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CONQUEST BY PATENT

BY

RAJEEV DHAVAN

ONE HUNDRED YEARS LATER ....

It is over a hundred years since the Paris Convention was agreed by powerful nations in 1883. Those that defend the Convention visualise its history as a linear development, with each change as an improvement over what went before. It is also possible, however, to see the major changes that were proposed and accepted as clumsy political compromises, each to be explained in its own milieu. The linear view is part of a nineteenth century legacy which projects history as progress. The disaggregated view of events is essentially cynical but also more hard edged in its emphasis on the need to examine the more immediate context in which historical changes occur. The linear view concentrates on the growth of ideas; whilst the disaggregated view is more concerned with how these ideas were appropriated and used as vehicles for social and economic action. To combine both would be to learn the seeingly easy lessons of history with unease. If we have looked at the discourse of ideas, it is because our cynicism has not been fed with the availability of enough data to fill out the context in which the discussion occurred.

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In one sense, we can see the concept of 'patents' as an ideological construct. The justification for this construct is the inventive genius of man; and, of course, the duty owed to the inventor. But, the inventor - although an important part of the justification - has long since ceased to occupy centre stage, either as a subject or object of concern or even as a justification for the vast apparatus of patent laws and policy built ostensivly to protect his creativity. The Paris Convetion continues to honour his memory in a grand, but otheriwse sad, gesture in Article 4 ter which reads

> " The inventor shall have the right to be mentioned as such in the patent"

With this obituary, the file on the inventor is closed. His work and labour have been systematically appropriated by powerful interests in society. They are the real actors in the drama even if the poor inventor was the sine qua non of the initial justificatory principle. But,there is a vast difference in providing a just recomepnse for creative genius; and finding a less absolute business equity for someone who has either stolen or appropriated the creator's work or simply footed the bill. And, so the argument shifts from creativity to business. Unsatisfactory questions loom large in both areas, for even creativity is never individual but builds on what went before and a great deal of inventive work cannot really be personalised as exclusive.

The nineteenth century origins of the Paris Convention 1883 are apparent from its inclusion of just about everything within the notion of industrial property. Everything was to be treated as invention; and Article 1(3) unabashedly includes "wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers and flour". And, this was only part of the shopping list. No nation could cope with such a list or even pretend to enforce the law if all these were included in the definition of patents. Yet, if this part of the Convention has been ignored, it is because it is redundant. However, it remains an important part of the rapacious principle that even common property which belongs to all of us can be appropriated and clothed with a patent right. It is better to start at the other end to being with the assumption that all invention and discovery belongs to society, subject to some reward for the discoverer or inventor. Very fundamental notions of property are at stake in this discussion. Yet, even those would become trivialised if the amplitude of patent rights should extend to the limitless excesses of the Paris Convention.

But, if the inventor and the absurd expanse of patentability have both exited from the scene, what we are left with is hard business demands. Industrialists and businessmen who have either commissioned or bought

the product of Research and Development (R&D) claim a price for it far greater than they paid. It is the complexity of the price demanded that needs to be de-constructed for more considered attention. It should not be overlooked that the R&D is subsidized by the State in which the R&D work is taking place (through tax incentives and tax deductions) as well as through the under-payment of scientists and others whose future claims are not part of patent law but contingent on the generosity of the largesse of the patent holder. This is assuming that the inventors can be identified. And, even then, they would be the first to acknoledge that their genius is built on the cumulative endeavours of persons in the past and elsewhere in the world. In this scenario, the claim for a patent is something like a lottery. Whoever gets there first gets the prize - not just a part; but all of it. And, the question is whether the prize (or the price, depending on how we look at it) should be a world wide domination of a particular sphere of economic activity; and for how long ?

