltd., and Ciba Ltd. jointly on 24th May 1946. On 12 th Sep 1946 a petition was presented by respondents Boots Pure Drug Co. Ltd., for revocation of the patent. On 28th March 1947 the patentee company applied by motion under section 22 of the Patent and designs act to amend the specification of the patent and the motion was ordered to come on for hearing with the trial of the petition. The Patentees informed the petitioners Boots that if the proposed amendments were not in substance allowed they did not propose further to contest the petition. The patentees had discovered two drugs Sulphathiazole and Sulphametylthiazole. Jenkins J. found that the production of these two drugs was a patentable invention and that they were useful drugs. The claims of the sepcification were not confined to those two drugs, but included a large number of sulphathiazole derivations. By the proposd amedments the patentees sought to restrict the patent so as to claim only the manufacture of the two substances to which the specification specifically referred. The court of appeal affirming Jenkins J., held that the specification as amended would claim an invention substantially different from that claimed in its original form, and that accordingly the court had no power to allow the proposed amendments. The patentees now appealed :

The house took time for consideration.

Lord Simonds said that there was no hint in the original specification that the exemplary drugs Sulphathiazole and Sulphamethylthiazole were essentially distinguishable from any other members of the vast group within which they fell, or that they had some peculiar characteristic which gave them a therapeutic value. No one could fairly read the document without concluding that their therapeutic value was derived from a generic quality, they illustrated the invention just because they had that quality. No separate claim was made for the manufacture of those two specific drugs, or for the drugs themselves or either of them. It had been contended for the patentees that to limit the claims of a specification to the only form of invention specifically described in the unamended specification and therein claimed in general terms connot be to claim a substantially different invention. But it was begging the question to say that in every case in which the patentee had stated the nature of his invention in wide and general terms and then given an illustration of it, he could shift his ground and claim that his invention was not the general but the particular; he could do so only if they were the same inventions. That problem was to be solved by the consideration of the facts of each case, and the court was not to be percluded from enquiring whether the illustration given by the patentee was in fact an illustration of the invention which he had generally described. In His Lordship's opinion the proposed amendment would make the invention claimed substantially different from that claimed before amendment. Accordingly it was not permissible under the act and the appeal should be dismissed.

Lord Normand agreed that the appeal failed.

Lord Morton dissenting said that the proposed amendment was in his opinion one by way of disclaimer, and not prohibited by the proviso to Sec 22 of the Patents and Designs acts 1907/46. He regarded the two drugs as being the preferred embodiment of the invention described in the sepcification. It seemed to him that the patentees were not claiming a substantially different invention, but something which was part of the wide invention originally claimed.

Lord Macdermott agreed that the appeal should be dismissed.

Lord Reid said that he thought that the proposed amendment was competent, but t hat it did not necessarily follow that the appeal must succeed. He was unable to agree that the appeal should be dismissed on the grounds which Their Lordships had stated. Appeal Dismissed.

(True copy from Solicitor's Journal Page 112 dated 18th Feb 1950).

Suit No.: 890 of 1946

In the High Court of Judicature at Fort William in Bengal Ordinary Original Civil Jurisdiction.

The Hon'ble Mr. Justice Chatterjee

May and Baker Ltd., of 42/43 St Paul's Churchyard London E. C. 4

Against

Boots Pure Drug Co. (India) Ltd. 10, Lall Bazaar st. Calcutta

Upon reading on the part of the Plaintiff company a notice dated the thirtieth day of September last from Messrs, Orr Dignam and Company, its attorneys to the defendant. Company and Beraj Mohum Ganguli of the due service thereof affirmed on the thirtieth day of September last and a petition of the plaintiff company and an affidavit of William Frederick De Penning in verification thereof sworn on the thirtieth day of September last and an exhibit annexed to the said petition and marked "A" all filed on 30 th Sep last, and the plaint filed herein and upon hearing S. M. Bose (Messrs B. N. Dutt Ryo and Eric Walker appearing with him) advocate for the plaintiff company and Mr. S. C. Choudhry (Messrs. H. N. Sanyal and K. K. Basu appearing with him) advocate of the defendant company.

It is ordered that the plaintiff company be at liberty to amend the specification of Indian Letters Patent No. 26513 as indicated in the schedule hereunder and that the Controller of Patents be informed of such amendment and it is further ordered that the plaintiff company do pay to the defendant company its costs of and incidental to this application including fees to two counsel to be taxed by the taxing officer of this court and this court doth certify that the validity of the Patent in suit cause in question under section 32 of Indian patent and designs ct (11 of 1911)

Witness Sir Arthur Trevor Harris Chief Justice, aforesaid the fifteenth day of March 1949.

S. N. Bannerjee for Registrar 6-9-49

I do hereby certify that this is a true copy of the original in my custody. Dated 21st day Sep 1949.

For Registrar High Court, Calcutta.

PHARMACEUTICAL Manufacturers Organization, AHMEDABAD

Phone: 7326 Shree Kunj"

Ahmedabad-9.

Memorandum on the Patent Bill .. 1965.

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Pharmaceutical Manufacturers Organization, Ahmedabad, represents the Small Scale Manufacturers of Pharmaceutical Products in Ahmedabad.

This is a Memorandum submitted after a very careful study. It is our sincere aim that Indian Industry should reach a stage when the Public at large and the Nation as a whole benefitted. Have we reached this stage ? One cannot deny that we have almost reached the initial stage of research. This is a stage when India's fundamental requirements have been covered by the Indian Industry. We have not been able to enter from the fundamental manufacturing to research-stage because of only one obstacle and that is the existing Patent Law. This Law has been a source of discouragement and never an encouragement is itself evident from the fact that the entire country is welcoming the Patent Bill 1965. In fact this Bill should have been introduced immediately after Independance in which case the 18 years would have taken the Indian Scientists and the Indian Industry a long way. Today 80% of the India's requirements are either covered by foreign firms themselves or with their associates in collobration and only 20% is met by the local industry and hence one would find that those Foreign Firms holding the patent protection and Manufacturers do not want this Bill to be passed in the Parliament. We do not understand why Japanese Delegation visited recently India advised to keep the Patent Law as it is while they themselves have not followed the same in their country ? This clearly means that Foreigners are interested in keeping this Law for their interests and not of India's.

Contd.....2nd page.

-page 2-

Difference with & Without Patent restrictions:

The need for a Patent Law arose to protect the Industries of the country where such inventions and discoveries are made. This was at a time when one country vied with another to achieve Industrial superiority with the scientific and technical advancement. This was more on a reciprocal way so that the progress is balanced. If Germany takes a number of Patents in U.S.A. then U.S.A. also takes an equal number of Patents in Germany. Similarly U.K. in U.S.A and U.S.A. It was in all highly developed countries a reciprocal in U.K. Law to maintain the balance of trade, and research. Does this exist in case of India ? Unfortunately the answer is 'NO'. India is far behind J.S.A, U.K. Germany, Swiz, France and other European Countries, Communist Countries like Russia, China and Hungary. During 1949 to 58 Patents taken by foreigners in India was 21,117. The number of Patents taken by foreigners for Drugs, Pharmaceuticals & Chemicals alone in 1955 to 57 was 1344 as per report of Shri Rajagopala Ayyangar on the revision of Patent Law in India. The fact is silent about the Patents taken by Indians in these foreigne Countries. Does this not reveal the fact that no patents were taken by Indians in any Foreign country and if at all, purely a handful. So far India versus other highly developed countries are concerned the Patent Law in India has acted purely as a One-Way traffic keeping aside the Indian interest and Law has not functioned as a reciprocal The Patent Bill has been introduced in order to -Law. i. foster more inventions in the country by the Indians. ii.to develop Local Industry and Scientists on research. iii. With the above twin objectives, the intention of serving the society with better and cheaper remedies. The following paragraphs will give a complete idea as to how the existing Patent were has not helped but rather has put the3rd....

barrier in playing its role.

We take the example of Tolbutamide. This compound has been patented by 'Hoechst'. 'Rastinon' a product of above compound is being sold today for Rs. 187/- per 100C tablets. Indian Manufacturers have also imported this raw material and have also marketted successfully and the cost of 1000 tablets was Rs.55/to Rs.60/- the maximum. Duying the raw materials from foreign Manufacturers particularly Italy paying the profits to the chemical manufacturers. If the same compound is manufactured in India, it could be sold for as a price as lowest - Rs.40/per 1000 tablets. This is the price of a Local Manufacturer while that of 'Hoecist' is Rs. 187/- which is 4 times higher than that of ours because 'Hoechst' are patent holders with monopoly for the product exclusively. This clearly means that the same product could be marketted by Indian Firms at 1/4th a rate of that PatertedFirm. When Indian manufacturers were in the market with this product unfortunately 'Hoechst' the said Firm sued the Indiar Manufacturers for infringement presently stopping the Indian Firms to offer it to the public at cheaper price. The decision is yet awaited from the Court. Because of this today indiar public are paying 400% higher than what otherwise they would be able to save! Here alone we find that our Patent Law is working against our own interest. Hafkin Institute, Bombay, have made a continuous research and they have been successful to offer a new process for the manufacture of Tolbutamide but to our great badluck, the said Firm 'HOECHST' have shown the Patert Law for shelter stating that 'Tolbutamide' the compound itself is patented, and none could market a finished product of Tolbutamide.

Because the case is pending in the Court since last f_{ovv} yeow without any decisionas a result the poor Indian Public have been compelled to pay 4 times higher-price. If 4% royalty is approved then anyone could compete'Rastinon' and the cost would be only Rs.2 to 3 more for 1000 tablets. This clearly shows that because 'kastinon' (Tolbutamide) has been monopolised the Patented Firm could exploit as many times as theyare capable of it. The victims are poor Indian Public. The same product is being mold at much cheaper rates in foreign countries and only in India at a higher price because of Patent restrictions. The aim of Patent Law is definitely to protect the interests of the Government and economy as a whole.

One more example before us is that 'Tetracycline', a life saving antibiotic is being sold today approximately \mathbb{R} .1/- per capsule. Hindustan Antibiotics, formed an Indian Manufacturer, have made continuous research and have been able to market this product at 50 np. a capsule. Before this Firm were in the market for competition with 50% cheaper rate, the Patent Holder (foreign concern) were successful in getting issued a Stay-Order against the Indian Firm for the manufacture and selling of this life saving antibiotic. Here again they have taken the shelter under Patent Protection and to sell their product at a random shop-up price as they fixed. Why a common man should pay unnecessarily 3 to 4 times more when he is in a position to get it at much lowest price ? Was this the aim of Patent few ? No..!

Now let us analyse the fact in Italy, Japan, Russia, Communist China, Hungary and other fast developing countries where they have no Patent restrictions. How these countries managed to progress without patents restrictions to an advanced stage and why only India have made a nil progress in the last 18 years after independence with Patent Law ?...

Kceping in mind the developments in research field shown by those countries without Patent restrictions, we now look to the history particularly in the Field of Drugs, Medicines & Chemicals, we firmly believe that there should not be Patent for the products coming out of that chemicals. The Patent should only be for the chemicals and even in chemicals only the manufacturing process in particular which the inventor has found out should only be patented and not the entire product in general. If any inventor finds out another process it should be allowed to be patented and by paying the royalty anyone could make the product. If there have to be progress, there should be a free trade. As any one can pay the royalty and manufacture the product, there will be an ever increasing number of firms paying the royalty to to the patentee and ultimately the patentee is benefitted at large as there will be dozens of people to pay the royalty and work for him in competition. Because of competition, there will be equally a benefit to the public as the product will be made available more and more cheaper day by day. Research is a continuous process and once something is started it would be difficult to make any progress with restrictions. This we could see for the past 18 years that there has been no incentive to the scientists and the Industry because only monopoly existed under the protection of Patent Law.

All the countries mentioned as having no patent restrictions in the initial stage are today standing shoulder to shoulder in research and this only shows that if from the initial stage we have to progress towards a stage of research, there should not be any Patent restrictions to mouthlock the scientists and industry. As we could see crystal clear, we have waited for the 18 years and now let us wait for another 18 years without patent ...6 restrictions and watch the progress ? Today we have reached a stage when our scientists are in a position to enter research pace. Our Scientists and Industry will be entering the second step of research when their capacity and intelligence is expanded to making of materials independently. The Patent Law should be applied only when the real stage of independent competition of research reached. For this we may have to wait for some years without the Patent restrictions when we shall see the real ingenuity of Industry & Scientists to apply new methods, more processess for new compounds and ultimately to make the product available more and more cheaper to the Public. This is the stage today in Italy & Japan and they are now thinking of making little amendments to safeguard their interest. This clearly shows that the initial stage will have to be done without restrictions.

Only Process Patentable: Clause 5: So far as chemical and Pharmaceutical products are concerned, the process of manufacture of a chemical or a drug can be MORE THAN ONE. A chemist or pharmacist by applying his knowledge and ingenuity can succeed to manufacture a certain product by several processes. The patent should not be given on all the processes, imaginary as well as possible except the ones which have been worked out actually by the patentee. This blocks all possible processes by which a particular substance can be reached. The Indian Scientists for this reason is completely non-plussed for he cannot reach the product by any possible chemical process as the blockade is there on all the possible routes leading to that product. This is the most important part of it.

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Clause 48: Patent rights not-infringed when used for certain purposes.

This clause is a "Must" as the Government has the moral as well as constitutional responsibilities for the health of the Nation and so any importation of any patented medicine or drug for its use should not be considered to constitute any infringement. This necessity has been even realised by a well developed country like U.K. who is bringing the amendment to Patent Law for 'Repeal of Section 41" so that U.K. Govt. can import patented drugs without infringement.

Clause 53: Term of Patent

The term should be 7 years and not 10 years in drugs and medicines, as previously passed in the Parliament and it has been made to 10 years with the pressure of foreign and interested parties in India. This is purely an overprotection. For example, how many years must have been required to recoup the expenditure on products like Chloramphenicol, Tolhutamide, Tetracycline ?

Licensing:

Licensing should be made so easy that anybody can take interest in going for the manufacture. There should be a very liberal and free issue of Licences with only one provision that by paying the royalty of maximum 4% to the Patentee anyone interested can make the product. The process of licencing should be totally eliminated but if it is kept then that should be made so easy that within 6 months from the date of application the rights are offered and there should not be any restriction on the manufacturing of that chemical by the Patentee if the manufacturer pays the maximum royalty. The process of licencing should not be a difficult one. Anyone paying the royalty should be allowed to commence the production even without waiting for the result of the application.

If there is an infringement or dispute, the case should be8

page-7

page 8

disposed off within ε maximum period of 12 months and the result should be out by maximum 12 months either by a Special Tribunal or by Licensing Committee on Patent Protection. Here we would point cut that the 'Tolbutamide' infringement case is yet to be decided though a considerable years have passed. Such a delay hampers the research and ultimately taxing the common-man for paying highest prices.

Conclusion:-

We have reached a stage when support of the Government for more progress is inevitable and therefore, in a nutshell, amendments are necessary on the following lines-

- i. As India is in itial stage of progress, till we reach a satisfactory stage of that developed countries in Research we should follow the Patent Laws of Japan, Italy, Russia, Communist China, Hungary and other countries where the progress depends purely without any restrictions on Patent.
- ii. Any one can pay the royalty to the maximum of 4% and start the production. As this will be a free-trade, number of Manufacturers will take interest and both the Patentee will be benefited because he gets the increased dividend with more number working for him also the public as there will be a keen competition and the product will be offered cheaper and cheaper.
- iii.If at all the protection is to be established, then only the particular process which the inventor has found out should be patented and not the product or finished products made out of it in general should be patented as it is today.
- iv. If there is a dispute or infringement case, it should be disposed off within a maximum period of 12 months and the penalty if established should be maximum 4% royalty.
 - v. There should be a provision of Patent rights not-infringed when used for certain purposes.
- vi. The term of Patent should be only 7 years and not 10 years in drugs & medicines.
- vii. To avoid monopoly, there should be a free-licencing and procedure should not at all be difficult as this only works as an incentive for Scientists and Industry to develop the product. Monopoly by anymeans should not exploit the Indian Economy when there are meansures to counter balance the trade & research.

The above points deserve full scrutiny and consideration as the progress of Industry in research lies purely on the incentive and interest.

ten Add. " MARAMANDAL " POST BOX No. 162, AHMEDABAD.

Office : 79225-36-27 Recentery Real 1 79829

GUJARAT VEPARI MAHAMANDAL

(GUJARAT CHAMBER OF COMMERCE)

: ROHITBHAL C. MEHTA Vice-President : HIRALAL H. BHAGWATI Hon. Secretary: KALYANBHAI T. SHAH

Ref. No.

LAW/1(2)/

To:

Secretary, Loksabha Secretariat, Parliament House, New Delhi.

Dear Sir,

Re: Petents Bill, 1965.

I am directed by the Committee of the Chamber to address you as under in regard to the provisions of the above Bill introduced in Lok Sebhe on the 21st September, 1965 and referred to the Committee for reviewing the provisions.

The main object of the Bill is to stimulate inventions amongst Indians and encourage the development and exploitation of new inventions for industrial purpose in India. The Committee of this Chamber would like tomake certain suggestions as under with a view to ensure smooth and efficient working of the Patents Act.

CLAUSE 3 (a): The present Patents Act provides that an invention which is scandalous will not be considered as an invention within the meaning of the Act. It is now proposed that an invention which is frivolous will not be considered an invention. We do not know why this change has been proposed in the Bill. But the change gives wide discretionary powers to the executive authority in discarding an invention. When we have to develop inventive talent in the country, it is necessary that the executive authority should be very careful in rejecting an invention and it is, therefore, desirable that the powers of the executive should be restricted to rejecting such inventions only as are against morality or

SHRI AMBICA MILLS-GUJARAT CHAMBER BUILDING RANCHHODLAL ROAD. AHMEDABAD-9.

20th January 1966



against society.We, therefore, suggest that the word "Scandalous " should be retained instead of the proposed word "frivolous". <u>CLAUSE 13(1)(c)</u>: In clause 13(1)(a) and (b) the scope of examiner's search regarding anticipation is provided. In order to enable the applicant for patent to understand properly why his application is considered as anticipated, he should be given the proper data to consider or to reconsider his scope of patent. We, therefore, suggest to add Clause 13(1)(c) as under:

" In case of the examiner being satisfied regarding the anticipation of an invention the applicant be furnished with full details of the anticipated patents and cross notice be issued to the Patentees of the anticipating patents."

CLAUSE 25(i): Clause 25 provides the grounds of opposition against the grant of patent. In the present Act, grounds of apposition are provided under Section 9(1)(a) to (e).But in the Bill the ground (e) is omitted. We suggest that the ground covered by Section 9(1)(e) should be incorporated in Clause 25 (J) verbetim.We have suggested this inclusion for the reason that as provided in clause 25 the opponent is permitted to take the opposition only on the grounds provided under the said Clause and on no other ground. It is, therefore, necessary that the ground already in existence in Section 9(1)(e) should be provided as Clause 25(J). We would make the position clear by an illustration as under:-

(A)files an application with a provisional specification which bears the date of the application. But as the complete specifica tion can be filed within nine months, A will have a chance to claim the prior date which is the date of the provisional specification. In between the time of filing the provisional and complete specification by A, if B files an application with complete specification, B's application will bear a date after the date of A's application with provisional specifications. Eventhough B's application is with a complete specification which describes the entire invention,

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B will be at a disadvantage so far as the claim of date is concerned and therefore, it is necessary that the ground as provided in Section 9(e) should be incorporated in the Bill.

<u>CLAUSE 28(1)(b)</u>: In the proviso to clause 28(1)(b), we suggest the addition of the words "In absence of anyagreement in writing to the contrary" between the words "shall" and "not confer...." etc. The reason for this addition is that a person cannot claim for the mention of his name as an inventor without sufficient documentary evidence and if this provision is made the inventor before parting his invention shall be required to execute an agreement in writing. If there is no agreement he will be required to support his case by documentary proof to the satisfaction of the Controller. If the words, as suggested by us, are not added in the proviso then any emplayee of a concern may create unnecessary trouble to the Patent office and also create an embarrassing situation for the applicant of the patent.

<u>CLAUSE 45(3)</u>: In this clause it is provided that no infringement action can be filed before the patent is accepted. It is known that nearly one year or more is taken by the Patent Office in accepting the application and in case of simple invention, infringements are coming forward during the pendency of the acceptance and the inventor has no interim remedy to prevent infringements. In Trade Mark cases the owner of the trade mark has common law rights to his assistance and he can enforce his rights during the pendency of registration by equitable remedies such as passing off action and complaint for false use of trade mark whereas the invention which involves greater expenditure during the experimental stage has no such remedy for the inventors. In view of this we propose that the inventor should be granted interim remedy after filing complete specification.We therefore suggest to provide as under:-

" Not-withstanding anything contained in this section, no proceeding shall be taken claiming damages of an infringement

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committed before the date of advertisement of acceptance of the complete specification, but if the controller gfants a certificate that the complete specification has been accepted, the applicant can file an action for infringement of patent".