There is a threat in all this. The argument ersatz inventors is that if they are not assured world domination for an extended period of time, they will quit. They will stop research and development. They will stop being inventive. Or, they will simply become terribly secret. This is not a threat; it is a bluff even if there are times when we tend to agree to take it seriously. The inventors will continue to invent although society must think through

less commercial ways in which their creativity can be given support. The profiteers will continue to seek profits having lost only an initial advantage, with their loss being the gain of the world. And, yet the argument is never about wholly taking away their advantages; but, how much and to what extent ?

So, let us return to the quest for world domination as a prize of having got there first. As things stand at pressnt, they are not denied this world domination. They always have the option to register their patent in indidiual countries, with each country negotiating its own terms through its laws. But, this is not acceptable to our patent holders. Someone else may get to some other country first. Why enter into a race when you can pre-determine the result ? The technique to do this is the right to priority in the Paris Convention (Article 4). This is the twelve month edge : a patent, <u>howsoever incompletely</u>, registeredn one country can be registered in all the others. And because the Convention decrees the independence of each patent in each country, one registration is not contingent on the others, including, perforce.

With the prospect of world wide domination assured, the next task is to work out the obligations that are owed to the countries who have permitted such domination. The first question is whether any serious obligation is owed to the country in question. The Paris Convention started off on the basis that no obligation was really due. The patent holder could simply use his patent rights as an import monopoly with no obligation to commercially work the patent in that country. The recipient country was, thus, treated as a dumping ground for goods, processes and technical information on terms wholly dictated by the patent holder. This initial position was so untenable, so unmistably absurd and so embarassingly one-sided that the entire history of the Paris Convention for the last hundred years has been taken up in correcting its absurdity.

But,this process has been slow and grudging. The suggestion that the patent holder should be forced after three years to compulsorilylicense someone was immediately undermined by allowing the patent holder to wriggle out of such a demand by pleading justification for his inaction for not working the patent in that country. And, the terms of the justification can be exasperatingly wide. The injunction that two years after the compulsory licence was granted, the patent should be revoked is de-limited by the requirement of a generous examination of whether the abuse of non-working has been rectified by the compulsory licence. In this way, the patent holder has his way all the way, with a formal concession to the recipient country that it can - in the ultimate analysis - force the patent holder to actually commercially work the patent in a country which he had hitherto simply used as an exclusive import zone.

The ultimate success of the Paris Convention lay in the fact that by creating terribly harsh sounding restrictive concepts like compulsory licensing, revocation and forfeiture, it gave the appearance that it was taking a very tough line on patent holders. The truth was less harsh and much more pleasing for the patent holder. With all the advantages of exclusivity, he was faced with some widely phrased stumbling blocks which if kept low-key and ambiguous were surely surmountable in any event he had a wide choice of potential licencees on payment. The Paris Convention appears to have made concessions to the public in erest by mystifying both the discourse and the need to define international objectives more clearly. The fidelity of multinational corporations and the more powerful nations to the Paris Convention rests on the fundamentally uncanny truth that they Convention has given away much less of the patent holder's right than it appears.

One of the real difficulties with all these discussions is that it is assumed that all the nations who are signatories to any international agreement are, by and large, equal in their economic prowess and capacity for technology. But, they are not. The result is that any international convention of this nature works elliptically to the advantages of the more economically and technologically powerful nations of the world. The assumption of equality is unfounded; but, as long as it is made, the sharp division of the world nations eludes a formal description for the record.

But, we need to return to basic questions about nature of the patent right. Never has so much been claimed by one entity for the work done by others. There is no reason why our starting point, like that of the Paris Convention, should be to create a mystical individual property right around what is the collective creation of society. Having cheated society by isolating a social creation as an individual right, we have conceded too readily to the patent holder's claim for national and world domination in that sphere of activity. The price asked, and readily given, is too high as either a national or global price. The responsibility assumed by the patent holder is too low, treating nations and socieites as market dumps and manufacturing sweat shops. The blackmail to whithold future technology and start a trade war is unconscionable; but, it helps to tell us what the debate is really about. The weaker nations are surely right to say that they will not pay the price, accede to the blackmail or give up their right to be treated as more than a market dump or a sweat shop. Yet the more powerful nations persis in their quest to divide the world into an over-expanding number of finite monopolies.