CLAUSE 87(1) (a)(iv) :-

Clause 87 provides restirctions in respect of particular items enumerated as (i),(ii) and (iii) which are not exhaustive. There may be other items which may also be capable of being included in this category in future. It is, therefore, desirable that as provided in the Atomic Energy Act, 1948, (Section 2 and 10) and in the Emblems and Names (Prevention of improper use) Act, 1950 (Section 4(2)), it should be provided in Clause 87(1)(a)(iv) as under

"Any substance, methods or processes which the Central Government may notify in future."

<u>Clause 102(3)</u> :-

This is a very important provision for the inventors , Since the Government has provided for acquisition of invention by paying compensation for it. It has been provided that the Central Government shall pay to the applicant or the patentee such compensation as may be agreed upon between Central Government and the applicant or the patentee, and in default of agreement, the compensation shall be determined by the High Court. It generally happens that in a bargaining stage, the Government can well afford to fix the compensation on a lower level well knowing that it is almost prohibitive for a person to go to the High Court for getting justifiable compensation. A man may have spent enormous amount and years in finding out an invention. The Government would, no doubt, take into consideration all these factors while fixing compensation. But there is always

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a fear that the officers concerned would use the descretion in favour of the Government to the detriment of the rights and interests of the inventor. We, therefore, suggest that there should be an independent Board which can go into the details of the claims put forward by the Central Government as well as by the inventor and fix the compensation. Thereafter if the central Government or the party is not satisfied with the Board's decision, they can go to the High Court for determination of the dispute. We of acquisition it is very necessary feel that in matters that the rights of the public should be properly safeguarded. we are not against acquisition of an invention by the Central Government, but what we desire is that the party concerned must get fair and equitable compensation for the in for long years for finalising efforts that he has put the invention and this can be done only by an independent Statutory body like a Board. We, therefore, suggest that clause 102(3) should be worded as under.

The Central Government shall pay to the applicant or as the case may be, the patentee and other persons appearing on the register as having an interest in the patent such compensation as may be agreed upon between the Central Government and the applicant or the patentee and other persons as may be, and in default of agreement <u>be referred to a Board of Trade set up by the</u> Central Government consisting of the nominees of that <u>particular trade for determining such compensation</u> <u>having regard to the expenditure incurred in connection</u> with the invention and in the case of a patent, the <u>term thereof</u>, the period during which and the manner in which it has already been worked (including the profits made during such period by the Patentee or by his Licensee whether exclusive or otherwise) and other

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relevant factors".

" The decision of the Board of Trade can be referred to the High Court for determination of the dispute". CLAUSE NO.103 :-

. In this clause wherever the words"High Court"occur, the words "Board of Trade" may be substituted in view of our above suggestion in Clause 102(3).

CLAUSE 115(3):-

we suggest that Sub-Section (3) should be added to Clause 115 as under.

"The Central Government shall maintain a list of the panel of the Scientific advisers for the guidance of the Court" We have suggested this addition with a view that the parties concerned can also make use of the services of the scientific advisers in case of any dispute with the Government. As in the Estate Duty Act the names of valuers are published for the guidance of the public as well as the Government, it is just and fair that the Central Government should publish a list of the panel of the Scientific Advisers.

CLAUSE 126 :-

This clause provides for the qualifications for registrati as Patent Agents. It provides that the person should not only have obtained a degree in physical science or engineering from any University or possess such other equivalent scientific or technical qualifications as the Central Government may specify, but that he should also be an advocate or should have passed the qualifying examination or should have been practicing as a patent Agent for a period of more than five years before the commencement of the Act and in addition, should have filed not less than 20 complete specifications during these five years.

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we would like to point out that in the whole of India, there are only 32 patent agents among whom there is only one patent agent in Gujarat State. The qualifications provided in the clause are such that no person can hope to be patent Agent in future. The Patents Law is a complicated legislation and as more and more inventions come up for registration it is desirable that atleast in the beginning, say for a period of seven to ten years, the qualifications should not be so stringent as provided in the Bill. It is well nigh impossible for a new man to have completed 20 specifications during the five years since at present the patent work is almost negligible and even the established patent agents find it difficult to have so many specifications on hand. We, therefore, suggest that the provision should be inoperative atleast for seven to ten years and during this period the clause 126 should be read substituting the words" and, in addition" in (c) by the word "or " and the words" and has filed not less than 20 complete specifications during the period" should be omitted.

The Committee of this Chamber would like to present the case before the Committee if called for.

Thanking you,

yours faithfully,

SECRETARY

KMS:SNP:80

Tele. Add "MAHAMANDAL"

PUST BOX NO. 162, AHMEDABAD.

GUJARAT VEPARI MAHAMANDAL (GUJARAT CHAMBER OF COMMERCE)

President :HIRALAL H. BHAGWATI (Seal) Vice-President: CHARANDAS HARIDAS Hon. Secretary: BIHARI KANAIYALAL SHRI AMBICA MILLS-GUJARAT CHAABER BUILDING, RANCHHODLAL RUAD AHHEDABAD-9

Ref. No. LAW/1(2)/3816

28th June, 1966.

The Dy. Secretary, Lok Sabha Secretariat, (Connittee Branch) Parliament House, New Dalhi-1.

Dear Sir,

Re:- Joint Committee on Patents Bill-

In continuation of our memorandum dt. 20-1-1966 on Patents Bill, we submit herebelow further observations on the Bill which may kindly be taken into consideration. Our representatives will be discussing these points also with the Joint Committee on 13th July, 1966.

Cl. 53 Term of Patent:-

We support the provision in the Bill that the term of the patent in respect of an invention claiming the method or process of manufacture of focd articles, medicine or drug snall be ten years from the data of the patent.

...ith the greater off-take of these articles and the people being favourably inclined to make more and more use of medicines, drugs and food articles, the company exploiting the patented invention would get sufficient return from the patent within ten years and hence it is not necessary to extend the time limit beyond ten years.

C1. 84 Compulsory Licence.

It is welcome that the provision for compulsory licence is retained in the Bill but looking to the past experience it is very necessary that there should not be enormous delay in granting the compulsory licence. We would therefore like to impress that it should be statutorily provided that the compulsory licence must be granted within one year from the date of the first application. This period will cover the time for back-references to the applicant by the Controller. If the application is not decided within that period, the applicant shall be free to exploit the invention

Copy of the Note received from Gujerst Vepari hanamandal (GujerstChamber of Comerce), Ahusdabai, re ATIRA Patents, and "Sanforiged" Process etc.

AHOMADAL TANTILE INDUSTRIT'S RESLARCH ADDOCTATION. ALLEDADAD_9.

A ATIAA

Law [13: 1. A shi is a coopertive research as ociation for the textile industry supported jointly by member mills and the Government of India through the Council of Scientific & industrial Mesearch. An in was started in 1949 by 74 mills of Ahmedebed as founder rembers. Subsequently, a new class of membership Viz. Associate hembership was introduced in 1953-14. and 12 Associate Lapisers.

The functions of ALMA cover basic research, t ochnological research ary invostigations, development of new processes, instruments & machinery, sud consultation and technical services to millis. Alla also uncertakes studies in sortain management sciences particularly in cost accounting, bas stary controls, personnel training and ranagement, operativel research Man interfirm comparisons of productivity, costs, etc. Wery member mill of Allah page an annual fac which at prosent as

maged on 12 paise per installed spindles and Red. 50 per installed 1. On. the grant from the Government of Judia, routed through the Gual is 50,0 of the nott recurring expenditure as well as of cepital expanditure instituting that out of depreciation). In the year 1905-00, this grant successed to on the recurring account k - 7.5 lakhs and on the capital "count in 1.35 121.8.

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2.	5.lio.	Title of Invention	Patent lio.	Date of Patent/Ap, In	status.
	1.	improvements in à relating to collulose (finishing) solutions			Frient
		for collens or rayon fabrics of the like.	4 9405 Incin	26-4-1953	grantus lur 16 years.
	2.	Arina Fibre Finances Testor.	70258 411 dis	5-1-1560	
	j.	neather frooting and not proving cellulosic head iles.	: 72578 India	1371960	-(
	4.	Comisions of Polyacry- lonicrile.	72579 Inga	-do-	-do-
	57	Readily mulsifiable polyscry lonitrils and and siche thereof.	79975 India	-cb-	-0-
		Stable solutions of starch are otherpoly-	00054	₹ê ^{t.} 6	
		s-eclaridos in ¹ izstari Sulixíd e .	1 85355 Juice	28-11-1962	14 ho 4

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7.	improvements in dysing of collulosic materials by periodate exidetion and subtequent reduction.	87800	10-5-1963	Patent fram ed for 10 Jears.
8.	Stable golutions of starch and polysacchu- riass in Sinsthyl Sulfaxids.	25201/63 (b.i.)	25-6-1% 3	Panding.
9.	Arisa Fitre Length Tester.	91092 India	2-12-1963	7
10.	An inproved aschod for producing drip-dry finishes on fabrics.	91544 India	1-1-1964	Completer' filed and succide
11.	− \$\$~~``	96:04 Insta	18-11-1966	do- Livisional application of No. 14 above
12.	Frocass for the prepara- tion of polyascharide ters (byrisicual out of provisional patent application No.85355 dated 28-11-1962).	٠	13-5-1964	Pending y
B .	Au improved method for oxidation of starches and other polyseccharices	95454 • (India)) 1-9-1964)	
		5503 (Ceylon)	do)	
	(New	139286 12001and)		
	(48788/34 Au stral ia		4
		306/64 (Pakistan)		
2 *****	,	35664/54 (U.K.)		
14.0	An improvement relating to machine for suffing of the webfrom the doffer in carding machines.	95 9 44 India	12-4-1905	Complement Hecepterica Pending

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A twisting head for ring spinning frames.	102790	1-12-1905	Provisional/ filed ther countries plan ned are: U.A. Switzerland and Japan.
		2-3-19-6	Coupleto/12106
Inproved cevico for producing curable creases in textile fabrics.	104409	19-3-1966	Provisional/ filed
A process for imparting stretch to textiles con- taining cottes.	سی ه	-`	Provas. Jack Splice Values being states.
	A twisting head for ring spinning frames. Proceeds for improving wet crease recovery and criptry perfortance of collulosic tatorials. Improved device for producing durable creases in textile fabrics. A proceeds for imparting stretch to textiles con-	ring spinning frames. 102790 Process for improving wet crease recovery and Grippry performance of 104139 collulogic materials. India Improved device for producing durable creases in textile 104409 fabrics. A process for imparting stretch to textiles con	A twisting head for ring spinning frames. 102790 1-12-1905 Proceess for improving wet crease recovery and cripery performance of 104139 collulosic materials. India 2-3-1906 Improved device for producing durable creases in textile 104409 19-3-1966 fabrics. A procees for imparting stretch to textiles con

Forsign Collaboration.

In these patents are independent of any foreign collabor tion. The subscription of the patent have been i row time to time discussed and the form of technical papers during the technological conferences dec.

S ASLAND STAD S PROCESS

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is (a) Throu patents are involved as fol ous :-

Sr No.	1. P. No.	Status of prient	Date
1.	91544	Complete/accepted	1-1-1954
2.	900 04	Complete/accepted	16-11-194
3.	104139		2-3-1964

- . (b) No foreign application has been made.
- is is) sotal number of mills presently licensed for using "trion such process is 20, out of which 21 are from Annedebad.
 - (d) A minimum royalty of km 7,500/- per annum for a minimum person of five years or 1 paise per netro for matric less than 100 cm and a and 4.5 paise per metro for fabric above 100 cm width, which were the ghor. However, the excess arount over the minimum to be place is to be calculated at the end of the licensing period of five years. The above rate of royalty is applicable to regular the of A ind while for non-member mills it is double the amountathe present licenses are inspers of family.
 - train 1997 And the physical for both the process and the called train 1997 and the called train 1997 and the called the train 1997 and train 1997 and the train 1997 and trai

- 4. (f) The royalty is paid on the bas's of yardage of cloth produced and stamped. The stamping of cloth neturally involves certifiextion of approval of the quality of fabric.
- 4. (g) Spinning mills do not use this process as the process is for chamical treatment of cloth.
- 4. (n) The process has been licensed since January, 1965. The following amount has been received as royalty during the period January, 1965 to December, 1965.

No. of Kills

Amount of revalty collected.

26(January 1965 to December 1965) Rs.1,95,000.

Other Petented Inventions

5. Of the other patents listed under item (2), the following have been licensed so far :

Mane of instrument: Liconsed to: Royaliy Term No. of instruents pold. Masarsi ALAMA Fibre Fine-1st 100 paeces 7% 43 pleces till Brothers 3rd 33 Private Ltda, 4th 33 Northers 3rd 33 nose Tester 6% today. - # 3 5~ ** 4.6 31 3. five pars from Aug. 1963. A IRA Fibre Length -do-1st 50 pioces Tester 55 204 50 42 87 3e thereafter . .

"SANFUR 1900 Process upod to Mills

There are 34 textile mills in Ahmrdabed using the trade mark Machinerized^R out of which 21 mills have their own plants while the remaining 43 mills get their cloth senforized at other mills. In the year, 1964, the Matel production of Senforized Cloth by these mills was 139 million metres the same 1 of royalty paid was half of lakhs.

Statistic is a registered Trade Kark of Lessra, Clust, Peakody Line, Mori, U.S.A. and under the Trade and herahandies hards Act, 1950, the registered users we granted by the Govern ent of India, Kinistow of the construction New Felhi, and the full details about the totol mamber of the details about the totol mamber of the deed of agreement can be obtained from the theory & users and copy of the deed of agreement can be obtained from the theory & users and copy of the deed of agreement can be obtained from the theory & the state and agreement is a public document. Hears, Clust the deed of Frances Foss, 950, of 1953 & 5527, of the deed of Frances Foss, 950, of 1953 & 5527, of the deed for pre-similaring and Ness, 3719, of 1954, and 41911 of 1954.

for proshrinking process. Further, in the registered user agreement there is no specific reference that the royalty to be paid shall be in respect of petent rights but Clustt, Peabody & Co., Inc., U.S.A. are proprietors of four patents Nos.37194 of 1947, 41911 of 1948, 49504 of 1953 and 53273 of 1954. The paragraphs of the agreement reading as under t-

(a) Whereas Clust, on basis of its long and wide experience is in possession of much valuable 'knowledge and data' relating to nathods, machinery and equipment for the comprehensive shrinking of fabric materials whereby the amo may be shrunk to the standard here mafter contioned and has disclosed and will continue to disclose such knowledge in confide.co to the company,

(b) "It is a condition of this agreement that the said Trade Lark "SANFURIZED" shall not be used by the company upon or in relation to may goods in respect of which the same may be registered unless:

- 1) Such goods are treated by a wind of comprehensive similars approved by Clustt, and
- ii) Coprohenity shrinkage machinery and equipment used in so treating such goods has been approved by Cluett, and
- iii) Such goods are of such a standard that they will not shrink or gain in either warp-wise or waft-mise direction by more than one percent.

(c) "Clust, shall furnish to the company from time to time data led it that of testing the said goods with a view to establish that they couply with the standards provided in the agreements.

It can be avered that the royalty charged is not only for the Trade Mark "SANFORIZED" but also include the royalty for the patents.

Tebilized Process

This process is used by textile manufacturers in Ahmedabad and elsewhere known as "TEBLIZED" process of tootal Broadburst Les Co. Ltd., of United Kington, for improving crease resisting properties and/or improving smooth dyeing properties.

MEMORANDEM submitted by the Pharmacy Council of India on the Fatent Eill, 1965

The Pharmacy Council of India is the foremost statutory body established under the Pharmacy Act, 1948. Being a representative body of the Registered Pharmacists in India, the views expressed below can be construed as the views of the profession of Pharmacy in the country.

The Council is appreciative of the proposed provisions of the Patent Bill, 1965 in the light of the objects and reasons which have prompted the Government in formulating the Bill. The Council is generally in agreement with the provisions of the Bill but would like to offer the following comments before the Joint Select Committee of the Parliament for favour of consideration.

Page 3; clause 2, sub-clause (1) (4) (iv).

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Page 6, Clause 5, Line 9.

The following proviso might be added after the word 'patentable': 'Frovided the method or process of manufacture is a substantial improvement over known methods or processes.'

Page 33, Clause 53, sub-clause $l(\varepsilon)$

It is well known that the time lag between the development of a laboratory process and its industrial utilization has been reduced to a very short period in the industrially advanced countries. The same does not hold true for India. The Indian research worker is likely to take a much longer time in developing an invention on an industrial scales. The period during which he can earn remuneration from the utilization of the Petent will, therefore, be much shorter and in certain ceses, due to difficulties in obtaining the necessary equipment, almost negligible. It may, therefore, be considered whether the life of a Petent taken by an Indian metional who has developed the process in the country can be increased to a longer period provided he is able to instal a pilot plant - 2 -

Fage .45, Clause 73, Sub-clause (2).

It has been observed in the past that many a process has been given Fatent protection in our country although they did not qualify for the purpose. The reason perhaps has been the lack of adequate technically qualified staff in the office of the Controller of Patents who could examine whether the process in the application can be patented or not. The provision in the present Bill do envisage the appointment of a number of technical assistants who could undertake this work.

However, it is felt that scientific research has been progressing at such a rate and scale and specialisation in a narrow fields has been so extensive that it is not possible for a small group of technical persons to render correct advice to the Controller in all cases. Although it is open to any individual to raise objections after the application has been notified yet scientific workers devoted to research do not normally go through the published list of applications from this point of view. It might, therefore, be desirable to have a panel of exports for specific fields who may be consulted from time to time on the acceptability of the applications. An alternative to this could be the creation of a Technical Advisory Board who could advise the Controller on scientific aspects.

Fage 50, Clause 89, Sub-clause (1).

It is feared that after a Patent is endorsed with the word 'licences of right', there might be many persons who might like to take advantage of the facilities provided under Clause 88. This might in turn lead to wastage of efforts and hinder establishment of production on a substantial and economical scale. It might, therefore, be desirable to add after sub-clause (1), the following words:

> 'after satisfying the Controller that the conditions of clause 85 (ii)(iii) and (iv) are adequately met.'

Page 55, Clause 95, sub-clause (3):

Whereas sub-clause (L) and (ii) appear to be justified, sub-clause (iii) which also permits import of the material, is likely to be abused as the licensee might be tempted to postpone or delay the production. The facility to import the material covered by a Fatent should therefore, be afforded only to the Government.

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In the light of the provisions under sub-clause 1(h) of clause 2, the Public Sector undertakings registered as commercial units under the Company Law which have been defined as 'Government undertaking' can utilise a Fatent without the necessity of paying any compensation to the owner of the Patent. This would create an element of discrimination against the private sector undertakings.

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File No. 51-5/65-FCI		Dated the Elst January, 1966
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FEDERATION OF INDIAN CHAMBERS OF COMMERCE & INDUSTRY

Telegrams : "UNICOMIND" Telephone Nos. 44281 FEDERATION HOUSE

<u>ZCOPY</u>J

Ref. No. F. 178/Comm/7.

6th January, 1966.

То

The Chairman, Joint Committee of Parliament on the Patents Bill, 1965, Lok Sabha Secretariat, <u>New Delhi.</u>

Dear Sir,

Sub: Patents Bill, 1965.

I am directed by the Committee of the Federation to address you as under in regard to the provisions of the above Bill introduced in the Lok Sabha on the 21st September, 1965.

The main purpose of the Bill is to stimulate inven-2. tions amongst Indians and to encourage the development and exploitation of new inventions for industrial progress in India, and to ensure that patent rights are not abused to the detriment of national interests. While the Federation Committee endorse these objectives, they are of the opinion that some Clauses of the Bill, as worded now, would tend to a great extent to defeat these very objectives, and instead of stimulating inventions by Indians, they are likely to discourage. Moreover, some provisions go counter to the fact of patents being industrial property though of intangible kind. And it is unfortunate that the Bill seeks to deny the fundamental rights of the patentees by proposing to vest the Government with wide and discretionary power to use or acquire patents without payment of reasonable compensation and even without due process of law.

3. The relevant Clauses to which the Committee of the Federation have objection are referred to below:

Clause 5: Under this Clause, in the case of inventions

- a) claiming substances intended for use as food or as medicine or drug, or
- b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and intermetallic compounds)

no patent will be granted in respect of the claims for the substances themselves, but claims for the method or process of manufacture are made patentable. Without going into the merits or otherwise of product patents, my Committee would like to emphasise that the lever for greater competition lies in liberalising the licensing policy and allowing a greater number of manufacturers in the field.

Clause 48 provides that import of medicines or drugs or medical equipment by Government for its own purpose or the production of a patented article by Government for its own use shall not be regarded as an infringement of patent "Own use" is defined to include use by Government rights. In addition, Government may also authorise undertakings also. certain classes of undertakings in the private sector to produce the product. What is most objectionable is that Government are assuming substantial rights without any payment to the patentees and without incurring any liability for infringing their rights in the patents. A point to be considered is whether such rights are not open to be challenged in the courts of law. It is also not desirable that Government or their nominees should have the right to import any patented medicine or drug simply because such importation is deemed to be cheaper. Our foreign exchange situation being what it is, every one has to be eternally vigilant about the use of our meagre resources. The provision also goes counter to the desired aim of Government to encourage indigenous manufacture. In any case if it is

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considered that medicines or drugs should be supplied cheaper, Government should in fairness compensate the patentee for any loss that he may incur in this behalf.