The argument is not one of principle; but of greed. That it is backed by the force of threats does not add to the argument. It simply unmasks it.

*S. Vedaraman**

The New Indian Patents Law

The new Patents Act,[1] which was passed by the Indian Parliament in September 1970, was on the anvil for quite a long time and evoked considerable interest both in India and abroad. The passing of the Act has been widely acclaimed, despite some criticisms in certain quarters concerning the legislation. Naturally, divergences of opinion and criticisms are bound to exist with such a complex piece of legislation as this, in which several interrelated interests have to be reconciled and accommodated.

The Joint Committee to whom the Bill was referred by the Parliament for a careful and detailed consideration not only received written memoranda from several individuals, business organisations and other associations, but also personally heard evidence given by as many as 35 associations and individuals from both India and abroad, although the process occupied the Committee for quite a length of time.[2] The Parliamentary Committee's decision to invite memoranda and oral witnesses from all areas of the world in a matter which concerned the Indian economy was widely acknowledged. Dr. Hans Harms of the Federation of the Pharmaceutical Industry of the Federal Republic of Germany had this to say: "I find it both remarkable and an expression of exemplary fairness that you have decided to study the opinion of organisations and experts of other countries concerning the provisions under consideration. The very fact that the Indian Parliament, before changing the existing patent law, is thoroughly weighing the pros and cons, and for this reason has again called in a Joint Committee, has been respectfully acknowledged in the Federal Republic of Germany."[3]

Before I proceed to explain the important aspects of the new legislation, I think it will be useful to state in brief the fundamentals of the patent system with reference to its legal, social and economic aspects, partic-

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1 The Patents Act, 1970 (Act XXXIX of 1970) (1970 The Gazette of India Extraordinary, Part II, Sect. I). The Act was passed by Parliament and received the assent of the President on September 19, 1970, and is to come into effect shortly.

2 Joint Committee on the Patents Bill, 1967, C.B. II, No. 239 (October 1969).

3 Dr. Hans Harms, Evidence Before the Joint Committee on the Patents Bill on January 23, 1969.

ularly from the viewpoint of economically underdeveloped and developing countries such as India.

Introductic

The material progress and advancement of any society depend on the capacity of its individuals to apply their minds and to invent new processes, products and mechanisms for the enrichment and betterment of the life of its people. The society receives with great gratitude the products of invention which make human existence richer, more worthwhile and less burdensome, and which in turn advance the frontiers of knowledge and open up new avenues of enquiry for breeding further inventions.

It is, therefore, imperative that the society should provide the necessary incentive to stimulate new innovations and technical improvements, since the desire for economic reward is an important factor motivating inventions. An invention which has been made but not disclosed or used is of no economic benefit to the community. Various incentives have been and are being tried, of which monetary plans, status recognition, inventor's certificates and the patent system are the most conspicuous. The monetary plans include cash and bonus awards, profit sharing schemes and retirement funds. The status recognition is made, for instance, by means of promotion to superior rank and increases in salary. Under the scheme of inventor's certificates, the right to exploit the invention vests with the State, but the inventor has a claim for appropriate remuneration. Some of the inventors might be content simply with the feeling of accomplishment of having their inventions recognised through publication in scientific and technical journals, though such instances might be few and far between.

Of all these schemes, experience has shown that the patent system — stemming from the desire to obtain proprietary rights in commercially valuable inventions — provides the most effective incentive to inventors, industrial undertakings and other research sponsoring organisations who derive from inventors the right to commercially exploit their inventions. For this reason, the system of granting patents for inventions has come to be universally adopted as the means for stimulating and encouraging inventions and for establishing and promoting industries within a country. Even the countries which had for some time abolished the system were forced to reintroduce the same in view of its economic importance to the evolution of inventions for the benefit of society.

A patent is a statutory grant by the Government to inventors and to other persons deriving rights from the inventors, for a limited duration, conferring on them the right to exclude others from manufacturing and

selling the patented article or using or imitating the patented process or vending the resulting product.

The legal basis of the patent grant arises from the concept that the inventor is entitled to enjoy the fruits of his invention which resulted from the exercise of his brain and skill. The patent does not give him any positive right with respect to his invention in the sense that the inventor does not derive the right to work his invention solely from the patent grant, but it does give him the right to exclude others from making, selling and using his inventions. But this right is to be subject to certain conditions in the public interest. No patent legislation contemplates an absolute or perpetual right of the inventor in his invention. For the sake of the public interest and in order to promote the economic development of the country, the legislation contains some restrictions on the patent grant such as, for instance, a limited term of patent protection for the invention, the requirement of compulsory working of the invention on a commercial scale, the licensing of the patent as a measure against abuse of the patent monopoly by the patentee; and, in accordance with the public interest, even the revocation of the patent for non-working, exclusion of certain categories of inventions from the scope of patent protection, etc. Inventor's rights must be recognised, but not without placing them in the proper perspective. Society should not submerge the interest of the individual inventor by denying him any right, nor should it allow him to run riot by giving him an absolute right in his invention. The patent system, therefore, provides the necessary checks and balances on the public and private interests in the invention: the interest of the inventor in his creation on the one hand, and the social interest of inducing the inventor to make the invention, the interest of the public in using the invention once it is marketed and the interest of the Government in promoting the economic development of the country on the other hand. As aptly put by P. J. Michel, "Patent systems are not created in the interest of the inventor but in the interest of the national economy. The rules and regulations of the patent system are not governed by civil or common law but by political economy."[4]

History of Indian Law

The Indian patent system had its origin in the "Act for Granting Exclusive Privileges to Inventors" of 1856,[5] which provided for the protection

4 1 P. J. Michel, *Introduction to the Principal Patent Systems of the World* 15.

5 Act VI of 1856. *See* 2 *Theobald's Legislative Acts of the Governor-General of India in Council* 397 (1868).

of inventions in India. Owing to certain formal deficiencies,[6] this Act was repealed in 1857, but the provisions of the repealed Act were later re-enacted with slight modification in 1859.[7] The "Patents and Designs Protection Act"[8] was passed in 1872 for the purpose of legally protecting designs, and an amending Act affording protection to inventors desirous of exhibiting their inventions at exhibitions was passed in 1883.[9] In 1888, the law contained in the three Acts of 1859, 1872 and 1883 was consolidated into a single Act,[10] which was subsequently revised and replaced by the existing Indian Patents and Designs Act of 1911.[11] This latter Act has also been amended from time to time, one of the notable amendments being the provisions introduced in 1952 relating to the compulsory licensing of patents in the field of food or medicines at any time after the sealing of the patent.[12]

As may be seen, the patent system has thus been in vogue in India for nearly one hundred and fifteen years. But it has not led to encouraging results in India since it is a developing country. It was obvious that the patent law of a country such as India, which is in its developing stage and which is being provided with a dynamic industrial base, should be so designed as to enable the country to achieve rapid industrialisation and to obtain, as quickly as possible, a fairly advanced level of technology, giving inventors and investors sufficient inducement and protection through patent grants while at the same time safeguarding its national, economic and social interests. To this end the law required substantial changes to provide for compulsory working of patented inventions for the public advantage, compulsory licences, and licences of right to prevent abuse of patent rights by patentees who use the system merely as a means of securing an importation monopoly without exploiting the patented invention by actually manufacturing within the country that granted the patent and thereby promoting the interests of its national economy and industry. The need for a comprehensive revision of the law relating to patents in India to suit our country's developing economy was, therefore,

6 Because the Queen had not given previous sanction, it was advised that the Indian Legislative Council was not competent to pass the Act, and therefore, the Court of Directors of the East India Company disallowed it.