<u>Clause 53</u>: Under this Clause, the term of a patent other than a patent in respect of inventions relating to food, medicines and drugs is proposed to be reduced to 14 years and in the case of food, medicines and drugs the term is to be only 10 years from the date of the patent. The term of existing patents in the latter field will be limited to 10 years from the date of the patent.

Other countries, it is understood, generally do not make such differentiation in regard to the validity period. The Committee of the Federation are, therefore, of the opinion that if the duration of patents in respect of foods and drugs for any reason cannot be increased, there must be a provision for extending the terms of select patents by at least another five years from the expiry of the patents.

<u>Clause 84:</u> This Clause deals with the granting of compulsory licences to work patented invention, where the reasonable requirements of the public with respect to the patented invention have not been satisfied. Under Sub-Clause (7) of this clause, the decision of the Controller in the matter of compulsory licences has been made appealable only to the Central Government. It is not desirable that those who administer the law should also be asked to interpret it. Under the 1911 Act, any order of the Controller made in respect of compulsory licences was appealable to the High Court. Subclause(7) should, therefore, be amended to permit an appeal from the decision of the Controller to the High Court and not

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to the Central Government as in the case of orders passed by the Registrar of Trade Marks under the Trade and Merchandise Marks Act.

Clauses 86 and 87: These Clauses deal with the endorsement of a patent with the words "Licences of right". In the case of patents other than those in respect of food, medicines or drugs, as well as the methods of processes for the manufacture or production of chemical substances, it is only after the expiry of three years from the date of the sealing of a patent that the Central Government can make an application to the Controller for endorsement of the patent with the words "Licences of right" on the ground that the reasonable requirements of the public with respect to the patented invention have not been satisfied. In the case, however, of patents relating to food, medicines or drugs which are at present in force and in the case of the methods or processes for the manufacture thereof as also methods and processes for the manufacture or production of chemical substances including alloys, optical glass, semi-conductors, inter-metallic compounds which may be granted under the new Act, the patents are deemed to be endorsed with the words "Licences of right" from the date of scaling of the patent. These provisions, therefore, discriminate as between inventions relating to the said goods and other inventions. The period of three years which has to elapse before Government can apply for the endorsement of a patent with the words "Licences of right" has been done away with in the case of inventions relating to food, medicines or drugs and the processes for the manufacture or production of chemical substances. Inventors in these fields are, therefore, deprived of the initial period of

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three years which they have under the 1911 Act of working

their inventions and reaping the full benefits thereof during that time. The Committee of the Federation are of the opinion that the discrimination pointed out above should be done away with, and that as in the case of other inventions, inventions relating to food, medicines or drugs and the processes for the manufacture and production of chemical substances should be liable to an endorsement with the words "Licences of right" on an application by the Central Government only after the initial period of three years from the date of the sealing of the respective patents.

Clause 88: This Clause deals with the effect of a patent being endorsed with the words "Licences of Right". Under sub-clause (5) of this clause, in the case of every patent which is deemed to be endorsed with the words "Licences of right" and which relates to the substances used or capable of being used as food or as medicines or drugs and the methods or processes for the manufacture or production of any such substances, the royalty and other remuneration payable by a licensee to the patentee where the patent was granted before or after the commencement of the new Act shall not exceed 4 per cent of the ex factory sale price in bulk of the patented article (exclusive of taxes levied under any law for the time being in force and any commissions payable). The Committee of the Federation feel that from the point of view of equity a blanket ceiling on royalty in respect of patents relating to food, medicines or drugs is not desirable. In some cases, the amount may be less while in some other cases, it may actually be taken as the minimum payable as royalty. The royalty is intended to cover the expenses of

research expenditure involved in the invention and also as a reasonable compensation to the inventor. It is not possible to fix a royalty rate under law which will reasonably cover all cases.

In the 1911 Act, the remuneration payable to the patentee in respect of a "Licences of right" was left to be determined by the Controller and was subject to an appeal to the High Court. Mr. Justice Rajagopala Ayyangar has himself stated in his Report that "Fixation of a reasonable amount of royalty payable for the use of a patented invention has to be arrived at on such a large number of factors depending upon the facts of each case that it is not practicable nor even desirable that these should be put in a straight jacket". He, therefore, suggested that no statutory ceiling on royalty should be fixed. It may also be pointed out that Government have other powers to regulate the payment of royalty. It is desirable, therefore, that in order that inventions in the field mentioned may be stimulated amongst Indians royalty payable should be left to be determined by the parties in each case and regulated by the Controdler. The decision of the Controller, may be subject to an appeal to a Court of law as at present.

<u>Clause 93</u>: Under sub-clause (6) of this Clause, the decision of the Controller is made subject to an appeal to the Central Government as in the case of decisions of the Controller passed under Clause 84 relating to compulsory licence. Here again, it is necessary and desirable that the decisions of the Controller should be made appealable to a High Court. If the appeal lies only to an administrative tribunal of the Central Government which will consist of civil servants, it is by no means a satisfactory procedure. :- 7 -:

In all the other countries, there is a provision for an appeal to the judiciary against the decision of the Controller. For instance Section 44 of the U.K. Patent Act provides for such an appeal. The Model Patent Law prepared by the United International Bureau for the Protection of Industrial Property at Geneva (BIRPI) and adopted by representatives of less developed countries also provides in Article 42 for an appeal to the Civil Court. It is necessary that in matters affecting industrial property rights, the appeal should lie to the judiciary. An appeal to an administrative tribunal will only mean that the framers of the law will themselves be its interpreters. This will not be in consonance with the established principles of jurisprudence and the principle of the separation of the judiciary from the executive. In the Trade and Merchandise Marks Act, there is provision for an appeal to a High Court against the decision of the Registrar of Trade Marks and trade marks is also industrial property. The Clause should, therefore, be amended providing an appeal to the High Court for the reasons mentioned hereinbefore.

The Committee of the Federation trust that the Joint Committee will give due consideration to their views mentioned above and modify the provisions of the Bill accordingly.

Thanking you,

Yours faithfully, Sd/- P. Chentsal Rao Secretary.

'Gupta'

SOME COMMENTS ON THE PATENTS BILL

PROCESSES AND PRODUCT PATENTS:

In the Textile and Chemical fields with which I am familiar, there are comparatively few inventions which claim for "Product" Patents. This is because of the fact that the raw materials are old and the industry is old. In the case of Pharmaceuticals, however, a new drug can legitimately be patented. In the case of Food Products, patentability applies to artificial Foods.

1. <u>Clause 1, Section 1</u> in the present Patent Law excludes patentability for Plant and Animal varieties and some Biological processes. It is now intended to extend this principle to Pharmaceutical or Food Products.

<u>Comment :</u> At the moment more than 95% of the patents arise out of the research done from outside the nation. The extension of the Law to Pharmaceutical and Food Products will, therefore, not affect appreciably Indian Research. Further, the obvious effect of the Law would be that certain disclosures that are made through Indian Patents will not be made. The present level of Indian Research does not favourably compare with that of advanced nations. The Law will, therefore, affect the flow of knowledge in the country. Furthermore, literature from advanced countries now flows freely into India in the form of Technical Journals. It would appear to be unfair to rely on foreign technical and patent literature for our knowledge and yet not give them a protection which is theirs by right. <u>Suggestion:</u> It is suggested that instead of excluding all Pharmaceutical and Food Products from patentability, the Government may insist on compulsory licences in all nationally important cases.

II <u>Clause I. Section 25</u>: This concerns the time for which a protection would last.

<u>Comment</u>: At the moment a large majority of the foreign patents are not being utilised in the country because there is no adequate industrial activity. The change of time from 16 years to 14 or 10 years has no significance at all until such time as the Indian industry grows in its stature.

What is important to remember in these cases is that, before one could take a decision as to whether one would like to use it for one's own purpose, it is necessary that it should be examined by (ompetent researchers and technologists in the field. By and large, the Indian industries are still not enlightened enough for this purpose.

<u>Suggestion:</u> It is recommended that the present clause governing the time of the patent may be left unchanged. Greater effort may be put to see that the system of compulsory licensing comes into effect.

III <u>Clause I. Section 34</u>: This clause provides for compulsory licensing.

- 2 -

<u>Comment</u>: In spite of the fact that this system of compulsory licensing has been into existence for quite a long time, it seems that the advantages of the clause have not been properly utilised for the good of the nation. Here again there is knowledge, competency and work which is required before a decision for licensing a patent can be taken. For various socio-political and economic reasons, the atmosphere in the country is still not conducive for the correct utilisation of this saving clause.

<u>Suggestion:</u> It is suggested that various Government and Irade Organisations should pool their resources together to see that new patent literature is properly circulated to interested industries and conditions be created by which the compulsory licensing system could be fully utilised.

IV <u>Clause I. Section 40</u> : No comment .

V <u>Clause I. Section 44</u> : No comment.

VI <u>Clause I, Section 45</u>: This section stipulates for licenses of rights compulsory to be introduced in the Patent Clause.

<u>Comment</u>: Since 95% or more of the patents belong to foreign patentees, this clause is considered healthy.

VII <u>Clause I. Section 51</u>: This refers to infringement.

<u>Comment:</u> The present procedure for providing infringements is such that only big parties with enough financial strength can make effective use of the clause. The smaller parties cannot make use of the same.

<u>Suggestion:</u> Some administrative reforms regarding infringement procedures appear to be necessary. One of the greatest points that may be made in this connection is the need for competent examination of all the patents that are **filed**. It is well-known that the examination in India is not very thorough and that many patents which could be dropped on the basis of prior knowledge make their way into the patent office.

GENERAL COMMENTS

1. The total experience available in India on all aspects of patents could be considered inadequate so that the approach to the Patent System at the moment appears more politically biased than technically biased. It is suggested that Sub-Committees of representatives of Patent Attorneys, Patent Examiners and Experts and Specialists with adequate experience in patenting and in the utilisation of patents, are formed with a view to make a report on the existing status of technical knowledge as applied to the present system. If this is not done, there is a great danger that the present confusion in Patents would get further confounded.

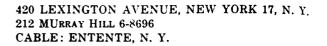
2. Far greater stress to make the compulsory licensing system more effective is called for. Unless greater experience is gained in this field, no far-reaching changes in the present Patent Law seem to be called for.

3. Since 95% of the patentees are foreigners, and since a majority of these patents are not utilised in India, it is obvious that the Indian Patent System merely acts more or less as a clearing house of a new patent literature. It would be far more useful to make an expert review of the utilisation aspects of the patents and concentrate on remedial measures.

4. The system of patent examination in India should be made more competent for this purpose. The number of examiners must be improved both in quality as well as in quantity.

BAL Jansharr

DIRECTOR SHRI RAM INSFITUTE FOR INDUSTRIAL RESEARC 19, UNIVERSITY ROAD, DELHI-7.



A Non-Profit Corporation

BUSINESS COUNCIL FOR INTERNATIONAL UNDERSTANDING

FRED C. FOY, Chairman HARVEY WILLIAMS, Vice Chairman JOHN G. COPELIN, Treasurer BROMWELL AULT, Secretary

JOHN HABBERTON, Executive Director

SUMMARY STATEMENT RELATING TO TESTIMONY TO BE OFFERED BY ROBERT F. MEAGHER, AS REQUESTED BY THE SPECIAL COMMITTEE ON THE INDIA PATENT BILL.

5

STATEMENT OF ROBERT F. MEAGHER TO JOINT COMMITTEE OF THE INDIAN PARLIAMENT CONCERNING BILL 62 of 1965

(PATENTS BILL 1965)

This statement is being submitted on behalf of the Business Council for International Understanding. (See Appendix I for a description of BCIU).

I am a lawyer by profession and in addition I am the Associate Director of International Legal desearch at Columbia University Law Johool in New York City. My appearance before this Committee is in my capacity as counsel for the Business Council for International Understanding. (See appendix II for curriculum vitae). My appearance before you is not as an expert on patent law but rather as one who is deeply concerned with the problems of economic development in India. My interest in India dates back to the late 1940's. My first visit to India was in 1952 when, as a Fulbright scholar, I studied at the Bombay School of Economics. I have been a frequent visitor to India since that date.

The BCIU is concerned with the pending legislation because in our opinion it will alversely affect the investment climate in India, the flow of technology to India and the development of scientific and technological research within India.

The current bill is an indication of the desire of the legislature to modernise India's patent legislation and to overcome what it considers to be inequities in the patent system as it operates at this time. Every government has the right and the duty to study the problems confronting it and to resolve them in a manner which is in its national interest.

To some the proposed legislation is extreme in some of its provisions. These provisions seem to strike at the very heart of the patent system leaving the form and destroying the substance. Particular concern is directed towards provisions which:

- permit use of the patent by the government without ~ ' . compensation
- permit licenses of right without inquiry into the means or ability of the licensee at a fixed maximum royalty
- remove specified appeals from the judicial system
- reduce the period of validity of existing patents.

It is always difficult for an outsider to juige the legislation of another mation. I remember reading the Indian Industrial Regulation and Development Act of 1951 many years ago and saying to myself that although the Government has many extraordinary powers it will probably never exercise them. In the case of that legislation my hunch was proved accurate. Most of the more disturbing regulatory sections of that piece of legislation have never been invoked. But how does a lawyer convince a client that statutory powers will not be exercised. Even today when individuals consider investing in India this 1951 Act constitutes a deterrent.

I don't know whether those sections of the Patent bill which deviate the most from the norm established by other countries will lie dormant or will be exercised frequently. Perhaps the real reason for many of these provisions is psychological inasmuch as they attempt to re-establish a lignity which was suppressed prior to independence. However my appearance here is not as an analyst but rather as a representative and spokesman for a group of industrialists who either are investing in India or hope to do so in the future. Their goal is to find some way to assist in the rapid economic and industrial development of India, for a dynamic India will also be one in which industry will flourish.

The questions raised by the current legislation fall into three main categories: investment climate, the flow of technology and the development of inigenous scientific and technological research.

Investment Climate

The current patent bill forms but a small part of the total investment climate. Investors are more concerned about economic and political stability, management, the flow of raw materials, administrative controls, taxes and so forth than they are about patent legislation. However the patent bill is one more negative factor in an investment climate where there are already numerous other negative factors.

Unler the Fourth Five-Year Plan the Government has estimated an annual inflow of 5120 million in private foreign investment. This is considerably more than has been flowing into India. It has been our experience that potential investors find the investment climate leaves something to be desired. Capital moves to those areas where it can receive the best returns under the best conditions. Unfortunately some companies which were initially interested in India have taken their projects elsewhere. This is discouraging to those who wish to see India develop at a rapid pace. India has lost not only the capital investment with its technology and jobs but perhaps more important has lost markets which may be impossible to regain.

Over the past fifteen years there has developed a much greater understanding between India and the foreign investor. This understanding reached a high point in 1964 at the New Delhi Conference between senior Indian Government officials and the BCIU. Through the technique of exploring the ten points which were of paramount interest to both sides a dialogue was opened. (See Appendix III). This permitted a frank discussion of the problems as seen by all of the participants.

The recent deaths of two Indian Prime Ministers and the extreme food crisis resulting from severe droughts have tended to turn the attention of the Government away from foreign investment toward more immediate matters. In recent months visits to the United States by the Indian Prime Minister and the Minister for Planning have brought forth a revived interest in India. People are once again saying - let's look at India.

The patent bill appears to be moving against the trend to encourage new investment in India. Perhaps this is an illusion but it appears to informed observers that the current legislation is a step backward at the very moment when India needs a very strong push forward.

The Flow of Technology

India desires the latest technology so that the gap between it and more developed countries will narrow. K. M. Pannikar argued in his book, "The Afro-Asian States and Their Problems" that India needed atomic physicists, and that was many years ago. He rejected the argument that India could satisfy itself with less modern technology. In his opinion if it did so the gap between India and more developed countries would widen.

The question posed by the bill under discussion is whether the proposed legislation will act as an incentive or a deterrent to the flow of new technology to India. Can those who are creative be forced to deliver up their ideas without traditional safeguards and incentives? Isn't it more likely that they will by-pass those countries whose legislation poses threats to their property rights.

If industrial development was no more than the securing of patent information India might find other ways to obtain this information. But technological development goes far beyond patents. It requires capital, training, know-how, skills etc. These elements are hard to come by and their source is usually the same countries where one finds major patent holders. For better or for worse industrial development is intimately interwoven with patent rights. It is unlikely that a country with an unfavorable patent law will be able to attract all of the other elements essential to industrial development.

Scientific and Technological Research in India

It is not likely that a restrictive patent bill will encourage Indian scientists and technologists to carry out fundamental research in India. Italy is a good case in point. The absence of patent legislation in the field of drugs has virtually eliminated Italian discoveries in this field. When discoveries are made they are patented outside of Italy.

One cannot expect a man to spend many years in research, with little or no recompense, only to have his industrial property rights severely limited when he finally does make a fundamental discovery.

It may be that other incentives could be created for inventors, but it would be wiser to test out those new techniques before rejecting well established techniques.

Conclusion

At the moment India finds herself in the midst of extraordinary development problems. These problems cry out for an innovative approach. However it would be a short sighted innovation which would curtail the flow of investment, limit the flow of technology and diminish the level of internal scientific and technological research.

Patent rights are inextricably linked with the flow of capital, know-how, skill and experience. Tampering with industrial property rights at this time may well prove a major deterrent to rapid development.

BUSINESS COUNCIL FOR INTERNATIONAL UNDERSTANDING

The BCIU is an organization which has as its membership various representatives of large business corporations operating in diverse fields. Its purpose is to develop both with its own and with foreign governments a broader understanding of the problems confronting industry and the governments where its members operate.

In April 1964, recognizing that there were opportunities as well as deterrents to private investment in India, the BCIU oponsored a conference in New Delhi for the specific purpose of opening a dialogue between senior Indian Government officials and key U. S. business representatives. The objectives of the conference were:

- (1) To obtain a clearer understanding of India's future policies toward foreign private investment, and
- (2) To explore jointly the steps that could be taken to facilitate the needed inflow of foreign private investment.

By the end of the conference, all agreed that a useful dialogue between Government and U. S. business had been initiated. The conference ended on a note of cautious optimism regarding future opportunities for foreign investment.

Upon return to New York a standing committee on India was selected from the 30 companies attending the New Delhi meeting. The Committee has a membership of about 15 companies including Union Carbide, Allied Chemical, Dow Chemical, IT&T, IMC and so forth. (See below for a list of committee members). The Committee holds monthly meetings for the purpose of (1) continuing the dialogue with visiting Government officials and (2) appraising the trends in India's investment climate since the 1964 New Delhi Conference, and (3) considering further with our Indian friends what might be done to achieve the Government of India's expressed objective of significantly increasing the net flow of foreign private capital.

MEMBERSHIP OF BCIU'S INDIA COMMITTEE

- N. D. Abbey, President, Abbey Etna Machine Co.
- D. A. Climan, Director, Foreign Finance, Allied Chemical Corp.
- J. G. Copelin, Vice President, International Telephone and Telegraph Corp.

- C. S. Dennison, Vice President, International Minerals & Chemical Corp.
- R. M. Dorman, Vice President, Asia Bechtel Corp.
- G. B. Doughman, Vice President, International General Electric Co: .
- J. R. Galloway, Vice President, Union Carbide Corp.
- F. R. Hoadley, Jr., Manager, International Operations, Farrel Corp.
- Willem Holst, Vice President and Director, Esso Standard Eastern, Inc.
- T. C. Keeling, Vice President, Koppers Co., Inc.
- A. T. Knoppers, M.D., President, Merck, Sharp & Dohme International
- E. H. Schulenberg, Executive Vice President, Firestone Tire & Rubber Co.
- E. K. Stilbert, Vice President, Dow Chemical Co.
- For BCIU: John Habberton, Executive Director, Business Council for International Understanding
- R. F. Meagher (Counsel for BCIU), Associate Director, International Legal Research, Columbia University Law School

Date of Birth: May 13, 1927.

Office Address: Columbia University School of Law, 435 West 116th Street, New York, New York.

Residence: 405 West 118th Street, New York, New York.

Education: Bombay School of Economics, Fulbright scholar, July 1952-May 1953 Yale Law School, LL.B., June 1952

City College of New York, B.S. (in social science) January 1949.

Current Professional Activities:

Associate Director of international legal research, Columbia University Law School, current questions include administrative discretion in dveloping countries in the allocation of scarce resources and the allocation of resources between competing public and private enterprises.

Conducting two seminars at the law school on international law and economic development and law and development problems in Africa.

Consultant (since 1960): Advice to governments, international organizations, and private groups primarily on questions relating to foreign aid and foreign investment in Asia and Africa.

Previous Professional Activities:

Assistant director, public international development financing project of Columbia University Law School (1961 to September 1965): Supervision and/or preparation of a series of studies on public international development financing in the following countries: Turkey, East Africa (Kenya, Uganda, Tanzania), Senegal, Sudan, India, and Thailand. The studies required residence abroad from March 1961 through November 1963.