7 Act XV of 1859.

8 Act XIII of 1872, passed in the form of an Act amending the 1859 Act.

9 The Protection of Inventions Act, 1883 (Act XVI of 1883), passed as a preliminary to the Calcutta Exhibition of 1883 and 1884.

10 The Inventions and Designs Act, 1888 (Act V of 1888).

11 The Indian Patents and Designs Act, 1911 (Act II of 1911) (Calcutta, Supdt. Govt. Printing, 1911).

12 Act LXX of 1952, adding Sec. 23CC to the Indian Patents and Designs Act, 1911.

recognised soon after independence; and the matter was the subject of two Expert Enquiries, the first by the Patents Enquiry Committee[13] and the second by Shri Justice Rajagopala Ayyangar.[14] Both the enquiries revealed that "the Indian patent system has failed in its main purpose, namely, to stimulate inventions among Indians and to encourage the development and exploitation of new inventions for industrial purposes in the country so as to secure the benefits thereof to the largest section of the public."[15] The new Patents Act is based mainly on these studies, although incorporating a few changes in the light of further examination at various levels, particularly with reference to patents in the important fields of food, drugs and chemicals.

I may now briefly refer to the salient features of the new Patents Law in India.

General Principles of Patent Grant

The Act recognises the importance of stimulating inventions and encouraging the development and exploitation of new inventions for the industrial progress of the country. Section 83 of the Act enunciates the general principles of patent grant and also broadly the general philosophy of the Act in the following terms:

> "(a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay; and
>
> (b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article."

Principle of National Treatment

The new Patent Act does not put any limitations or restrictions on foreigners in the matter of applying for or obtaining patents in India.

Science and technology has no territorial barriers, and, as such, there is no discrimination between nationals and non-nationals in any respect;

13 Patents Enquiry Committee 1948-1950, *Interim Report* (August 1949), *Final Report* (April 1950).

14 N. Rajagopala Ayyangar, *Report on the Revision of the Patents Law* (New Delhi, 1959).

15 Patents Enquiry Committee 1948-1950, *Interim Report* 165 (August 1949).

and all the provisions of the Act are applicable *mutatis mutandis* to both nationals and foreigners. However, Section 134 of the Act provides that where any country does not accord to the citizens of India the same rights with respect to the grant of patents and protection of patent rights as it accords to its own nationals, no national of such country shall be entitled to any privilege under the Indian Law.

Inventions Not Patentable

The kinds of inventions which are not patentable are codified in the Act. In the past, the question of patentability had been governed generally by British precedents, but with the rapid expansion of technological developments and the broadening of the area of inventions and discoveries, it was considered necessary that there should be a specific provision in the law concerning this matter. Section 3 of the Act stipulates that the following are not inventions within the meaning of this Act and, hence, are not patentable. As may be seen, the kinds of inventions included in this Section are almost universally not patentable.

"(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 use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;

(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the compounds 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 human beings 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."

Under Section 20 of the Atomic Energy Act of 1962, inventions relating to atomic energy are already unpatentable. Accordingly, Section 4 of the Patents Act of 1970 specifically excludes inventions in this field from being patentable so as to make the Patents Act self-contained.

Search for Novelty

The Indian Patents and Designs Act of 1911 did not contain any specific provision requiring the Controller to make a compulsory search to ascertain the novelty of an invention before its acceptance. Nor did the Act deal clearly with the problem of what constituted anticipation. The new Patents Act, however, removes this ambiguity and provides for a compulsory search, extending to prior publications not only in India, but also in any other part of the world.[16] The basis of this provision is that an invention which is published abroad before the date of the corresponding application for a patent should not qualify for the grant of a patent. Accordingly, publications which are capable of constituting anticipatory prior art include publications in India and elsewhere appearing before the priority date. This brings the legal position in India, in this respect, in line with most of the other countries of the world.

We are aware of the problems and difficulties in organising the search system with the ever increasing volume of search material and the development of narrow fields of science and sophisticated technology. This has rendered the examination of inventions more difficult than ever before. However, we have been trying to organise and equip our Patent Office adequately, not only for the purpose of fulfilling the statutory provisions of the Act, but also to enhance the utility of the Indian Patent Office by rendering it an effective instrument for diffusion of scientific and technical knowledge.

Patentability of Inventions in the Area of Chemicals, Food and Drugs

Section 5 of the Act provides that in the case of inventions relating to substances intended for use as food, drugs or medicines, or substances

16 Sec. 13 (2).

produced by chemical processes, patentability will be limited to claims for the methods or processes of manufacture only. In other words, patents containing claims for the substances themselves are not allowable in such cases. It should be appreciated, however, that this provision is neither unique nor novel. Many of the European countries, during the last 100 years, particularly when they were in the developmental stage, had similar restrictions with regard to the patentability of such inventions.[17] Mr. Justice Rajagopala Ayyangar, on whose recommendation this provision is based, had observed: "I have considered the matter with the utmost care and have reached the conclusion that the chemical and pharmaceutical industry of this country would be advanced and the tempo of research in that field would be promoted if the German system of permitting only process claims were adopted."[18] It is clear that if claims for the products themselves are allowed, it might act as a brake on further scientific research and retard the development of new manufacturing processes. Such a practice is, therefore, undesirable, particularly in underdeveloped and developing countries. In this regard, there are many countries which impose restrictions on the patentability of chemical inventions by allowing claims only for processes. In such countries, the restrictions are even more stringent in the case of inventions relating to food, drugs and medicines, in view of their importance to public health.

Term of Patent

Under Section 53 of the new Act, the term of a patent is 14 years from the date of patenting, *viz.*, the date of filing the complete specification. However, in the case of inventions in the fields of food, drugs and medicines, which, as I said earlier, are vital for national health and well-being, the term of patent protection is stipulated as 7 years from the date of filing the complete specification or 5 years from the date of sealing, whichever period is shorter.[19] In other words, as against the duration of 14 years for other categories of patents, the duration of patents for food, drugs and medicines will be 7 years from the date of filing the complete specification. The term of 5 years will be reckoned from the date of sealing only if the patent is sealed within a period of 2 years. Now that the tempo of development and evolution of new processes all over the world is so rapid, many inventions are becoming obsolete much faster than in the past. Many drugs and pharmaceuticals are being replaced by more effective

17 *E.g.*, Austria, Germany, the Netherlands, and the Scandinavian countries.

18 Rajagopala Ayyangar, *supra* note 14, at 36.

19 Sec. 53 (1) (a).

and better ones within a short period of time. Accordingly, it is felt that a shorter term for patents in this field would not in any way prejudice the interests of the patentees, and would be adequate. The pharmaceutical industry, particularly in the international area, feels that if the term of the patent is short, it will not enable them to obtain a reasonable return and realise the expenses incurred with respect to research. However, it should be appreciated that all such research expenses may be recovered not only from a single market but from markets all over the world where patent rights may also have been secured. Apart from this, in a majority of cases the expiration of the term of any particular patent does not, by itself, immediately result in adoption of the invention by a number of competitors in the country, thereby prejudicing the interest of the patentee. In other words, the patentee himself continues to enjoy the privilege of his patent despite the fact that the invention has fallen into the public domain. This is particularly so in developing and underdeveloped countries which lack the necessary technological base.