Legal officer, United Nations Relief and Works Agency for Palestine Refugees in the Near East, Beirut, Lebanon (May 1958 to December 1959): Legal work in the fields of private and public international law. Principal responsibility related to the commercial problems of the Agency. Agency entered into 5,000 to 6,000 contracts annually covering subjects including procurement of basic commodities, hospital agreements, educational agreements, construction contracts, insurance contracts, an air charter agreement, shipping contracts, labor, trucking and bus contracts. The negotiation and administration of such contracts took place in Syria, Lebanon, Jordan, Gaza, Egypt and, in relation to an arbitration, in Paris.

Lawyer (July 1954 to May 1958): Winthrop, Stimson, Putnam & Roberts, 40 Wall Street, New York, New York. Engaged primarily in corporate, financial, public utility, and administrative law. Work included appearances before Federal administrative agencies and courts. On occasion carried on negotiations in India and Pakistan on behalf of clients.

Educational exchange grantee under U. S. Department of State leader specialist program (September 1953 to June 1954). Lectured to professional, educational, military, cultural and business groups throughout India from September 1953 through December 1953, and Pakistan from January 1954, through June 1954 on current international, economic, political, and social questions.

Professional Organizations:

American Bar Association: African Law Committee. Association of the Bar of the City of New York: Foreign Law Committee (1956-58 and 1965 to Present). International Commission of Jurists Committee. American Foreign Law Association. American Society of International Law. International Law Association. World Peace Through Law Center: Committee on Foreign Investment. Association for Asian Studies. African Studies Association (fellow). Council on Foreign Relations. Society for International Development. Columbia University seminars: Seminar on peace. Seminar on modern Africa. Seminar on south and southeast Asia. Asia Society: India Council. Council of the African-American Institute.

Military Service: 20 months in the U. S. Army from May 1945 through December 1946, including 14 months in the European theater. Principal Research Projects:

Problems of private capital investment in India-legal, economic, political, and social (study carried out in India in 1952 and 1953 under a Fulbright scholarship).

The investment guarantee program of the International Cooperation Administration (as a member of the Foreign Law Committee of the Association of the Bar of the City of New York, 1956-58).

Public international development financing in a series of Asian and African countries (January 1961 through August 1965).

Publications:

"International Financial Aid: A Comparative Study of Policies, Institutions and Methods"-- joint author with Wolfgang Friedmann and George Kalmanoff (at press).

"Industrial Financing in Five African Countries," December 1965--to be published by the Economic Commission for Africa.

"Public International Development Financing in Sudan," Columbia University Law School, April 1965.

"Public International Development Financing in Senegal," Columbia University Law School, November, 1963.

"Public International Development Financing in Thailand," Columbia University Law School, February, 1963.

"Public International Development Financing in East Africa (Kenya, Uganda, Tanzania)," Columbia University Law School, January 1962.

"The Guaranty Program of the ICA-One Approach to the Protection of American Investments Abroad," 14 Association of the Bar Record 269 (1959) (author of the section on convertibility).

"The Indian Five-Year Plan-the Final Draft," Far Eastern Survey, April 1953.

"Post-War Foreign Policy of the United States," Panchshila (Bombay), January 1957.

Educational Activities:

Currently I offer two seminars at the Columbia Law School on international law and economic development, and on law and development problems in Africa.

During the summers of 1964 and 1965 I participated in teaching a seminar to senior Government officials of East and

Central Africa (Kenya, Uganda, Tanzania, Zambia and Malawi) on law and development problems in Africa. These seminars were held at the University of East Africa Law School in Dar es Salaam, Tanzania. The third and final seminar will be held during the summer of 1966.

Over the years I have offered a number of adult education programs for the Foreign Policy Association, Fund for Adult Education, and the Scarsdale Adult School. Topics have included: "India," "Tensions in Southeast Asia," "Major Decisions of U.S. Foreign Policy," and Africa-Continent in Turmoil."

Since 1950 I have lectured extensively in the United States and abroad primarily on questions relating to foreign policy.

Travels: My activities have taken me to the following areas:

Asia: India, Pakistan, Ceylon, Burma, Thailand, Malaysia, Singapore, Vietnam, Philippines, Hong Kong, T₁iwan, Japan, Syria, Lebanon, Jordan, Gaza, Aden, and Israel.

Africa: Kenya, Uganda, Tanzania, Sudan, Ethiopia, French Somaliland, United Arab Republic, Libya, Tunisia, Morocco, Senegal, Gambia, Ivory Coast, Ghana, and Congo (Leopoldville).

Europe: United Kingdom, France, Belgium, Netherlands, Spain, Italy, Switzerland, Gormany, Yugoslavia, Greece, Bulgaria, Turkey, Denmark, Finland.

Latin America: Mexico.

June, 1966

I	LOEK L OBJECTIVES VIID THE ENTITY	VES FOR	VIGNI NI DA
	INDUSTRIAL POLICY OBJECTIVES		INCENTIVES FOR PROMOTING
	FOR THE DEVELOPING INDIAN ECONOMY*		FOREIGN INVESTOR CONFIDENCE
	Overall Objective :		Overall Incentive :
	Accelerated economic development to improve the standurd of living consistent with resources available therefor.		A demonstrable intent and program on the part of the Indian Government to improve the climate for foreign private investment.
्री	Specific Objectives :	Spec	Specific Incentives :
۱.	Substantial contribution to foreign exchange carnings or savings.	÷	Acceptable return on capital employed as compared to competitive opportunities outside India.
'n	Acceptable level of local participation in equity consistent with availability of needed foreign exchange.	4	Acceptable level of foreign participation in equity and management control, commensurate with contribution of foreign exchange and "know-how".
'n	Reasonable equity to loan ratio and acceptable repatriation schedule for loans and dividends.	ŗ.	Reasonable amortization and dividend policy with greater freedom to reinvest locally for expansion, technological and quality improvements.
4	Acceptable unit costs for project investment and operation consistent with safety, performance and quality standards.	4	Reasonable import duty and other controls, to assure minimum unit investment and operating costs.
s.	Priority on manufacturing investments in locations acceptable to government.	S.	Need for investment in both manufacturing and distribution, in relation to regional demand.
6.	Competitive prices on imported raw materials, together with economic utilization of available local supplies.	Ŀ Ŀ	Freedom to select raw material source consistent with commercially competitive pricing and impact on foreign exchange.
7.	Reasonable ex-plant and consumer price levels, with safeguards against excessive profits.	7.	Flexible product pricing policy consistent with acceptable return on investment.
œ	Foreign and local private enterprise, subject to same controls, regulations and tax treatment.	%	Stable, simple and equitable tax and depreciation policy ; avoidance of retroactive tax.
6	Creation of employment. together with accelerated training and development of Indian personnel.	.	Adequate staffing by foreign technical experts and managerial talent.
10.	Development of certain industries designated as the exclusive responsibility of the State.	10.	Expeditious approval procedures, based on well- coordinated planning with equitable allocation of capacity to the foreign private investor.
	*Interpretation based on policy statements of 1948, 1949 and 1956 and the approval process as experienced.		

MEMORANDUM

ON

THE PATENTS BILL 1965

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Organisation of Pharmaceutical Producers of India

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MEMORANDUM ON THE PATENTS BILL 1965

PREFACE

This Memorandum is being presented on behalf of the Organisation of Pharmaceutical Producers of India (O.P.P.I.). This Organisation comprises members who represent 70% of the total production capacity of pharmaceuticals and fine chemicals in India and 80% of the total export of pharmaceuticals from India. Our members employ 60% of the total number of workers employed by the pharmaceutical industry in India.

The pharmaceutical industry in India is growing very rapidly. From 1948, it has grown from an industry producing goods worth Rs. 110 million per annum to one producing goods worth Rs. 1,350 million in 1965. In the early stages, the manufacture consisted mainly of the processing of bulk materials. Now, basic manufacturing facilities have been established and the industry is manufacturing bulk drugs, intermediates and pharmaceutical preparations. Many pharmaceutical concerns in India have plans for extensive expansion of their existing manufacturing activities; for new manufacturing projects and for establishing and developing research facilities.

We, therefore, believe that we are competent to represent the interests of the Indian pharmaceutical industry.

Before we deal with the relative clauses of the Bill in detail, we feel that it is necessary to obtain a general idea about the functioning of the patent system in an industrial society.

What are Patents?

Patents are statutory grants which in return for the disclosure of an invention confer on the inventor for a limited time the exclusive privilege of working an invention and selling the invented product.

The theory on which the Patent System is based is that the opportunity of acquiring exclusive rights in an invention stimulates research and technical progress.

It is, therefore, clear that the inventor in return for the disclosure of his invention must secure a reward which is commensurate with the value of his invention. Mr. Justice Ayyangar in his Report on the Revision of the Patents Law quotes from Michel's commentary on "Principal National Patent Systems" (Vol. I, page 15) that "Patents are not created in the interest of the inventor but in the interest of national economy". He further observed that due to the patent system new products and processes are created, industry encouraged to manufacture new and better products, expansion of industry based upon the invention takes place and thus employment, national wealth and higher living standards are created.

Working of Inventions

The laws of many countries contain provisions which in the interest of national economy secure the working of inventions in the country in which the patent is applied for.

The Model Law for Developing Countries on Inventions, drafted by a committee of experts under the auspices of The United International Bureaux for the Protection of Intellectual Property (B.I.R.P.I.) composed of representatives of 22 countries (including India) out of the total number of 69 countries who considered themselves as developing countries states that adequate provisions for compulsory licences are of exceptional importance for developing countries. However, the said committee was of the opinion that the following kinds of compulsory licences should not be granted :

(a) Whereby the Government of the country is always entitled to such a licence;

(b) Whereby such licences are granted in the public interest without exactly specifying the categories of events which would justify the grant of such licences.

The draft of the said Model Law as well as the patent laws of all countries which have compulsory licensing provisions provide that the royalties payable to the inventor under such licences should be commensurate with the value of the invention.

The law relating to patents was enacted in 1911 and has undergone amendments up to 1956. It is acknowledged that

there is need for a more comprehensive law due to changes in the economic conditions within the country and the development of technology and patent laws throughout the world. However, the main purpose of the Patents Bill 1965, namely, to stimulate inventions among citizens of India and to encourage development and exploitation of new inventions for industrial progress in the country will not be achieved if the Bill is passed in its present form.

In particular, Clauses 5, 47, 48, 53, 87, 88, 93(3), 99, 100, 102 and 116, will act against national interests and national economy particularly in the field of articles of medicine and food which are important and vital to the public health. The most important provisions of the Bill are dealt with, in short, hereinafter (up to page 7) whereas a more detailed discussion will be found on pages 9 to 84.

Examination of Vital Clauses of the Bill.

Clauses 5 and 47 of the Bill provide that for inventions of food and medicine and substances produced by chemical processes patent protection shall extend only to the process of manufacture and not to the product itself. For other articles the protection extends to the product itself. We explain later in greater detail (vide pages 19 to 29) why, in our opinion, such a discrimination, particularly for medicine, is not warranted. It is an acknowledged fact that pharmaceutical research is extremely difficult, is risky and expensive so that adequate patent protection in this field is especially necessary.

Clause 48, allows the Central Government to use a patented invention and/or to import a product covered by a patent without any compensation to the patentee and provides that such use or importation will not amount to an infringement of the patent. This clause grants unlimited powers to the Government which, if exercised, will act against the interests of local industry and will hamper industrial progress and research initiative. Further, this clause militates against the fundamental rights of a citizen of India, which have always been jealously safeguarded in this democracy. Industrial property rights such as patents should not be treated differently from rights attached to any other kind of property.

We have, therefore, prayed for the deletion of this clause.

Clause 53 provides that the term of a patent for inventions of food and medicine shall be 10 years, whereas for other classes of inventions the term shall be 14 years.

At present, the term of all patents is 16 years and it is possible, under certain circumstances, to extend this term. There is no country in the world which provides for a term of 10 years without making a provision for extension of the term.

We explain later in greater detail (vide pages 33 to 38) why, particularly for foods and medicine, such a short term is unrealistic because the inventor, due to the long periods of pharmacological, toxicological and clinical testing, does not derive a benefit from his invention during a substantial period of the term. We have, therefore, strongly recommended that for food and medicine the term should be at least the same as for patents in other fields; that is 14 years or, in the alternative, 10 years from the date of sealing of the patent with a possibility of extension of the term beyond 10 years where the patent has not been sufficiently remunerative.

Clauses 87 and 88 of the Bill provide that all existing and future patents for inventions relating to food and medicine shall be deemed to be endorsed with the words "licences of right" which will enable any person at any time to apply to the Controller to work the invention; and the Controller, in his turn, is obliged (without taking into consideration the capability of the applicant and the technical facilities available with him) to grant a licence to him. The royalty or other remuneration payable to the licensee shall not, in any event, exceed 4% of the bulk price of the patented product.

The present provisions of the Act do not make any such distinction between different classes of inventions. If these clauses are passed in their present form, it would enable a limitless number of persons to apply for a licence as of right, whether they are qualified to work the invention or not. There is no other country in the world which makes a similar provision in its patent laws.

We explain later in the following pages (vide pages 47 to 57) why these clauses, if enacted, will hamper industrial progress and restrict research and new inventions in the country in the field of food and drug. The result is nothing short of a complete erosion of patent rights with regard to this particular class of inventions. We have, therefore, prayed for the deletion of these clauses and have suggested that for inventions relating to food and medicine the compulsory licensing provisions should be on the lines similar to those

applicable to other classes of inventions with certain modifications aimed at avoidance of delays in granting such licences which should also be valid for all types of inventions.

Clause 93 (3) provides that the Government shall have powers to direct the Controller to authorise any licensee to import products covered by a patented invention. No appeal or other compensation is provided for. Since the effect of this clause is similar to Clause 48, we have submitted that this clause should be deleted.

The provisions of Clauses 99, 100 and 102 deal with the use of inventions for purposes of Government and the acquisition of patents by the Government. Clause 99 provides that the use of an invention by any undertaking in a class or classes of industries which the Central Government may notify, shall be deemed to be "use for the purpose of Government". This provision is very wide in scope and would result in a limitless number of undertakings being permitted to make use of a patented invention. We have, therefore, submitted that the use of an invention for undertakings (which are so notified) should not be provided for especially because all undertakings have the right to apply for compulsory licences. We have further recommended that as Government corporations and Government companies are incorporated for the purpose of carrying on the business of manufacture and sale of certain articles and for profit, they should not be placed on a better footing than any other class of undertakings insofar as the use of a patented invention is concerned.

As regards the use of an invention for the purposes of Central or State Governments we have submitted that such use should be limited to certain specified purposes such as for defence, or in the case of epidemic or for similar public purposes in the event of an emergency.

We have further submitted that in view of the ample means provided for in the Bill whereby third parties can make use of a patented invention there is no legitimate reason for such complete expropriation of property rights by means of acquisition of a patent.

Clause 116 prevents a patentee from appealing to a judicial tribunal against the decision of the Controller or the Central Government under the clauses mentioned above. In our detailed submissions we have set out reasons why, in our

opinion, there should be a proper judicial review from such decisions.

CONCLUSION

The vital clauses summarised above will, in our submission, erode patent protection to such an extent that inventors will not get adequate reward in return for the disclosure of their inventions and there will be no incentive for them to carry on research. If the said clauses are passed as proposed in the Bill, inventors will tend to keep their processes and knowhow secret as far as possible and will not disclose them to the public.

Patents and Prices

The patent system has no significant bearing on the prices of drugs and medicines. The report of UNESCO entitled "The Role of Patents in the Transfer of Technology to Under-Developed Countries" (Report E/3861, E/C.5/52/Rev.1, 9th March, 1964), at page 19 states as follows :

"In any case, the effect of higher prices specifically due to patent protection is almost impossible to disentangle from higher prices due to such factors as exclusive know-how, trade secrets, restrictive practices, or the dominant market position of the supplier, all of which are intrinsically unrelated to the patent system. Since patents are thus only one of the factors which may bring about higher prices, the question arises whether measures directly effecting price levels or general antitrust legislation are not an economically more effective and administratively more feasible technique of coping with the problem, than legislation devoted specifically to the patent system."

We submit that in any event the Government has sufficient means at its disposal to adopt adequate steps under existing legislation to check the prices of all commodities.

Although there has been a steady rise in the prices of most commodities, it is particularly noteworthy that in the drug industry, prices have not only been maintained but have, in many cases, been reduced with the increase in production and other economies in the manufacturing processes.

The Index Number of Wholesale Prices in 1962-63 was 122.9. At the end of July 1965, it was 165.9, a rise of 35%; the

All India Consumer Price Index for working classes 1962-63 was 131 and in May 1965 it was 161, a rise of approximately 23%; yet the selling prices of drugs and medicines, by the manufacturer, have been kept at the level of 1st April 1963. Indeed, it is well known that there are various factors which taken together form into the expression "the cost of medical care". Some of these are cost of hospital care, physicians' fees and cost of drugs. The cost of drugs is only one of the smaller factors which constitute a fraction of the total cost of medical care.

The Technical Sub-Committee of the Development Council for Drugs & Pharmaceuticals (1962-63) came to the conclusion that, despite the fact that the cost of basic drugs is usually higher in India than in other developed countries, the cost of finished preparations is, in most cases, much less than the domestic prices of similar products in foreign countries. The Committee further reported that in the conversion of a basic drug into dosage form, a number of operations are involved which contribute to the cost of finished preparations and the cost of these operations is quite often much more than the cost of the basic drug content of the product. In certain cases, the incidence of this cost is so large that, in comparison to the cost of the active ingredient, the cost of the finished preparations is not significantly affected, even if the cost of the active ingredient is reduced by half. It is indisputable that drugs and pharmaceuticals are among the few sectors of the economy where the prices have been successfully held at a steady level.

The subject matter under discussion is of immense importance to the future of the industrial development of this country, especially the pharmaceutical industry; and therefore, we invite your serious attention to the following detailed comments on certain clauses of the Bill.

Introductory Note

The objects of this Memorandum may be briefly summarised as follows :

(a) To draw attention to the very serious defects and shortcomings in the Patents Bill 1965, especially insofar as they affect the Indian Pharmaceutical Industry and drug research adversely.

(b) To compare the existing Patent Law of India and the Law which is sought to be brought into force by the Bill.

(c) To examine :----

(i) what would be the effect of the proposed legislation on research and utilisation of its results in India.

(ii) whether the fruits of research and development in other countries would be readily introduced to this country if the Bill becomes law.

(iii) whether the provisions of the Bill provide adequate means which would enable Indian firms to obtain technical direction and know-how from abroad in order to carry out the newly developed manufacturing processes and to produce new drugs.

(iv) whether the proposed legislation would have the effect of promoting the inventor's ability to obtain low unit costs from high planned utilisation and to decrease the cost of food and medicine.

(v) whether the Bill would in any substantial way enhance the degree of control over drugs and drug prices now exercised through the media of other legislative enactments and whether the results would truly be remedial.

(d) To set out the substance of the amendments desired by the industry to the proposed Bill which will have the effect of encouraging the inventor in the pharmaceutical industry by enabling him for a limited but reasonable and adequate term of years to seek a reward and to benefit from his patent rights, subject to adequate but fair safeguards in the public interest against the abuse of monopoly.

Clause 2 (g)

(g) "food' means any substance intended for the use of, or capable of being used by, babies, invalids or convalescents as an article of food or drink, which the Central Government may, by notification in the Official Gazette, specify in this behalf;

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Clause 2 (g)

DEFINITION OF FOOD:

"Food" has been defined as any substance intended for the use of, or capable of being used by babies, invalids, or convalescents as an article of food or drink, which the Central Government may, by notification in the Official Gazette, specify in this behalf.

The Central Government has, therefore, wide powers to decide which of the substances used by babies, invalids, or convalescents shall, or shall not, fall within the definition of "Food".

The purport of this definition is not understood, neither is it evident from the Notes on Clauses. This provision does not find a parallel either in the Patents Bill 1953 or in Justice Ayyangar's report and is likely to create considerable complications of interpretation.

In this connection, it is important that the public can be certain of the status of, and rights under, any particular patent which is under consideration without reference to numerous notifications which may be issued by Government under the proposed sub-clause.

We, therefore, submit that the words "which the Central Government may, by notification in the Official Gazette, specify in this behalf", be deleted from this sub-clause. In the alternative, we suggest that "Food" be defined as follows :----

" "Food" means any nutrient substance which is readily assimilated and which is beneficial to babies, invalids or convalescents".

Clause 2 (h)

(h) ''Government undertaking'' means any industrial undertaking carried on—

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(i) by a department of the Government, or

(ii) by a corporation established by a Central, Provincial or State Act, which is owned or controlled by the Government, or

(iii) by a Government company as defined in Section 617 of the Companies Act, 1956.

and includes the Council of Scientific and Industrial Research, any University established by law in India and any other institution for scientific or technical education which is financed wholly or for the major part by the Government;

Clause 2 (h)

DEFINITION OF "GOVERNMENT UNDERTAKING":

Effect of the Definition

The Council of Scientific and Industrial Research, any university established by law in India and any other institution for scientific or technical education which is financed wholly or for the major part by the Government, are sought to be brought within the definition of the term 'Government Undertaking'. The scope of this definition has, therefore, become very wide so as to include all universities or other institutions for scientific or technical education which may be carrying on their activities independent of any control by the Government.

Position in U.K.