In this context, I may state that there was a strong section of opinion in India advocating that there should not be any patent protection at all for inventions in the important fields of food, drugs and medicines, which are deemed indispensable to the sick, babies, invalids and convalescents. The medical profession in India, and perhaps also in other countries, considers it unethical to take proprietary rights for such inventions and make them a means of profiteering. It may be recalled that the Royal Commission in Canada highlighted the fact that exorbitant prices for drugs and pharmaceuticals were due largely to patent protection, and they recommended that nothing short of abolition of patents in these fields would serve the interest of the public.[20] The Sainsbury Committee in England also came to a more or less similar conclusion in this respect and recommended that a shorter term of patent protection coupled with provisions for licensing patents in these fields would be adequate,[21] though it is true that the subsequent Banks Committee[22] in England did not endorse the suggestion. Even in the United States, there is a contingent thinking along these lines. The recent testimony before a U.S. Senate Committee[23] regarding the exorbitant prices charged by U.S. firms with respect to pharmaceutical

20 *See* the recent report on these matters by the Restrictive Trade Practices Commission.

21 *Report of the Committee of Enquiry into the Relationship of the Pharmaceutical Industry with the National Health Service 1965-67*, Cmnd. No. 3410 (1967).

22 *The British Patent System. Report of the Committee to Examine the Patent System and Patent Law*, Cmnd. No. 4407, at 112-119 (1970).

23 *See*, e.g., the reports by the Monopoly Subcommittee of the Senate Small Business Committee (1967) and by the Subcommittee on Antitrust and Monopoly (1961).

products, particularly in the developing and underdeveloped countries, would seem to be very revealing. I am referring to these matters just to emphasize that the special steps taken by the Government of India through this patent legislation were dictated by social needs and the public interest, and that these steps are supported by opinions held even in the developed countries. The Government and the Parliament in India have considered the views of all schools of thought regarding this issue and have brought about a fair and reasonable compromise between the extreme views, *viz.*, total abolition of patents in these fields on the one hand and a liberal protection of patent rights on the other, keeping in view the interest of the patentee as well as the interests of the public at large.

The term of grant for drug patents as laid down in the Act would thus seem to be adequate to ensure a fair return to the patentee. Besides, this shorter term of patent protection might also stimulate quicker and wider commercial exploitation of patented inventions within the country, thereby making available these common necessities in adequate quantity and at reasonable prices.

Licensing Provisions

As I said earlier, one of the serious handicaps which India in common with other countries has been experiencing has to do with patents which are not worked for the benefit of indigenous industrial development but which are merely held to secure a monopoly for importation. The Act thus includes elaborate provisions to discourage abuse of patent rights. Compulsory licences can be applied for at any time after the expiration of three years from the sealing date of the patent. The provisions for granting compulsory licences[24] are more or less along the lines of the provisions contained in the statutes of the United Kingdom and other Commonwealth countries. In order to obtain a compulsory licence an applicant has to prove one or more grounds (under Section 90 of the Act) and satisfy the Controller as to his ability to work the invention and as to certain other facts. The procedure in such cases is basically the same as in the past. The new Act also provides for an appeal to the High Court from the decision of the Controller in such cases.[25] Involving as it does protracted legal proceedings before courts of appeal, experience has shown that the provision relating to compulsory licensing has not been, nor is likely to be, very effective even under the new Act since

24 Sec. 84.

25 Sec. 116(2).

the patentee can delay the actual grant of the licence by resorting to judicial processes. By the time the case is finally settled, the patent itself might already have expired. While this situation can be tolerated in ordinary cases, remedial measures have to be found and provided for in the vital areas of public interest. Accordingly, in view of their paramount importance to public health and well-being, it was considered necessary that the legal procedure for the granting of licences for food, drugs and medicines be simplified. Because chemicals are directly related to the production of pharmaceuticals, apart from their general importance in the context of industrial development, it is obvious that the granting of licences with respect to such patents should be handled similarly. The statute has, therefore, provided that all patents granted under the new Act in the area of food, drugs, medicines and chemicals shall, upon the expiration of a period of 3 years from the dates of their grant, be deemed to be automatically endorsed with the words "Licences of Rights",[26] and that any interested person shall, as a matter of right, be entitled to a licence under such patents[27] subject, of course, to the payment of royalties. The Controller may, before the terms of the licence have been mutually agreed upon or decided by him, permit the prospective licensee 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.[28] This provision is intended to ensure that legal proceedings do not delay the establishment of production in such vital fields as food, drugs, medicines, and chemicals.