The Swan Committee which was entrusted with the task of recommending desirable amendments to the Patent Law in the U.K. expressed themselves against enlarging the scope of the Government's power in this regard. In paragraphs 70 and 71 of their Final Report, the Swan Committee observed as follows :—

"Nor do we see any adequate reason for enlarging the purposes for which the Crown may, in normal times, use inventions under the powers conferred by Section 29, the compendious expression "for the services of the Crown" being, in our opinion, suffcient to cover, not only the needs of the armed forces and the requirements of national defence, but also the requirements generally of the various Government Departments for their own use.

The status of the bodies who will be managing the the nationalised industries has not, so far as we know, as yet been decided, and we feel that it would be premature to discuss the powers which will be available to them. For the purposes of this report we assume that they are not to be regarded as Government Departments, and that the use of the products of any manufacture they undertake, insofar as they are not applied for the use of Government Departments, would not be regarded as being use of those products for the services of the Crown."

Comments and Suggested Amendments

Regarding the use of an invention by a corporation or a Government Company as defined in sub-clauses 2(h)(ii) and

2(h)(iii) our submissions appear under clauses 99 and 100 at pages 67 to 71. Justice Ayyangar, in his Report, did not consider that the Government's use of an invention should also include use by the Council of Scientific and Industrial Research or any university statutorily established in India or any other institution for scientific or technical education which is mainly financed by the Government.

It may be pointed out that the needs of the Council of Scientific and Industrial Research, a university or other research institution for the experimental use of a patented invention are already satisfied by clause 48(d) under which any person is entitled to use a patented invention for the purpose merely of experiment or research, including the imparting of instruction to pupils. To the best of our knowledge, the Patent Laws of no other country in the world contain provisions which define 'Government Undertaking' so widely.

We, therefore, submit that if the institutions and universities set out above fall within the scope of the definition of "Government Undertaking", it is tantamount to withdrawal of the effective value of patent protection.

The Government's needs in the case of war or emergency are well provided for in clauses 100 and 102 discussed below; while clauses 66(4), 89, 90, 93 and 97 are designed to overcome the abuse of a patent. We, therefore, submit that the words "Council of Scientific and Industrial Research, any university which is statutorily established in India and any other institution for scientific or technical education which is financed wholly or for the major part by the Government" should be deleted from the definition of 'Government Undertaking'.

(I) "medicine or drug" includes---

(i) all medicines for internal or external use of human beings or animals,

(ii) all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of diseases in human beings or animals,

(iii) all substances intended to be used for or in the maintenance of public health, or the prevention or control of any epidemic disease among human beings or animals,

(iv) all chemical substances, to the extent to which they are used as intermediates in the preparation or manufacture of any of the medicines or substances above referred to,

but does not include insecticide, germicide, fungicide or any other substance intended to be used for the protection or preservation of plants;

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Clause 2 (I)

MEDICINE OR DRUG :

Effect of the Definition

This is a new definition and does not appear in the Indian Patents & Designs Act 1911 as amended upto-date. The definition of "medicine or drug" as proposed in the Bill goes far beyond the literal meaning of the term 'medicine or drug' and is, therefore, very wide in scope.

All chemical substances, to the extent to which they are used as intermediates in the manufacture of medicines or any other substances which might in future be held to fall within the scope of clauses 2(I)(ii) and 2(I)(iii), are proposed to be included within the definition of 'medicine or drug'. Now, it is well known in the scientific world that the same chemical substance can be used both in the manufacture of medicine or drug and also in the manufacture of chemicals other than pharmaceuticals, e.g. dyestuffs. Further, even products used in some industries as solvents may be also utilised as intermediates in the manufacture of drugs and fall within the scope of this definition.

Comments

This sub-clause will restrict the rights of a person who obtains a patent for a process to manufacture a chemical substance which at the time of the grant of the patent is intended or capable of being used in the manufacture of chemical substances other than medicines or drugs. It is quite possible that after the grant of a patent for a process to manufacture the chemical substance contemplated in the preceding sentence, such substance may acquire utility as an intermediate in the manufacture of a medicine or drug, with the result that the rights of the inventor will be restricted to the extent to which such substance is used in the manufacture of a medicine or drug. Such a possibility is likely to create difficulties as to the interpretation and the effect of the patent in question as also administrative inconveniences. This concept of restricting patent rights is unheard of in the history of patent legislation. Mr. Justice Ayyangar, in his report did not include in the scope of the definition of medicine or drug, chemical substances used as intermediates in the manufacture of medicines.

Suggested Amendments

We submit that clause 2(I) (iv) should be deleted. In the alternative, the said sub-clause, together with clause 53 (discussed at pages 33 to 38) should be suitably amended to cure the anomaly explained above.

Clause 3

3. The following are not inventions within the meaning of this Act---

(a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;

(b) an invention the primary or intended use of which would be contrary to law or morality or injurious to public health;

(c) the mere discovery of a scientific principle or the formulation of an abstract theory;

(d) the mere discovery of any new property or new use for a known substance or of the mere new use of a known process, machine or apparatus;

(e) a claim to a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

(f) the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;

(g) a method or process of testing applicable during the process of manufacture for rendering the machine, apparatus or other equipment more efficient or for the improvement or restoration of the existing machine, apparatus or other equipment or for the improvement or control of manufacture;

(h) a method of agriculture or horticulture;

(i) any process for the medicinal, surgical, curative, prophylactic or other treatment of man or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.

Clause 3 WHAT ARE NOT INVENTIONS :

In view of our submissions under clause 5, this sub-clause should be deleted. Without prejudice to these submissions we state as follows:

A known process is one which is disclosed in prior literature and which describes a method of preparing a substance according to certain steps. If any person manufactures this substance according to this method which is already described in a prior publication, he is not entitled to get a patent because he makes a known substance only by the known process.

It is an internationally accepted rule that the value and the importance of an invention cannot always be seen by contemplating a patented process **alone**. It is necessary also to evaluate the results of the process which in chemistry means evaluating the compounds obtained by the process. If the fact is that the invention has led to new products with new properties or improved efficacy, it constitutes the strongest evidence that prior knowledge did not give an obvious clue to the invention. A patentable process is one in which the starting materials are so selected as to produce new compounds having better properties than compounds of similar constitution known before.

Most of the processes in respect of which inventions are made and patents are granted especially, in the pharmaceutical field, are what are known as "analogous processes". An "analogous" process is one which has already been used in literature for the manufacture of known substances but it amounts to a new patentable invention of considerable importance if the analogous process is applied to other starting materials in order to obtain new products with improved properties. Although the claim for an analogous process recites process steps which in themselves are known, the justification for the validity of such claim resides in the selection of special starting materials and in the unexpected properties of the new products produced by the analogous process.

As a majority of chemical processes which are used in pharmaceutical research are analogous processes, this sub-clause should, we submit, be substituted by the following sub-clause

"The mere discovery of any new property or new use for a known substance or of the mere new use of a

known machine or apparatus, or of the mere new.use of a known process, unless the product produced by that process is novel."

Clause 5

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5. In the case of inventions-

(a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or

(b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds),

no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.

Clause 5

NO PRODUCT PATENTS FOR FOOD AND MEDICINE :

Deviation from the Present Law

This clause for the first time in the Indian Patent Law makes a distinction between different classes of inventions insofar as the type of protection is concerned and is discriminatory in character because in respect of inventions other than those for food and medicine, a patent can be granted for the products themselves.

According to the present law, there is nothing specifically stated which would exclude product protection per se (vide paragraph 89 of Justice Ayyangar's Report). The Indian Patent Office, however, in effect and in practice has granted protection not only for the process of manufacture of a substance but also for the substance itself when made by the patented process. Further, the Patent Office has also granted claims for pharmaceutical preparations as such.

Justice Ayyangar's comments

In his report on the revision of patent law, Justice Ayyangar, after reviewing patent laws of other countries in Europe, the U.K. and U.S.A., reached the conclusion that the chemical and pharmaceutical industry of India would be advanced and the tempo of research in that field would be promoted if the system of permitting only process claims were adopted. Justice Ayyangar has, however, voiced the views expressed by the legal authorities and scientists in certain countries granting process claims which were based primarily on the technological developments in the field of chemicals and pharmaceuticals over 50 years ago. Since then there have been immense advances in technology and the arguments in support of process protection, as advocated by Justice Ayyangar, will no more hold good at present. Justice Ayyangar, at the time when his report was made, also relied on the views expressed on the subject by certain Eastern Bloc countries. Whereas India has access to know-how developed anywhere in the world, these Eastern Bloc countries did not have the opportunity to acquire know-how developed outside the Eastern Bloc. As is known these Eastern Bloc countries have discovered hardly any new pharmaceutical preparation which may be considered as an important advance in drug therapy.

Comments

Patents in the field of medicine are necessarily in respect of chemical inventions. In the chemical field, exploration of a

chemical process is undertaken for usually only two reasons. The first is to improve the production of an existing and useful substance. In this case only the new process can be protected. The second is to synthesise and to examine new substances, in order to find valuable compounds with improved properties. So far as new compounds in the pharmaceutical field are concerned, they are practically always prepared by analogous processes. New starting materials are used in known processes in order to attain new and unexpected results. It is, therefore, impossible to evaluate a process. If the patent granted to the inventor gives protection only for the process, an important feature of the invention is not accounted for.

The novelty or value of a patent relating to a medicinal substance does not reside merely in the process of manufacture but even more so in the therapeutic properties of the compounds involved. In fact the inventor has to make and examine many hundreds of chemically related substances out of which only one, if any at all, will prove to be a successful discovery. It is the immense cost of this research effort which is one of the justifications for patent protection. When looking for adequate patent protection, product protection per se, i.e. protection of the factor which really advances therapy, suggests itself.

During the last decades it has been observed throughout the world that fundamentally new chemical reactions are discovered only in exceptional cases. This is especially true in the field of pharmaceuticals. As mentioned before, most of the products are manufactured today according to well known processes called analogous processes. The need for offering incentive for the development of new chemical processes has thus diminished considerably, and it is far more important to develop new active substances according to known processes, that is to say, in an analogous way. It is logical to grant patents for valuable products newly synthesized. Granting protection of the known manufacturing processes because of the valuable properties of the products obtained by them would not be the best approach.

In countries where the protection granted under a patent is for the process only, (such regulations always going back to the 19th century), an inventor cannot restrict himself to one single manufacturing process but has to attempt to utilise, describe and claim all processes available, in order

to have adequate protection also under the system of process claims. If he overlooks even one manufacturing process, it would enable a competitor to manufacture and market the same valuable product discovered by the inventor, by manufacturing it, or pretending to manufacture it, according to an unprotected process. The inventor has, therefore, to work not only on the most economical manufacturing process, but has also to explore and experiment with and patent all available processes, however uneconomical they may be. If he would not do so, once the substance has been discovered and tested and found to be active, competitors having had no expenses and taken no risks could enter the field. We, therefore, emphasize the view that it is senseless to waste time and money on the elaboration of such other processes. This is likely to make drugs unnecessarily more expensive.

To the argument that there is a definite stimulus to research if it is open to others to employ alternative methods of manufacture of a known compound, we have already remarked that this argument would be true for the time passed; but, as mentioned above, at present it happens very rarely that fundamentally new chemical methods are discovered. Today an imitator usually tries to find other analogous methods not mentioned by the first inventor. By using such other known methods for the production of a valuable compound, the imitator at the same time makes use of all pharmacological, toxicological and clinical tests of the first inventor and he even takes advantage of the promotional work that the first inventor did by informing physicians, hospitals etc. of his new development and of the merits of his new compound. It would be more beneficial to the country if inventive skills are directed towards discovering new drugs rather than towards finding other processes for making already known drugs and which in effect amount to attempts to find ways and means of evading competitor's patents and to save the costs incurred by the inventor for all the medical tests which are much more expensive, time consuming and risky.

Another reason why product patents give the most adequate protection is that, in the case of an imported substance, proof of infringement of a process patent is virtually impossible, because it is impossible to ascertain, by analysis of a finished product, by what process it has been manufactured abroad.

Position in other Countries

The Joint Chemical Committee on Patents in U.K. has pointed out that the inventive step is often the conception

of the compound desired and that the method of making it may well be obvious to a chemist.

The Swan Committee was, therefore, of the opinion that a patent should be dealt with in the public interest and in particular in such a way that the fullest practical use was made of the rights conferred by the patent. The Patent Laws of Belgium, South Africa, New Zealand, Australia, United Kingdom, France, Israel, Ireland, Philippines and the United States of America and several other developing countries grant patent protection for the product per se. A complete list of these countries appears in Appendix 'A'. The draft of the European Common Market Patent Law also provides for product protection per se and it is well known that after the said draft law is ratified by the countries who are members of the European Common Market, the said member countries would make a similar provision in their domestic patent laws.

Furthermore, in November 1963 the European Council in Strassbourg published an Agreement on the unification of certain aspects of Patent Law which has been accepted by its members according to which product protection shall be granted for chemical and pharmaceutical products.

Clause 96 of the Bill, which deals with the licensing of related patents, provides an ample safeguard for those inventors who discover an inventive process which makes a substantial and genuine contribution to the state of the art so that product claims could not stop further development of technique.

The industry, therefore, firmly believes that the most beneficial form of patent protection, in order to stimulate indigenous research, and industrial development, is product protection per se.

Alternative Suggestion—Shifting the Burden of Proof

If, notwithstanding our submissions mentioned above, the Joint Select Committee is of the opinion that the time is not yet ripe to have product protection in this country, we would like to place the following submissions for consideration:

According to the law of evidence the patentee or his assignee, who alleges that his rights are infringed or are threatened with infringement has to prove that the infringer manufactured the product according to one or more of the processes

described and claimed in the Patent Specification. To prove that the infringer has used a process claimed in the Patent Specification it is usually necessary to gain access to his plant, which neither the patentee nor probably the Court can enforce. An indirect method of proving infringement by means of adverse inferences has been accepted by Courts in India and in England; but it has been found to be unsatisfactory. In any infringement action, therefore, unless the plaintiff (patentee) on whom the burden of proof as to infringement primarily rests, discharges such burden of proof, he will not succeed.

Position in other Countries

To overcome these difficulties, the patent laws of Germany, Austria, Finland, Greece, Switzerland, Japan, Poland, Yugoslavia, Norway, Netherlands, Sweden and Canada provide that, where a product is new and a process for its production is patented, it shall be assumed that any other product of the same constitution is made according to the process patented to the Plaintiff until the contrary is proved.

The Model Law for Developing Countries on Inventions, prepared in May 1965 by the United International Bureaux for the Protection of Intellectual Property (B.I.R.P.I.), to which 69 developing countries (including India) were a party, has under Section 51 made a similar provision.

We, therefore, recommend that the Indian Patent Law should also contain a similar provision in order to protect an inventor and that the following clause be added at the appropriate place in the Bill :

"Notwithstanding anything contained in the Indian Evidence Act, if a patent is in respect of a process for the manufacture of a new product, the same product, manufactured by a third party, shall, in the absence of proof to the contrary, be presumed to have been manufactured by that process."

25. (1) At any time within four months from the date of advertisement of the acceptance of a complete specification under this Act (or within such further period not exceeding one month in the aggregate as the Controller may allow on application made to him in the prescribed manner before the expiry of the four months aforesaid) any person interested may give notice to the Controller of opposition to the grant of the patent on any of the following grounds, namely :---

(a) that the applicant for the patent or the person under or through whom he claims, wrongfully obtained the invention or any part thereof from him or from a person of whom he is the legal representative;

(b) that the invention so far as claimed in any claim of the complete specification has been published before the priority date claimed—

(i) in any specification filed in pursuance of an application for a patent made in India on or after the 1st day of January, 1912; or

(ii) in India or elsewhere, in any other document, not being a document of the class described in subsection (2) or sub-section (3) of Section 29;

(c) that the invention so far as claimed in any claim of the complete specification is claimed in a claim of a complete specification published on or after the priority date of the applicant's claim and filed in pursuance of an application for a patent in India, being a claim of which the priority date is earlier than that of the applicant's claim;

(d) that the invention so far as claimed in any claim of the complete specification was used in India before the priority date of that claim.

Explanation—For the purposes of this clause, an invention relating to a process for which a patent is claimed shall be deemed to have been used in India before the priority date of the claim if a product made by that process had already been imported into India before that date;

(e) that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant's claim;

(f) that the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act;

(g) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed;

(h) that the applicant has failed to disclose to the Controller the information required by section 8 or has furnished the information which in any material particular was false to his knowledge;

(i) that in the case of a convention application, the application was not made within twelve months from the date of the first application for protection for the invention made in a convention country by the applicant or a person from whom he derives title;

but on no other ground.

(2) Where any such notice of opposition is duly given, the Controller shall notify the applicant and shall give to the applicant and the opponent an opportunity to be heard before deciding the case.

(3) The grant of a patent shall not be refused on the ground stated in clause (c) of sub-section (1) if no patent has been granted in pursuance of the application mentioned in that clause; and for the purpose of any inquiry under clause (d) or clause (e) of that sub-section, no account shall be taken of any secret use.

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OPPOSITION TO GRANT OF PATENT :

This clause enumerates various grounds of opposition to the grant of a patent and has been re-drafted with certain modifications on the lines of Section 14 of the U.K. Act.

We would like to point out that the explanation to subclause (d) of this clause is, in our opinion, most unusual and unfair.

The explanation to sub-clause (d) of this clause provides that if a product, made by a process claimed in a patent application, had already been imported into India before the priority date, such user would constitute a ground for opposition to the grant.

Whereas in principle the industry would have no objection to the prior user of an invention in India by importation as constituting a ground of opposition, we would like to submit that, where a patented product is imported into India before the priority date for the purposes of reasonable trial or experiment, such as clinical trials, exhibition and research purposes, such importation should not amount to prior user as contemplated in the explanation to sub-clause (d) of this clause. Such a provision could deprive the country from deriving advantage from valuable discoveries in the field of drugs.

We, therefore, submit that the following words should be added after the explanation :

"Provided that for the purposes of this sub-clause no account shall be taken of any use of the invention by way of importation before the priority date of the claim if such use is made by the applicant for the patent or on his behalf for the purposes of reasonable trial or experiment only."

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47. (1) Subject to the other provisions contained in this Act, a patent granted, whether before or after the commencement of this Act, shall confer upon the patentee----

(a) where the patent is for an article or substance, the exclusive right by himself, his agents or licensees to make, use, exercise, sell or distribute such article or substance in India;

(b) where a patent is for a process of manufacturing an article or substance, the exclusive right by himself, his agents or licensees to use or exercise the process in India and of using or selling in India articles or substances made by such process and of authorising others so to do.

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(2) The rights conferred on the patentee by this section shall be exercisable only subject to the provisions of any other law for the time being in force.

EFFECT OF GRANT OF A PATENT :

Product-by-Process Protection for Inventions Relating to Food and Medicine.

This clause provides that where a patent is for a process, the patentee has the exclusive right to use or exercise the process in India and of using or selling in India articles or substances made by such process. This means that products made abroad, according to the process patented in India must not be imported, into India. This kind of protection is known as "product-by-process" protection. In other fields, however, the protection granted under a patent extends automatically to the products per se if claimed, irrespective of the method or process by which the substance is produced.

As we have stated under clause 5, according to the present law in India there is nothing which specifically excludes product protection per se. We would like to offer the same comments and make the same recommendations in respect of this clause as appear in clause 5.

However, we would emphasise that if product protection per se could not be accepted at the present time, the grant of product-by-process protection as proposed is necessary indeed because on the basis of process claims alone the patentee could not prevent importation into India of the new compounds developed and patented by him, if these compounds are manufactured according to the process patented in India by manufacturers in countries which do not grant patent protection. The patent could only be enforced against manufacturers in India, but not against foreign manufacturers.

48. Notwithstanding anything contained in this Act,----

(a) the importation by or on behalf of the Government of any patented machine, apparatus or other article for the purpose merely of its own use, or

(b) the importation by or on behalf of the Government of any patented medicine or drug for the purpose merely of its own use or for distribution in any dispensary, hospital, or other medical institution maintained by or on behalf of the Government or any other dispensary, hospital or other medical institution which may be specified by the Central Government in this behalf by notification in the Official Gazette, or

(c) the making of a patented machine, apparatus or other article or the use of a patented process or the making of an article by the use of the patented process by or on behalf of the Government for the purpose merely of its own use or by persons on its behalf who may be specially authorised for the purpose, or

(d) the making or use of a patented machine or apparatus or other article or the use of a patented process or the use of an article made by the use of the patented process, machine or apparatus for the purpose merely of experiment or research, including the imparting of instructions to pupils,

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shall not be deemed to constitute an infringement of the rights conferred on the patentee by this Act.

PATENT RIGHTS NOT INFRINGED IN CERTAIN CASES :

Effect of the Clause

This clause grants unlimited powers to the Government and allows the Government's incursion into the patentee's market to an unjustified extent. Its effect is to place the pharmaceutical industry in a very vulnerable position. In view of the increasing improvement in the medical health services a large portion of the entire output of the ethical part of the pharmaceutical industry is consumed by the Government and the other Agencies covered by this clause, and this percentage is even higher in respect of drugs for treatment of tuberculosis, leprosy, filaria, etc. used for implementing schemes of the Ministry of Health. Therefore, the loss of patent protection over such a wide field is an objectionable and dangerous invasion of the "Rule of Law" in placing the Government in a privileged position not bound by Patent Law.

This clause is a repudiation of the fundamental concept of a patent and militates against the basic objectives behind the grant of a patent as set out in Clause 83. It is most damaging to the general public policy which is intended to encourage inventions and the development of indigenous industry. It is particularly injurious in that it encourages import of "pirated" goods in circumstances of grossly unfair competition with home industry. As recent examination in the United Kingdom has clearly demonstrated, it opens the door to importation of life-saving drugs of doubtful quality and potency.

Those who are authorised to import under this clause will continue to make big profits, even if they are offering their finished products at a price lower than that of the inventor because, by copying the invention and by making use of all the scientific and promotional work of the inventor, they do not incur research and development costs of their own and they do not take any risks. Only products well established on the Indian Market by the activities of the inventor and promising a good return will be offered by them.

It is submitted that this provision not only unduly cuts into the rights of the patentee but also obliterates one of the purposes of patents and the licensing provisions, viz. to encourage home industry. It is certain that indiscriminate imports of drugs and medicines will in many cases completely dislocate the indigenous industry.

If the object of importation is to ensure a lower price to the consumer for the product concerned, it is submitted that the Government already possess ample powers under Section 18 G of the Industries (Development & Regulation) Act, which empowers the Government "so far as it appears to it to be necessary or expedient for securing the equitable distribution and availability at fair prices of any article or class of articles" to provide by Notified Order for the control of the prices at which any such article or class thereof may be bought or sold.

Patents are a species of intangible property. If any other form of property were to be used or acquired by Government, without payment of reasonable compensation and without due process of law, such use or acquisition would, it is submitted, offend the fundamental rights which have always been jealously safe-guarded in this democracy. In effect, this provision if exercised is tantamount to taking of property under power of eminent domain without due process of law (that is, notice and hearing), without provision for an appeal to a judicial tribunal and without just compensation.

Position in other Countries

The relative provisions of this clause do not find a parallel in the patent laws of any country of the world.

Suggested Deletion

No useful reform of this clause seems possible and it is submitted that this clause (excluding sub-clause (d)) should be deleted, particularly as there are adequate provisions in the Bill for use of an invention by the Government for certain specified purposes, e.g. vide clause 100.

53. (1) Subject to the provisions of this Act, the term of every patent granted after the commencement of this Act shall—

(a) in respect of an invention claiming the method or process of manufacture of a substance, where the substance is intended for use, or is capable of being used, as food or as a medicine or drug, be ten years from the date of the patent; and

(b) in respect of any other invention, be fourteen years from the date of the patent.

(2) Notwithstanding anything contained in the Patents and Designs Act, 1911, or in the patent granted thereunder, the term of every patent granted before the commencement of this Act in respect of an invention claiming a substance or the method or process of manufacture in respect thereof, where the substance is intended for use, or is capable of being used, as food or as medicine or drug shall be ten years from the date of the patent :

Provided that where at the commencement of this Act any such patent is in force by reason of an extension granted under the Act aforesaid, the patent shall cease to have effect on the expiration of the period of such extension.

(3) A patent shall cease to have effect notwithstanding anything therein or in this Act on the expiration of the period prescribed for the payment of any renewal fee, if that fee is not paid within the prescribed period or within that period as extended under this section.

(4) The period prescribed for the payment of any renewal fee shall be extended to such period, not being more than three months longer than the prescribed period, as may be specified in a request made to the Controller if the request is made and the renewal fee and the prescribed additional fee paid before the expiration of the period so specified.

TERM OF A PATENT :

This clause provides that for inventions claiming a process for the manufacture of food, medicine or drug, (including all chemical substances used as intermediates in the manufacture of medicine or drug) the term of a patent shall be 10 years and in respect of any other class of inventions the term shall be 14 years from the date of the filing of the complete specification. In respect of patents at present in force for inventions relating to food, medicine or drug the term shall be 10 years from the date of the patent. Further, if at the commencement of this Act the term of any patent has been extended under the old Act, such patent shall cease to have effect on the expiry of such extended period.

Existing Law

The present Act provides that the term of all patents shall be 16 years. The present law also contains provisions which enable the patentee to apply for extension of the term of a patent by a further term of 5 years and in exceptional cases to even 10 years if the Government is satisfied that the patent has not been sufficiently remunerative. The proposed legislation again makes a distinction between different classes of inventions in respect of the term of a patent and does not provide for extension of its term.

Comments

The proposal to reduce the term of a patent from 16 years to 10 years is unrealistic, particularly in the case of patents relating to drug and medicine, for it fails to take into account the fact that, though the term of a patent is at present 16 years from the date of the application, the holder of a patent cannot drive benefit from the invention during a substantial portion of this term.

Time-Lag

It is well recognised that, in India, a majority of the pharmaceutical products presently marketed have been discovered in other countries. If a new product has been synthesised and preliminary testing has shown that it has a desirable type of activity, applications are usually made in countries which grant patent protection (including India) for the grant of a patent. Between the date of the application in India for the grant of a patent and the introduction of the product in the Indian Market there is a very considerable time-lag because

There can, therefore, be a time-lag of between six to eight years, (in some cases even more) between the date of the application in India for the grant of a patent and the availability of the product in the Indian market. Statistical data in support of this statement will be furnished at the time of hearings before the Joint Committee.

If, therefore, the term of a patent is reduced from 16 to 10 years, by the time a drug can be made available, the term would be due to expire and the holder of the patent will not be able to receive any reasonable return for the expenses which have been incurred on research, tests, clinical trials, and commercial development.

There is no technical field where the time necessary for introducing a new invention is as long as in the pharmaceutical field. It would, therefore, be logical that in this risky and difficult domain the duration of a patent should be even longer than in any other field.

Adverse Effects

It is submitted that, if the term of a patent is reduced to 10 years, it would, in effect, be as good as the abrogation of patents in the field of drugs and medicines. Patent protection would end as soon as by the activity of the inventor, the new drug has taken its place amongst the assortment of remedies in the field of medicines. Such a step is likely to have a profound adverse effect on :—

- (a) investment climate;
- (b) development and expansion of indigenous industry;
- (c) research development and promotional programmes;

(d) Supply of chemical, technical and medical knowhow for the manufacture of new drugs; and

(e) export to foreign countries.

Position in other Countries

Further reduction of the term of a patent to 10 years will surely put India out of step with the general trend of patent legislation in other countries. The Patent Law adopted as the uniform law for the African and Malagasy Office of Industrial Property, created by 12 African States, following upon the French Patent Law provides for a term of 20 years

from the date of filing. Likewise, the "Model Patent Law for Developing Countries" prepared by the Committee of Experts appointed by BIRPI (United International Bureaux for the Protection of Intellectual Property at Geneva), comprising 69 countries (including India) and adopted by representatives of the member countries, provides for a term of 20 years from the date of filing.

The Committee of Experts who drafted the Model Law observe as follows :----

"The proposed basis of calculating expiration—20 years is longer than in most countries. Although the same basis exists in several laws, the average is perhaps some two years shorter. A relatively longer term of protection, however, seems to be justified in the case of developing countries. In fact, in the case of a developing country, the owner of the patent will generally need some time for studying the possibilities of working the patented invention in the country and for making the preparations for its working. If, after these studies and preparations, the remaining term of protection of the patent would appear to be too short for lucrative exploitation, this circumstance might substantially diminish the attractiveness which a patent should have for industrial investments in the country.

However, any country may, if it so wishes, shorten the duration and adopt, for example, 16 or 18 years only. This is indicated in the Alternatives.

A problem of a different, although related, kind arises in the case of countries which adopt a system with preliminary examination as to the substance of the patent applications (Alternative B under Section 18). Such examination might take quite some time. Practice shows that it usually takes several years: two, three or even more. In view of the fact that protection only starts upon grant, i.e., once the examination is completed, the duration of the examination might shorten too much the 20 years calculated from filing. Therefore, these countries may wish to adopt a system in which the calculation of the term is based on the date of grant (rather than the date of application), or they may wish to complete the provision appearing in this Section by a provision to the effect that, in any case, a patent will be valid for at least 10 years after grant.

It is, however, to be noted that too great deviations from the generally accepted standards would not be to the advantage of any country, because it is in the general interest that the rules concerning duration be fairly uniform throughout the world. If they are, the protection of a given invention will end approximately at the same time in all countries. This would eliminate the inconveniences which might be caused to industry and trade by the fact that an invention, already free in some countries, is still protected—perhaps for a considerable number of years—in others."

It may be noted that there is hardly any country in the world which provides for a term of 10 years in respect of patents for drugs and medicines without making adequate provision for the extension of the term. It is also significant to note that Justice Ayyangar (whose recommendations have been mainly adopted in the Bill) vide page 186 recommended that the term of every patent shall be 16 years from the date of the patent. The Report did not make any distinction in the term of a patent between different classes of invention. A list setting out the term of patents granted in various countries of the world appears in Appendix "B" hereto.

Suggested Amendments

If it should not be possible to adopt the term of a patent which is usual in most countries, it is submitted that the term of a patent should be 14 years irrespective of the class of invention. The barest minimum period which may be expected to give reasonable reward to an inventor in the case of drugs and medicines is 10 years **from the date of sealing** or 12 years from the date of filing of the complete specification. It is also submitted that the existing law, as to extension of the term of a patent by a further term of at least 5 years where Government is satisfied that a patent has not been sufficiently remunerative, should be continued.

Further, clause 53 should not be made retrospective in operation, as it will adversely affect the existing rights of patentees which are already crystallised. Sub-clause (2) of clause 53 should, therefore, be deleted.

64. (1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, on the petition of any person interested or of the Central Government, be revoked by the High Court on any of the following grounds, that is to say—

(a) that the invention, so far as claimed in any claim of the complete specification, was claimed in a valid claim of earlier priority date contained in the complete specification of another patent granted in India;

(b) that the patent was granted on the application of a person not entitled under the provisions of this Act to apply therefor :

Provided that a patent in force at the commencement of this Act shall not be revoked on the ground that the applicant was the communicatee or the importer of the invention in India and therefore not entitled to make an application for the grant of a patent under this Act;

(c) that the patent was obtained wrongfully in contravention of the rights of the petitioner or any person under or through whom he claims;

(d) that the subject of any claim of the complete specification is not an invention within the meaning of this Act;

(e) that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was known or used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in section 13;

(f) that the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was known or used in India or what was published in India or elsewhere before the priority date of the claim;

(g) that the invention, so far as claimed in any claim of the complete specification, is not useful;

(h) that the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed, that is to say, that the description of the method or the instructions for the working of the invention as contained in the complete specification are not by themselves sufficient to enable a person in India possessing average skill in, and average knowledge of the art to which the invention relates, to work the invention, or that it does not disclose the best method of performing it which was known to the applicant for the patent and for which he was entitled to claim protection;

(i) that the scope of any claim of the complete specification is not sufficiently and clearly defined or that any claim of the complete specification is not fairly based on the matter disclosed in the specification;

(j) that the patent was obtained on a false suggestion or representation;

(k) that the subject of any claim of the complete specification is not patentable under this Act;

(I) that the invention so far as claimed in any claim of the complete specification was secretly used in India, otherwise than as mentioned in sub-section (2), before the priority date of the claim;

(m) that the applicant for the patent has failed to disclose to the Controller the information required by section 8 or has furnished information which in material particulars was false to his knowledge;

(n) that the applicant contravened any direction for secrecy passed under section 35 or made an application for the grant of a patent outside India in contravention of section 39;

(o) that leave to amend the complete specification under section 57 or section 58 was obtained by fraud.

(2) For the purposes of clauses (e) and (f) of subsection (1),---

(a) no account shall be taken of secret use; and

(b) where the patent is for a process or for a product as made by a process described or claimed,

the importation into India, of the product made abroad by that process shall constitute knowledge or use in India of the invention on the date of the importation.

(3) For the purposes of clause (I) of sub-section (1), no account shall be taken of any use of the invention—

(a) for the purpose of reasonable trial or experiment only; or

(b) by the Government or by any person authorised by the Government or by a Government undertaking, in consequence of the applicant for the patent or any person from whom he derives title having communicated or disclosed the invention directly or indirectly to the Government or person authorised as aforesaid or to the Government undertaking; or

(c) by any other person, in consequence of the applicant for the patent or any person from whom he derives title having communicated or disclosed the invention, and without the consent or acquiescence of the applicant or of any person from whom he derives title.

(4) Without prejudice to the provisions contained in sub-section (1), a patent may be revoked by the High Court on the petition of the Central Government, if the High Court is satisfied that the patentee has without reasonable cause failed to comply with the request of the Central Government to make, use, or exercise the patented invention for the purposes of Government within the meaning of section 99 upon reasonable terms.

(5) A notice of any petition for revocation of a patent under this section shall be served on all persons appearing from the register to be proprietors of that patent or to have shares or interests therein and it shall not be necessary to serve a notice on any other person.

REVOCATION OF PATENTS:

Grounds of Revocation

Clause 64 sets out several grounds on which a patent can be revoked. Sub-clause (1)(h) provides that if the description of the method or the instructions for the working of the invention as contained in the complete specification are not by themselves sufficient to enable a person "in India" possessing "average" skill in, and "average" knowledge of, an art to which the invention relates, to "work" the invention, the patent can be revoked.

Underlying Principle

The principle that the complete specification in respect of a patent should be addressed to a person skilled in the art to which the invention relates is conceded. This principle has been established by courts in U.K. as well as in India.

However, the sub-clause in question goes beyond this wellestablished principle and provides that the method or instructions for working the invention (as opposed to the method or instructions for carrying out the invention) as contained in the complete specification should be sufficient to enable a person in India possessing average skill in, and average knowledge of, the art to which the invention relates, to work the invention. This sub-clause has been adopted in pursuance of the recommendations made in Justice Ayyangar's Report (vide pages 207-208). Justice Ayyangar has observed that the said sub-clause merely summarises the effect of the decisions in the U.K. as regards the sufficiency of the instructions which a complete specification ought to contain. Justice Ayyangar observes that the decisions on sufficiency of description relate the required quantum of instructions to the state of the art in the country to whose technicians the specification is addressed. In other words, the patent specifications would be required to be worded differently in each country according to the state of the art prevailing in each country.

Comments

With all respect to the learned Justice, we submit that these observations seem to be erroneous. To the best of our knowledge, there is no decision on sufficiency of description which relates the required quantum of instruction to the state of the art only in the country to whose technicians the specification is addressed. Apart from certain industries

which are still to some extent based on traditional techniques which may vary in methods and terminology from one country to another, technology based on modern science is universal in character. Therefore, there will be no "Indian Chemistry" or "British Chemistry" but only the "art of Chemistry" which is known throughout the world. In those cases where a technology does vary from one country to another, the Indian Patent Office Examiner will be the best person to determine whether the description given in the specification is adequate for the performance of the invention in India and it is fully within the powers of the Controller to examine the specification in this respect.

Besides, the proposition laid down in this sub-clause is quite contrary to the concept of anticipation of an invention by prior publication which appears in sub-clause (e) of clause 64. According to this sub-clause, a prior publication "anywhere in the world" may anticipate an invention and may prevent the grant of a corresponding patent in India.

We, therefore, submit that the words "in India" should be deleted from clause 64(1)(h).

Clause 64(1)(h) further provides (as per Justice Ayyangar's recommendations) that the complete specification must be addressed to a person in India possessing "average skill" in and an "average knowledge" of the art to which the invention relates, "to work" the invention.

The terminology "working an invention" has acquired a specialised meaning in Patent Law and has relation to the matters dealt with in Chapter XVI of the Bill, namely, the compulsory licensing provisions which relate to the commercial working of the invention in the country in which the patent is in force. In our opinion, there is no need to use an expression which is different from that established in Patent Laws in those countries of the world whose laws are in the English language. We, therefore, submit that the words "working of the invention" and "to work the invention" and "to carry out the invention".

As regards the words "average skill" and "average knowledge", we would like to invite reference to Terrell & Shelleys' commentary on the Law of Patents (Tenth Edition on pages 72-74) which refers to various decisions which have

laid down the proposition of law, namely, that the complete specification should be addressed to a person of competent skill in the art (to which the invention relates) and that the inventor is entitled to assume that the person to whom the specification is addressed is in possession of such knowledge and is skilled in the art to carry out the invention. Lord Parker in Osram Lamp Works Ltd. vs. Pope's Electrical Lamp Co., said that a specification may be considered as addressed at any rate primarily to the persons who would in normal course have to act on the directions given for the performance. These persons may be assumed to possess not only a reasonable amount of common sense but also a competent knowledge of the art or arts which have to be called into play in carrying a patentee's directions into effect.

Generally speaking, the inventor is not required to give directions of a more minute nature than a person of ordinary skill and knowledge of the art might fairly be expected to need. Furthermore, the existence of these words in this sub-clause would put an impossible burden on the draftsman of the specification. In important cases, it would result in an unnecessary enlargement of the description of the invention in the specification and it could also lead to much useless and frivolous litigation by persons who take shelter under a disputable point of law.

We, therefore, submit that the word "average" appearing in this clause should be deleted.

There is no need to fear that the modifications suggested will allow an incomplete disclosure of the process for carrying out an invention, because such incomplete disclosure carries with it far greater risks for the patentee, in that his own patent becomes liable to be declared invalid on the grounds of insufficiency of description.

Clause 64 (1)(m)

This clause, read with clauses 8 and 25 (h) enables a patent to be revoked on failure of the applicant to disclose the requisite information or if the applicant has furnished information which is false. It is suggestive that the penalty of revocation is too severe in cases of unintentional omissions and mistakes and that provision should be made accordingly to mitigate the hardship.

Clause 64 (2)(b)

Our comments on this sub-clause are the same as those under clause 25 above. This sub-clause should be amended as suggested in our comments under clause 25 (see pages 25 to 27).

66. Where the Central Government is of opinion that a patent or the mode in which it is exercised is mischievous to the State or generally prejudiced to the public, it may, after giving the patentee an opportunity to be heard, make a declaration to that effect in the Official Gazette and thereupon the patent shall be deemed to be revoked.

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REVOCATION OF PATENT IN PUBLIC INTEREST :

This clause is likely to create considerable complications as to interpretation because no indication is given as to what act or omission is deemed to be mischievous to the State or generally prejudicial to the public.

We, therefore, submit that this clause should be modified in order to define exactly the Government's powers to revoke a patent and to specify the circumstances in which this power shall be exercised.

We further submit that, in any event, the patentee should have a right to have recourse to a judicial tribunal by way of appeal against the decision of the Central Government to revoke a patent in pursuance of this clause.

87. (1) Notwithstanding anything contained in this Act,-

(a) every patent in force at the commencement of this Act in respect of inventions relating to-

(i) substances used or capable of being used as food or as medicine or drug;

(ii) the methods or processes for the manufacture or production of any such substance as is referred to in sub-clause (i);

(iii) the methods or processes for the manufacture or production of chemical substances (including alloys, optical glass, semi-conductors and intermetallic compounds); and

(b) every patent granted after the commencement of this Act in respect of any such invention as is referred to in sub-clauses (ii) and (iii) of clause (a);

shall be deemed to be endorsed with the words "Licences of right", in the case of inventions referred to in clause (a), from the commencement of this Act, and, in the case of inventions referred to in clause (b), from the date of sealing of the patent.

(2) In respect of every patent which is deemed to be endorsed with the words "Licences of right" under this section, the provisions of section 88 shall apply.

Clause 88

88. (1) Where a patent has been endorsed with the words "Licences of right", any person who is interested in working the patented invention in India may require the patentee to grant him a licence for the purpose on such terms as may be mutually agreed upon.

(2) If the parties are unable to agree on the terms of the licence, either of them may apply in the prescribed manner to the Controller to settle the terms thereof.

(3) The Controller shall, after giving notice to the parties and hearing them and after making such enquiry as he may deem fit, decide the terms on which the licence shall be granted by the patentee.

(4) The Controller may at any time before the terms of the licence are mutually agreed upon or decided by the Controller, on application made to him in this behalf by any person who has made any such requisition as is referred to in sub-section (1), permit him to work the patented invention on such terms as the Controller may, pending agreement between the parties or decision by the Controller, think fit to impose.

(5) In respect of every patent deemed to be endorsed with the words "Licences of right" under sub-clause (i) or sub-clause (ii) of clause (a) of sub-section (1) of section 87, whether the patent was granted before or after the commencement of this Act, the royalty and other remuneration reserved to the patentee under a licence granted to any person after such commencement shall in no case exceed four per cent. of the net ex-factory sale price in bulk of the patented article (exclusive of taxes levied under any law for the time being in force and any commissions payable) determined in such manner as may be prescribed.

(6) Save as otherwise provided in sub-section (5), the provisions of sub-sections (1), (2), (4), (5) and (6) of section 93 (regarding the powers of the Controller) and of sections 94 and 95 shall apply to licences granted under this section as they apply to licences granted under section 84.

Clauses 87 and 88

LICENCES OF RIGHT-CEILING ON ROYALTY :

I. Endorsement, "Licences of Right" and Grant of such Licences.

Clause 87 provides that every patent in force, as well as every patent granted after the commencement of the Act relating to articles of food, medicine or drug (including all chemical substances used as intermediates in the manufacture of medicine or drug) and the processes for their manufacture **shall be deemed to be endorsed** with the words "Licences of Right".

Clause 88 provides that where an endorsement "licences of right" has been made any person who is interested in working a patented invention in India shall be entitled to do so on application to the Controller. This provision proceeds on the footing that the Controller shall grant permission to any person to work the invention in question. The Order of the Controller fixing the terms on which the licence shall be granted is not governed by the provisions of clause 92 pertaining to the procedure for dealing with applications for compulsory licences. The applications made under this clause can be summarily disposed of by the Controller. No appeal has been provided for.

Read in conjunction with clause 89(1), any person interested can apply after the expiry of 2 years from such endorsement for revocation of the patent if the reasonable requirements of the public have not been satisfied.

This clause (88) compels the Controller to grant a licence without taking into consideration the requirements to be fulfilled by the applicant for a compulsory licence under clause 84 as specified in clause 85. The implementation of clause 88 is likely to create an absurd situation whereby a limitless number of applicants will be entitled to a licence of right without the Controller taking into consideration the financial and technical ability of the applicant and also whether the applicant would be granted permission to work the invention under the Industries (Development and Regulation) Act.

II. Exposition of Present Law

These provisions are entirely new and do not appear in the Indian Patents & Designs Act 1911. According to

Section 23 A of the present Act, the Central Government can at any time after the expiration of 3 years from the date of sealing of a patent apply to the Controller for endorsement of a patent with the words "licences of right" on the ground that by the refusal of the patentee to grant a licence on reasonable terms the establishment or development of commercial or industrial activities in India is unfairly prejudiced or the development of an industry, the control of which is declared to be expedient in the public interest, is being prevented or hindered. Where the Controller makes an endorsement upon a patent "licence of right" any person is entitled as of right to a licence under the patent, upon such terms as may in default of agreement be settled by the Controller. (vide Section 23 B) The powers of the Controller upon an application under Section 23 A can only be exercised with a view to ensuring that inventions can be worked on a commercial scale in India without undue delay and to the fullest extent reasonably practicable; that the inventor shall receive reasonable remuneration having regard to the nature of the invention and that the interests of any person working or developing an invention in India under a patent are not unfairly prejudiced. In so far as compulsory licences for inventions relating to food and medicine are concerned, they are governed by the provisions of Section 23 CC of the present Act, according to which the Controller is obliged on application made to him by any interested person to order the grant to the applicant of a licence under a patent relating to food and medicine on such terms as he thinks fit, unless it appears to him that there are good reasons for refusing the application.

III. Discussion of Effect of Endorsement "Licences of Right" Clauses 87 and 88 are entirely new and discriminate between different classes of inventions to an unjustifiable extent. They are also in contrast with the recommendations made by Justice Ayyangar, vide pages 219 and 232—234 of his Report. At page 219 (paragraph 608) of his Report, Justice Ayyangar observed :—

"Persons interested" in working the invention might not be expected to desire that others besides themselves should also have the right to obtain licences under the patent and so it appears to me to be sufficient and desirable that the right to apply for endorsements should be restricted as it has hitherto been".

Justice Ayyangar has further observed in his Report (vide page 233) that

"as this class of inventions touch public health, it is very necessary that there should be a guarantee that persons who are permitted to work the inventions are those who are qualified to work them honestly and efficiently. I consider that for this purpose, the screening of the persons who might be permitted to work these inventions should be done by the Central Government instead of by the Controller, as the former would be in a position to discharge these functions more satisfactorily having regard to the means of information available to them".

We believe that the opinion of Justice Ayyangar is correct. A company contemplating the manufacture and/or the sale of a patented product under a licence has to spend money to inform the customers of its intentions and to describe the product as well as to convince the customers of its advantages. Often the properties of a compound must be demonstrated to the customers. The said company would only spend the money and do all the work in connection with the product if an adequate profit could be expected and if it could reach a sufficiently great proportion of the sales volume for the product and maintain it for a longer period of time. If the said company has to consider that another firm or a great number of others could also get the right to sell the patented product under a licence later on and that they would make use of its efforts to prepare the market for the product, it would come to the conclusion that it would not be worthwhile to take a licence at all. Only if there would be one licencee or if the number of licencees would be very much restricted, would there be an incentive to demand a licence. The patentee himself would hesitate to work and to promote his invention if he has to expect that others will try to reap the fruits of his work although he would be in the best position to introduce the invention to India because he developed it and introduced it in his home country and in many other countries where the grant of licence is more restricted and is subject to severe conditions.

According to the notes on clauses, the changes in the existing law as contemplated under clauses 87 and 88 are "intended to secure the proper development of the food, drug and chemical industries in the country". We respectfully submit that these purposes will under no circumstances be achieved if these clauses are passed in their present form.

According to the Industry, these provisions will hamper industrial progress and restrict research and inventive Innovation in the country in the field of food, drugs and chemicals. From the Industry's point of view, a patent is not aimed against the Government's interests. It is aimed at safeguarding the interests of the inventor against the unjustified encroachment on his rights by third persons. The prime consideration to the general public in the grant of a patent is the disclosure of new knowledge and experiences gained by the inventor. The consideration to the inventor is a period of exclusivity after which the invention passes into the public domain. In the case of licences of right, however, the advantage accrues neither to the Government and the general public nor to the inventor but to third parties, who will not market pharmaceuticals more cheaply but will be enabled to make unjustified profits; unjustified because such third parties have contributed nothing towards the costs of research and industrial development. Even if the licencee were to sell at a lower price, his profits would still be greater than that of the inventor because he would not have any risks or incur expenditure on research and development.

It has often been said that a patent is a sort of temporary monopoly. But patents have always been considered to be a necessary institution. A patent covers an invention the subject of which was not available to anybody before the invention was made. The inventor would not have invented the product if he did not have an incentive in the form of a patent. By granting a patent the public is not deprived of anything it had before but it receives something new in addition. Once the short period of patent protection ends, the subject matter of the invention becomes common property.

Foreseeable Disadvantages

The provisions of Clauses 87 and 88 will have the following disadvantages :---

- (i) They are an unacceptable violation of property rights and strike directly and crucially at the industry's capacity and incentive for the discovery of new and improved medicines.
- (ii) They will reduce the value of patents as an incentive to invention so severely that inventive activity would be seriously retarded.
- (iii) They would adversely affect firms with expensive research laboratories because frequent experimental failures and the risks of obsolescence can only be

supported if an invention promising commercial success is adequately protected. The success of one "winner" found perhaps after decades of research has to pay the costs of many "losers".

- (iv) Each firm knowing that it has legal access to new products and markets developed by others would let others bear the risks of research and discovery. When all leave these risks to others, research and new discoveries would cease and, in that event, no new products would be introduced, promoted and brought to the attention of the medical profession.
- (v) If firms would continue research work at all, they would naturally tend to by-pass the patent system altogether and resort to secrecy, especially in the case of extremely important discoveries. Such secrecy would dry up the flow of scientific knowledge, which the patent system encourages.
- (vi) The granting of a licence of right to any person could result in an increase rather than a decrease in the cost of food and medicine to the public because the licencee will either have to spend money for developing his own know-how or for acquiring it and further because each licencee can produce only on a small commercial scale.
- (vii) The prosecution of research in India would be discouraged as the fruits of research by others would be available as of right upon payment of a royalty which is inadequate. It would rob the country of the benefits which have in the past been substantially attributable to the patent laws. It is further submitted that the other provisions of the Bill contain sufficient safeguards to prevent **any** abuses of patent rights as appear to be envisaged **by** Government. If licences are issued indiscriminately, and as a matter of right to several applicants, no one will be willing to invest risk capital in working the invention.

We believe that the proposals would not alter, in practice, in any substantial way the degree of control over drugs and drug prices now exercised through the media of other legislative enactments, which secure the controlling or checking of the alleged rises in drug prices. Whatever results might follow would be merely palliative and not truly remedial.

IV. Ceiling on Royalty

Sub-clause 5 of Clause 88 provides that, in respect of patents in the field of food, medicine and drug, the royalty and "other remuneration" payable under a licence shall not exceed 4% of the net ex-factory sales price in bulk of the patented article exclusive of taxes and commissions determined in the prescribed manner. It may be noted that the ceiling of 4% also applies when the terms of the licence are mutually agreed between the parties without the intervention of the Controller. The decision of the Controller under this clause is not appealable at all.

Present Law

According to the provisions of Section 23 CC(2) of the present Act, the royalty is to be determined by the Controller who is directed to endeavour to secure that food and medicines shall be available to the public at the lowest price "consistent with the patentees' deriving reasonable advantage from their patent rights".

Comments

This new provision is again discriminatory in its very nature. Justice Ayyangar in his said Report, after having considered the patent systems of various other countries, came to the conclusion that it is not feasible to arrive at a uniform rate of royalty which would be reasonable for licences in respect of each and every invention and that it is not desirable to fix statutorily the maximum rate of allowable royalty (See page 72 of the Report).

The pharmaceutical industry is characterised by a high level of fixed expenses not only on plant and equipment, but also on control laboratories, medical services, selling and general administration and research, all of which must be incurred almost irrespective of a firm's manufacturing and sales volume, if its effectiveness in the industry is to be maintained. To recompense the patentee for the disadvantages resulting from the grant of a compulsory licence, royalty payable under the licence should, in normal circumstances, give the patentee "a reasonable advantage from his patent rights" (See wording of existing Section 23 CC(2)).

The pharmaceutical industry is research-oriented, highly competitive and requires very heavy investment in equipment, men and materials. In spite of the mounting costs of

production, the pharmaceutical industry continues to hold the price line at the level of April 1963. It is the promise of **reasonable** gain, afforded by the present patent protection, which stimulates the vast research programmes which must be conducted in order to discover and perfect new drugs. The proposed royalty of 4%, in return for the use of valuable patent rights on which vast sums on research have been expended, will not enable the patentee to recover even a part of his outlay.

Royalty and Cost of Drugs

It is argued that the cost of drugs are high because the royalty payments are exorbitant. It is submitted that, even if royalty payments were eliminated, overall prices of drugs would not be reduced significantly. In India, the grant of a licence under a patent is usually coupled with technical collaboration with the inventor. The incidence, if any, of royalty payments, under such collaborations, is negligible, since these are strictly regulated by the Government of India. It is said in some circles that royalties are paid only in one direction, viz. from India to Western countries. This is a position which is natural to every developing country, but whilst this may be the position today, it is unlikely to continue for long. Already there is evidence to show that the new antibiotics Hamycin and Dermostatin, developed by the research staff of Hindustan Antibiotics Limited (a Government undertaking) have created interest abroad, and patent coverage has been sought at least in the U.K. and royalty fees have been offered under such patent rights. Such examples will multiply and, before long, there will be a two-way traffic with Indian inventions which will develop. India now stands on the threshold of advancement; Indian industry has now reached a stage of development when its own inventions and processes need to be safeguarded.

Position in Other Countries

In this connection, it is significant to note that in all other countries which have patent laws providing for compulsory licences in respect of drugs and medicines, the royalty payable has to be fixed having regard to various factors, including the nature of the invention and the expenditure incurred by the patentee in making the invention, and developing it. In Italy, in the patent law which will shortly be introduced, the provision for payment of royalty lays down that it shall be fair in relation to the importance of

the invention; its expected economic return; the duration of the licence and every other factor relevant to its use. The provisions of patent laws of other countries which grant compulsory licences for patents relating to drugs and medicines are similar. The Model Law for Developing Countries (prepared by BIRPI) which was accepted in principle by India provides under Section 40 that "A compulsory licence shall only be granted subject to payment of adequate royalties commensurate with the extent to which the invention is worked."

The framers of the said Model Law comment as follows :----

"A compulsory licence naturally involves the obligation to pay royalties. Otherwise it would amount to confiscation.

As it is practically impossible to predict, at the time the compulsory licence is granted, of what economic value the licence will be to the licencee, a lumpsum compensation would be haphazard and arbitrary. This is why the provision requires royalties commensurate with the extent to which the invention is worked. Thus, for example, the compensation may be expressed in terms of a given percentage of the sales made.

Naturally, the parties may agree on the compensation. In this case the competent authority will be relieved of the duty of fixing it."

If the proposed fixation of a ceiling on royalties becomes law, India will be the only country in the world having such a provision. A blanket ceiling of 4% gross on royalties is nothing less than an erosion of industrial property rights and will be contrary to the basic concept of the patent system. The rate of royalty should, in our submission, not be statutory but should be flexible in relation to the complexity of manufacture of the drug; the nature of the invention; the expenditure incurred by the patentee in making the invention or in developing it, and must be such as to enable the patentee to recover a substantial part of the expenditure so incurred. We submit that the intention of the Government to secure the proper development of the food, drug and chemical industries in India as set out in the Notes on Clauses will not be fulfilled. Although it will, prima facie, seem to be more profitable for an Indian industrial organisation to copy foreign inventions, in the long run, it is beneficial to the country if a part of its trading profits are utilised to develop its own Indian research under a strong patent system.

We may summarise by saying that, in our opinion, Clauses 87 and 88(5) should not be enacted in their present form, in the existing economic and industrial environment of the country. These clauses wear an air of unreality in that they discriminate against a category of inventor which **prima facie** merits more than average treatment. We submit that these clauses will adversely and widely affect an important and valuable local industry, with the result that inventions in India in the pharmaceutical industry will progressively diminish, and the industry will deteriorate to a level consisting mainly of imitative manufacturers and importers depending on foreign inventions for advances in therapy.

V. Proposals for Licensing of Patents for Food and Medicine

We, therefore, submit that Clauses 87 and 88(5) should be deleted and recommend that, in respect of patents covering inventions relating to food, medicine or drug, the provisions of Clauses 84 and 85 should be made applicable, bearing in mind the provisions of the existing Section 23 CC of the Patents & Designs Act 1911.

The industry is aware of the reasons why applications for compulsory licences under Section 23 CC are very few in number and that such applications have been finally adjudicated upon only after considerable delay, expense and inconvenience to both the applicant as well as the patentee. The following suggestions are, therefore, made by the industry in order to obviate such criticism of the present compulsory licensing procedure.

We recommend that the Controller should be directed to decide applications for compulsory licences relating to inventions in the field of food, medicine or drug, as well as in other fields, within a specified time and that the application of Clause 84 should be modified to that extent.

We further recommend that an appeal against the decision of the Controller as to the grant of a compulsory licence should lie to the Central Government, which should in its turn decide the appeal within a specified time and that an appeal against the decision of the Controller settling the terms of the grant of a compulsory licence, including the payment of royalty, should lie to a judicial tribunal.

89. (1) Where, in respect of a patent, a compulsory licence has been granted or the endorsement "Licences of right" has been made or is deemed to have been made, the Central Government or any person interested may, after the expiration of two years from the date of the order granting the first compulsory licence or, as the case may be, the date of the endorsement, apply to the Controller for an order revoking the patent on the ground that the reasonable requirements of the public with respect to the patented invention have not been satisfied.

(2) Every application under sub-section (1) shall contain such particulars as may be prescribed and the facts upon which the application is based, and, in the case of an application other than by the Central Government, shall also set out the nature of the applicant's interest.

(3) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied, may make an order revoking the patent.

Clause 90

90. For the purposes of Sections 84, 86 and 89, the reasonable requirements of the public shall be deemed not to have been satisfied—

(a) if, by reason of the default of the patentee to manufacture in India to an adequate extent and supply on reasonable terms the patented article or a part of the patented article which is necessary for its efficient working or if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms,—

(i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry of any person or classes of persons trading or manufacturing in India is prejudiced; or

(ii) the demand for the patented article is not being met to an adequate extent or on reasonable terms from manufacture in India; or

(iii) a market for the export of the batented article manufactured in India is not being supplied or developed or such market capable of being created is not being created; or

(iv)- the establishment or development of cornmercial activities in India is prejudiced; or

(b) if, by reason of conditions imposed by the patentee (whether before or after the commencement of this Act) upon the grant of licences under the patent, or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced; or

(c) if the patented invention is not being worked in India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable; or

(d) if the demand for the patented article in India is being met to a substantial extent by importation from abroad by---

(i) the patentee or persons claiming under him; or

(ii) persons directly or indirectly purchasing from him; or

(iii) other persons against whom the patentee is not taking or has not taken proceedings for infringement; or

(e) if the working of the patented invention in India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by the patentee or the other persons referred to in the . preceding clause.

Clauses 89 and 90

REVOCATION FOR NON-WORKING:

Clause 89 is an entirely new provision and does not find a place in the existing Act.

Consequential Amendment

In view of the submissions and recommendations made by us under clauses 87 and 88 above, we submit that the words :

- (a) "or the endorsement 'licences of right' ",
- (b) "or is deemed to have been made",

(c) ''or, as the case may be, the date of the endorsement'' should be deleted from sub-clause (1) of this clause.

When Reasonable Requirement of the Public Deemed not Satisfied

Clause 90 sets out the circumstances under which the reasonable requirements of the public shall be deemed not to have been satisfied. One of such circumstances is "if the patented invention is not being worked in India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable".

Comments

According to Justice Ayyangar the object of incorporating this condition is to avoid grant of a monopoly merely for the importation of a patented product. Further, Justice Ayyangar has recommended that the condition as to capability of commercial working should be removed from the infringer. Consequently, where an invention is not capable of being commercially worked in India for no fault of the patentee, the patent is liable to be revoked.

We submit that the condition will cast an obligation on the patentee which he cannot fulfil and is, therefore, unfair. Adequate safeguards should be provided in this sub-clause for a patentee who, in spite of all bonafide attempts to work the invention, is unable to do so for reasons beyond his control.

Suggested Modification

We submit that the words "for reasons within the patentee's control" be added after the words "if the patented invention is...", in this sub-clause.



Clause 93 (3)

(3) Where on an application made under Section 84 the Controller orders the grant of a licence, he may direct that the licence shall operate---

(a) to deprive the patentee of any right which he may have as patentee to make, use, exercise or vend the invention or to grant licences under the patent;

(b) to revoke all existing licences in respect of the invention.

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Clause 93(3)

POWERS OF THE CONTROLLER :

Effect of the Clause

This sub-clause empowers the Controller, in the absence of any justifiable cause, to deprive the patentee not only of his entire patent rights but also of his right to use his own invention and, furthermore, to revoke all existing licences under a patent.

Comments

It is submitted that this clause goes far beyond any measure reasonably necessary for the safeguard of public interest. While the exclusivity granted to a patentee may well, under circumstances defined by law, be lifted, it would be intolerable to shift exclusivity in such a manner that it would operate against the inventor and/or his successor in law.

Suggested Deletion

We, therefore, submit that this sub-clause should be deleted, and further that, against the powers of the Controller for grant of compulsory licences under clause 93, an appeal should lie to a judicial tribunal.



95. (1) In settling the terms and conditions of a licence under Section 84, the Controller shall endeavour to secure----

(i) that the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors;

(ii) that the patented invention is worked to the fullest extent by the person to whom the licence is granted and with reasonable profit to him;

(iii) that the patented articles are made available to the public at reasonable prices.

(2) No licence granted by the Controller shall authorise the licensee to import the patented article or an article or substance made by a patented process from abroad where such importation would, but for such authorisation, constitute an infringement of the rights of the patentee.

(3) Notwithstanding anything contained in sub-section (2), the Central Government may, if in its opinion it is necessary so to do in the public interest, direct the Controller at any time to authorise any licensee in respect of a patent to import the patented article or an article or substance made by a patented process from abroad (subject to such conditions as it considers necessary to impose relating among other matters to the quantum of import, the sale price of the imported article, and the period of importation), and thereupon the Controller shall give effect to the directions.

TERMS AND CONDITIONS OF COMPULSORY LICENCE :

Clause 95 sets out the considerations to be borne in mind by the Controller in settling the terms of a compulsory licence under clause 84.

Sub-clause (2) of this clause expressly provides that no licence shall be granted by the Controller which would authorise the licensee to import the patented article or a substance made by the patented process from abroad where such importation would, but for such authorisation, constitute an infringement of the rights of the patentee.

Sub-clause (3) of this clause, however, empowers the Central Government to direct the Controller to authorise any licensee to import the patented article or the article made by the patented process from abroad in the public interest on certain terms and conditions. This sub-clause also does not provide for payment of any royalty or compensation to the patentee. This is another attempt to erode industrial property rights to the detriment of the inventor which will hamper research and industrial progress in the country. No appeal has been provided against any action taken in pursuance of this sub-clause.

The provisions of sub-clause (3) are contrary to the general principles applicable to working of patented inventions as set out in clause 83 and amplified by various other clauses in Chapter XVI of the Bill, including sub-clause (2) of clause 95. Our submissions with regard to Government's right to direct the Controller to authorise a licensee to import the patented product or the product made by the patented process have been stated in clause 48 above (pages 30 to 32) which we reiterate and to which we invite attention.

In our opinion, the enactment of sub-clause (3) seems to be unnecessary and superfluous, inasmuch as the Central Government has sufficient authority under Chapter XVII of the Bill to import a patented product or article made by a patented process for the purposes of Government.

Suggested Deletion of sub-clause (3)

It is submitted that this provision not only unduly cuts into the rights of the patentee but also obliterates one of the purposes of patents and the licensing provisions, namely to encourage home industry. Therefore this sub-clause should be deleted.

96. (1) Notwithstanding anything contained in the other provisions of this Chapter, at any time after the sealing of a patent, any person who has the right to work any other patented invention either as patentee or as licensee thereof exclusive or otherwise, may apply to the Controller for the grant of a licence of the first mentioned patent on the ground that he is prevented or hindered without such licence from working the other invention efficiently or to the best advantage possible.

(2) No order under sub-section (1) shall be made unless the Controller is satisfied that the applicant is able and willing to grant, or procure the grant to the patentee and his licensees if they so desire of, a licence in respect of the other invention on reasonable terms.

(3) When the Controller is satisfied that the conditions mentioned in sub-section (1) have been established by the applicant, he may make an order on such terms as he thinks fit granting a licence under the first mentioned patent and a similar order under the other patent if so requested by the proprietor of the first mentioned patent or his licensee.

(4) The provisions of Sections 92 and 110 shall apply to licences granted under this section as they apply to licences granted under Section 84.

(5) The decision of the Controller shall be subject to appeal to the Central Government.



LICENSING OF RELATED PATENTS :

This clause provides that any person who has the right to work any other patented invention may apply to the Controller for a licence under an earlier patent if he cannot work his invention without infringing the earlier patent.

Comments

The idea underlying this clause is sound. It was introduced into the draft European Patent Law and appears in Section 36 of the Model Law for Developing Countries on inventions (B.I.R.P.I.). However, clause 96 gives this right to any person who has **any other patented invention** without any qualification. Under the procedure for examinitation set out in the Bill, as has been customarily followed in all countries modelled on British procedure, the powers of the Controller/Examiner to reject an application on the grounds of lack of patentable subject matter (obviousness) are strictly limited. Therefore, it is possible for anyone to obtain a dependent patent describing and claiming a trivial or frivolous modification of the invention in the earlier patent. As a result, many patents are granted which could be held to be invalid in a court but not by the Controller.

The Clause, as at present written, would allow anyone to obtain such invalid dependent patent and to apply for a compulsory licence.

Suggested Amendment

We submit that the principle laid down in Section 36 of the B.I.R.P.I. Model Law should be introduced into this clause. The following clause should be added after sub-clause (1) of this clause :

"(2) For the purpose of sub-section (1) above the Controller shall not grant a licence unless he is satisfied that such other patented invention serves industrial purposes different from those of the invention forming the subject of the earlier patent, or constitutes noteworthy technical progress in relation to it". Sub-clauses (2), (3) and (4) should be renumbered as (3), (4) and (5) respectively.

Sub-clause (4) should provide that the decision of the Controller should be appealable to a Judicial tribunal.

99. (1) For the purposes of this Chapter, an invention is said to be used for the purposes of Government if it is made, used, exercised or vended for the purposes of the Central Government, a State Government or a Government undertaking or any other undertaking in a class or classes of industries which the Central Government, having regard to the interests of the general public may notify in this behalf in the Official Gazette.

(2) Nothing contained in this Chapter shall apply in the case of any such use of an invention as is deemed not to constitute an infringement of the patentee's rights under Section 48 and under which no royalty or other remuneration is payable to the patentee.

Clause 100

100. (1) Notwithstanding anything contained in this Act, at any time after an application for a patent has been filed at the patent office or a patent has been granted, the Central Government and any person authorised in writing by it, may make, use, exercise or vend the invention for the purposes of Government in accordance with the provisions of this Chapter.

(2) Where an invention has, before the priority date of the relevant claim of the complete specification, been duly recorded in a document, or tested or tried, by or on behalf of the Government or a Government undertaking, otherwise than in consequence of the communication of the invention directly or indirectly by the patentee or by a person from whom he derives title, any use of the invention for the purposes of Government may be made free of any royalty or other remuneration to the patentee.

(3) If and so far as the invention has not been so recorded or tried or tested as aforesaid, any use of the invention made by the Central Government or any person authorized by it under sub-section (1), at any time after the acceptance of the complete specification in respect of the patent or in consequence of any such communication as aforesaid, shall be made upon terms as may be agreed upon either before or after the use, between the Central Government or any person authorised under sub-section (1) and the patentee. or, as may in default of agreement be determined by the High Court on a reference under Section 103.

(4) The authorisation by the Central Government in respect of an invention may be given under this section, either before or after the patent is granted and either before or after the acts in respect of which such authorisation is given or done, and may be given to any person, whether or not he is authorised directly or indirectly by the applicant or the patentee to make, use, exercise or vend the invention.

(5) Where an invention has been made, used, exercised or vended by or with the authority of the Central Government for the purposes of Government under this section, then, unless it appears to the Government that it would be contrary to the public interest so to do, the Government shall notify the patentee as soon as practicable after the use has begun and furnish him with such information as to the extent of the making, use, exercise or vending of the invention as he may, from time to time, reasonably require; and where the use of the invention has been for the purposes of a Government undertaking or an undertaking in a class or classes of industries notified by the Central Government under Section 99, the Central Government may call for such information as may be necessary for this purpose from such undertaking.

(6) The right to make, use, exercise and vend an invention for the purposes of Government under sub-section (1) shall include the right to sell the goods which have been made in exercise of that right, and a purchaser of goods so sold, and a person claiming through him, shall have the power to deal with the goods as if the Central Government or the person authorised under sub-section (1) were the patentee of the invention.

(7) Where in respect of a patent which has been the subject of an authorisation under this section, there is an exclusive licensee as is referred to in sub-section (3) of Section 101, or where such patent has been assigned to the patentee in consideration of royalties or other benefits determined by reference to the use of the invention (including payments by way of minimum royalty), the notice directed to be given under sub-section (5) shall also be given to such exclusive licensee or assignor as the case may be, and the reference to the patentee in sub-section (3) shall be deemed to include a reference to such assignor or exclusive licensee.

Clauses 99 and 100

USE OF INVENTIONS FOR THE PURPOSES OF GOVERNMENT :

Clause 99 defines "use of invention for the purposes of Government". When an invention is used for the purposes of the Central or State Government or a Government undertaking or any undertaking in a class or classes of industries which the Central Government having regard to the interests of the general public may notify in this behalf, such use is deemed to be for the purposes of Government.

Clause 100 gives power to the Central Government to use inventions for the purposes of Government. It also empowers any person authorised in writing by the Central Government to use the invention for the purposes of Government. All that is required for such use is that the invention must be used in conformity with clause 99 above. Such user need not necessarily be made by a Government Department or undertaking in the interests of the general public or for a public purpose.

Existing Law

The existing law on patents contains a provision (Section 21) which authorises Officers or Authorities administering any department of the service of Government, by themselves or by their authorised agents, to make use or exercise inventions in the service of the Government on such terms as may in default of agreement between the patentee and such authorities be decided by the High Court, or an official referee or an arbitrator appointed by the High Court.

We would like to reiterate the submissions made by us under ciause 2(h) above (pages 11 to 13) and to recommend that the definition "Government Undertaking" should be restricted to the extent set out in the said comments. Regarding the use of an invention by a Corporation or a Government company as defined in sub-clause 2(h) (ii) and 2(h) (iii), we submit that a Corporation established by a Central, Provincial or State Act which is owned or controlled by the Government and a Government company as defined in Section 617 of the Companies Act 1956 should stand on the same footing as any other person, firm or company, which is interested in working or using the invention. Indeed, it is well known that such Corporations and Government Undertakings named above carry on business and/or manufacturing activities for profit and it stands to reason that, therefore, such Corporations should not be placed on a better footing or in a more advantageous position than any other person, firm or

company. We, therefore, submit that such Corporations and Government Undertakings should be excluded from the scope of the definition of "Government Undertaking" as appearing in clause 2(h) of the Bill and also from the scope of clause 99. If, however, such Corporations or Government Undertakings desire to make use of an invention, they should be obliged to apply for a compulsory licence under clause 84 of the Bill.

Clause 100 gives the Government unrestricted powers to use patented inventions. Whereas the industry would have no objection to the Central Government exercising its powers under this clause for certain public purposes, such power should be exercised by the Central Government in such a manner that the interests of the industry, and the patentee, are not unfairly prejudiced.

Although Clause 103 enables the patentee to refer any dispute as to the exercise by the Central Government of the powers conferred by clause 100, to the High Court, this clause (100) enables the Central Government to make use of the invention even during the pendency of such a reference.

Suggested Modifications

We submit-

(a) that the use of an invention for the purposes of the Government should be only for the purpose of the Central Government or State Government or a Government Undertaking (as suggested by us) as otherwise the cases in which this clause would apply would become limitless. Therefore, the words "or any other undertaking in a class or classes of industries which the Central Government, having regard to the interests of the general public, may notify in this behalf in the official Gazette" should be deleted from clause 99.

(b) that a Corporation established by a Central, Provincial or State Act, which is owned or controlled by the Government and a Government Company and which carries on business for profit should not be covered by clause 99 and that it should make an application for a compulsory licence, if it desires to work an invention.

(c) that the use of an invention for the purposes of Government should be limited to certain specified purposes; as for defence; or in case of an epidemic, or in an emergency. An exact definition of the term ''defence purposes'' should be drafted.

(d) that in view of our submissions under clause 48, subclause (2) of clause 99 should be deleted.

(e) that the powers of the Central Government under Clause 100 should not be exercised before granting the patentee an opportunity of being heard and that the said clause should be suitably amended, and

(f) that the High Court should be empowered in appropriate cases to pass an order directing the Government or its authorised agents not to make use of the invention pending its decision.

102. (1) The Central Government may, if satisfied that it is necessary that an invention which is the subject of an application for a patent or a patent should be acquired from the applicant or the patentee for a public purpose, publish a notification to that effect in the Official Gazette, and thereupon the invention or patent and all rights in respect of the invention or patent shall, by force of this section, stand transferred to and be vested in the Central Government.

(2) Notice of the acquisition shall be given to the applicant, and, where a patent has been granted, to the patentee and other persons, if any, appearing in the register as having an interest in the patent.

(3) The Central Government shall pay to the applicant, or, as the case may be, the patentee and other persons appearing on the register as having an interest in the patent such compensation as may be agreed upon between the Central Government and the applicant. or the patentee and other persons; or as may in default of agreement, be determined by the High Court on a reference under Section 103 to be just having regard to the expenditure incurred in connection with the invention and, in the case of a patent, the term thereof, the period during which and the manner in which it has already been worked (including the profits made during such period by the patentee or by his licensee whether exclusive or otherwise) and other relevant factors.

ACQUISITION OF INVENTIONS:

This clause gives power to the Central Government to acquire an invention for a public purpose by notifying its intention in that behalf. After such notification is issued, the patent and all rights in respect of the invention shall vest in the Government. This clause provides for a notice of acquisition being given to the applicant for a patent and the patentee. Compensation for such acquisition is to be determined in such manner as may be agreed and in default by a reference to the High Court. This clause also recognises the principle that a patent is a species of intangible property and hence provides for compensation if such property is acquired for public purposes.

Suggested Deletion

We are of the opinion that, in view of the ample means provided for in the Bill, there is no legitimate reason in such complete expropriation of industrial property rights. This clause should, therefore, be deleted. In any case, it is submitted that the acquisition of an invention should also be limited to certain specified public purposes, such as for defence, in case of an epidemic or in an emergency.

103. (1) Any dispute as to the exercise by the Central Government or a person authorised by it of the powers conferred by section 100, or as to terms for the use of an invention for the purposes of Government thereunder or as to the right of any person to receive any part of a payment made in pursuance of sub-section (3) of that section or as to the amount of compensation payable for the acquisition of an invention or a patent under section 102, may be referred to the High Court by either party to the dispute in such manner as may be prescribed by the rules of the High Court.

(2) In any proceedings under this section to which the Central Government is a party, the Central Government may----

(a) if the patentee is a party to the proceedings, petition by way of counter-claim for revocation of the patent on any ground upon which a patent may be revoked under section 64; and

(b) whether a patentee is or is not a party to the proceedings, put in issue the validity of the patent without petitioning for its revocation.

(3) If in such proceedings as aforesaid any question arises whether an invention has been recorded, tested or tried as is mentioned in section 100, and the disclosure of any document regarding the invention, or of any evidence of the test or trial thereof, would, in the opinion of the Central Government, be prejudicial to the public interest, the disclosure may be made confidentially to the advocate of the other party or to an independent expert mutually agreed upon.

(4) In determining under this section any dispute between the Central Government and any person as to terms for the use of an invention for the purposes of Government, the High Court shall have regard to any benefit or compensation which that person or any person from whom he derives title, may have received, or may be entitled to receive, directly or indirectly in respect of the use of the invention in question for the purposes of Government.

(5) In any proceedings under this section, the High Court may at any time order the whole proceedings or any question or issue of fact arising therein to be referred to an official referee. commissioner or an arbitrator on such terms as the High Court may direct, and references to the High Court in the foregoing provisions of this section shall be construed accordingly.

(6) Where the invention claimed in a patent was made by a person who at the time it was made was in the service of the Central Government or of a State Government or was an employee of a Government undertaking and the subjectmatter of the invention is certified by the relevant Government or the principal officer of the Government undertaking to be connected with the work done in the course of the normal duties of the Government servant or employee of the Government undertaking, then, notwithstanding anything contained in this section, any dispute of the nature referred to in sub-section (1) relating to the invention shall be disposed of by the Central Government conformably to the provisions of this section so far as may be applicable, but before doing so the Central Government shall give an opportunity to the patentee and such other parties as it considers have an interest in the matter to be heard.

REFERENCE TO HIGH COURT :

In view of the submissions made under clause 100 above, we submit that this clause should be amended in order to secure that the High Court has powers in appropriate cases to pass an order directing the Central Government or the persons authorised by them not to make use of an invention, pending a decision under this clause.

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112. If in proceedings for the infringement of a patent endorsed or deemed to be endorsed with the words "Licences of right" (otherwise than by the importation of the patented article from other countries) the infringing defendant is ready and willing to take a licence upon terms to be settled by the Controller as provided in section 88, no injunction shall be granted against him, and the amount (if any) recoverable against him by way of damages shall not exceed double the amount which would have been recoverable against him as licensee if such a licence had been granted before the earliest infringement.

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RESTRICTION ON POWERS OF THE COURT :

This clause restricts the powers of the Court to grant an injunction in proceedings for infringement of a patent which is endorsed or deemed to be endorsed with the words "licences of right" (otherwise than by the importation of the patented article from other countries) where the infringing defendant is ready and willing to take a licence upon terms to be settled by the Controller as provided under clause 88. In such a case, the amount of damages recoverable from the infringing party shall not exceed 8% of the net ex-factory sale price in bulk (exclusive of taxes and commissions) of the infringing article. This clause is retrospective in operation and affects also existing patents which are deemed to be endorsed with the words "licences of right".

Present Law

According to the present law (Section 23B) the restriction on the power of the Court to grant an injunction in terms of this clause applies only when the Controller has, in pursuance of an application made by the Central Government under Section 23A of the Act, made an endorsement upon a patent "licences of right".

Suggested Amendment

In view of the submissions made by us for the deletion of clauses 87 and 88 above and our submission that patents for inventions in the field of food and medicine should not be automatically deemed to be endorsed with the words "licences of right", we submit that this clause needs the following consequential amendment:

The words ''or deemed to be endorsed'' should be deleted from this clause.

116. (1) No appeal shall lie from any decision, order or direction made or issued under this Act by the Central Government, or from any act or order of the Controller for the purpose of giving effect to any such decision, order or direction.

(2) Save as otherwise expressly provided in subsection (1), an appeal shall lie to a High Court from any decision, order or direction of the Controller under any of the following provisions, that is to say,

section 15, section 16, section 17, section 18, section 19, section 20, section 25, section 27, section 28, section 51, section 54, section 57, section 60, section 61, section 63, sub-section (3) of section 69, section 78, section 86 and section 89.

(3) Every appeal under this section shall be in writing and shall be made within three months from the date of the decision, order or direction, as the case may be, of the Controller, or within such further time as the High Court may in accordance with the rules made by it under section 158 allow.

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APPEALS:

For the reasons explained below, we are of the opinion that this is a most undesirable provision.

It is not only essential, but also in keeping with democratic principles and the rule of law, that an appeal against the orders and/or direction of the Controller and the Central Government should lie to a judicial tribunal. It is submitted that the denial of judicial review from the orders of the Controller or the Central Government is a serious departure from the orderly adjudication of claims relating to industrial property rights.

If the object of the Government in enacting clause 116 is to do away with delays which might occur in the disposal of appeals to Courts, it is suggested that it is not proper to attempt to do away with an unsatisfactory possibility by an equally unsatisfactory remedy. The proper course would be to do away with delays by improving the administrative machinery but still maintaining judicial recourse. Government is empowered, and has means at its disposal, to secure that appeals to a judicial tribunal are expeditiously disposed of.

Position in other Countries

In all countries deriving their general laws from the British statute, there is provision for judicial appeal against the decision of the Controller. Section 44 of the U.K. Act 1949 is a typical example. The Patents Appeal Tribunal in the U.K. comprises a single judge of the High Court who, by virtue of his function in this respect, acquires a deep knowledge of patent law and case-law and, therefore, the proceedings are greatly speeded up, compared with the situation where the case goes before a judge who has very little or no experience of the patents legislation and has also to attend to other matters.

It is significant to note that according to the U.K. Act 1949 (Section 44) an appeal lies to the Patents Appeal Tribunal from all decisions of the Controller, passed in pursuance of Sections 7 to 42 of the U.K. Act, including, in particular decisions on the following matters :---

(a) Voluntary endorsement of patents (Section 35).

(b) The compulsory endorsement of the patent with the words "licences of right", under certain circumstances at the instance of any person interested (Section 37).

(c) Provisions as to licence under Section 37 (Section 38) corresponding to clause 93 of the Bill.

(d) Exercise of powers on application under Section 37 (Section 39) corresponding to clauses 94, 95(1) and 95(2) of the Bill.

(e) Order for grant of Compulsory Licences in respect of inventions relating to Food and Medicine (Section 41).

The provisions of the U.K. Patents Act 1949 regarding appeals to the Patents Appeal Tribunal are, in practice, working effectively and are considered in that country to be an improvement on previous legislation on the subject.

The Model Patent Law prepared by BIRPI referred to previously, and adopted by representatives of 69 developing countries (including India) provides, under Section 44, that an application for a compulsory licence shall be made to the Court. The framers of the Model Law have indicated that any country may adapt Section 44 to its special circumstances. They further observe as follows :

"For example, countries having a system in which patent applications are examined as to their substance and, consequently, having Patent Offices specialised in the technical side of inventions may provide that the first decision on the grant of compulsory licences will be made by the Patent Office. Such decision should be made open to appeal to a Court, because of the safeguards of impartiality which are implicit in court proceedings."

Justice Ayyangar's Comments

Justice Ayyangar, in his Report (at page 110) observed that

"the orders of the Controller which are now subject to appeal to the Central Government are all matters of judicial determination and it is but appropriate that appeals in these matters should lie to the Courts and not to an executive authority like the Central Government."

We, therefore, firmly believe that an administrative tribunal, whatever its merits from the point of view of possible quicker disposal of appeals, is no substitute for a Court of Law in administering justice. If appellate powers were to be vested in an administrative tribunal an anomalous situation is created, viz. that those who interpret the law will themselves

sit in judgment on their own interpretation. This is a serious departure from the established and fundamental principle of 'separation of powers' which ensures that those who enforce the law do not themselves assume the role of judges.

Recommendations

We, therefore, submit that with the exception of our recommendations under Clauses 87 and 88 (which provide that an appeal against the decision of the Controller as to the grant of a compulsory licence should lie to the Central Government) wherever no appeal is provided against the decision of the Controller or Government, or wherever an appeal is provided to the Central Government, the orders or directions of the Controller or Central Government, as the case may be, should be appealable to a statutory judicial tribunal. We would like to suggest that a Patents Appeal Tribunal should be constituted to hear such appeals on the lines set out in Section 85 of the U.K. Patents Act 1949. In the alternative, another judicial tribunal should be constituted on the lines of the Income Tax Tribunal or the Sales Tax Tribunal to hear such appeals. In particular, such tribunal should hear appeals against the decisions of the Controller or the Government as the case may be, under clauses 66, 84 (insofar as the settlement of the terms of the compulsory licences are concerned), 93, 96, 97, and 122.

Regarding clauses 48 and 95(3) and 102 we have already made our submissions above, for their deletion. If, however, our recommendations are not accepted, we submit that appeals against decisions or directions of the Central Government under these clauses should also lie to the judicial tribunal referred to above.

Furthermore, the clauses of the Bill which make technical definitions, e.g. clause 2(h) (definition of Food), 2(1) (Medicine or Drug), 3(d) (Discoveries of known processes not patentable), 5 (only processes patentable, not substances produced by chemical processes) and 87 (Licences of Right) or other clause to replace them under our submission, will give rise to many difficult points of interpretation which can only be resolved by a procedure which allows the careful and expert examination of evidence. It is, therefore, important that the appeal provisions of the law provide for the adequate consideration of these problems.