Provisions in the patents laws relating to the endorsement of patents as "licences of right" are not infrequent. There is, for instance, a provision for the endorsement of patents, at the request of the patentee or on application by the Government or a third party in the U.K. Patents Act.[29] Even in the Model Law for the Developing Countries on Inventions drawn up by BIRPI, similar provisions have been referred to.[30] The significant difference in the recent Indian Patents Act, however, is that the endorsement is automatic and statutory,[31] although the effect of such an endorsement is the same. Only recently, the Economic Council of Can-

26 Sec. 87 (1).

27 Sec. 88 (1).

28 Sec. 88 (4).

29 Patents Act, 1949, 12, 13 & 14 Geo. 6, c. 87, § 35.

30 BIRPI, *Model Law for Developing Countries on Inventions* 67 (Geneva, 1965).

31 The automatic endorsement applies only to food, medicines, drugs or chemicals. However, according to Sec. 86 the Government may apply for endorsement of any particular patent as a "License of Right", and in such cases the Controller does make an investigation similar to that for "compulsory licences."

ada, after four and one-half years of study, has made a similar proposal that all Canadian patents should normally become eligible for an automatic non-exclusive licence to manufacture in Canada 5 years after the application for the patent.[32] We do not have, however, any information concerning the result of this recommendation. But, the special provision in India,[33] as may be seen, is limited to the vitally important sectors of national health and welfare and does not apply in other cases. Here again, the endorsement is effected only after 3 years from the date of sealing in the same manner as is the case for the compulsory licensing provision. This is in keeping with the spirit of the Paris Convention.

In this connection, it has been questioned why the Controller should not look into the technical competence and the financial ability of the applicant for a licence under an endorsed patent just as in the case of an application for a compulsory licence. But it may be pointed out that though such questions would be relevant in the case of an application for a compulsory licence, in the case of a patent endorsed with the words "Licence of Right", such requirement will be out of place. After a patent is endorsed with the words "Licence of Right", the licence is to be granted as a matter of right, and any questions which may have the effect of denying him the right to a licence will be doing violence to the language of the expression "Licence of Right". After all, a licence under a patent is not a manufacturing licence but only a legal protection against infringement of the patent. It may be mentioned that in such important fields as food, drugs, and medicines, the prospective manufacturer — be he either the patentee or a licensee — will have to obtain a licence under the Drugs and Cosmetic Act or the Prevention of Food Adulteration Act, as the case may be, and satisfy the Government that the products conform to the required standards.

In this regard it is relevant to recall BIRPI's commentary on Section 45 of the Model Law:

> "There is a substantial difference between compulsory licences and licences of right in that in the case of compulsory licences the applicant must justify his request . . . and meet certain requirements . . . whereas this is not the case as far as licences of right are concerned. This system may be specially attractive to developing countries because once a patent is thrown open to licences of right it will no longer depend on the will of the owner of the patent whether

32 Economic Council of Canada, *Report on Intellectual and Industrial Property* 91 (Ottawa, Information Canada, 1971).

33 Sec. 87 (providing for the automatic endorsement for patents in the fields of food, medicines, drugs and chemicals).

> the patent will be exploited in the country; anybody can obtain a licence, and, on the basis of that licence, work the patented invention in the country."[34]

The effect of the provision in the new Patents Act is precisely as above. If the Controller were to make any sort of investigation before granting a licence, it would result only in delaying the grant of the licence and would defeat the very purpose of the provision. In order to protect the interest of the patentee, the statute, however, provides for an appeal to a superior court of law on the question of the terms and conditions of licences granted with respect to patents endorsed or deemed to be endorsed under the Act.[35]

It should be appreciated that the basic intention of these provisions is to ensure that essential articles like drugs, medicines and food will be available to the public in sufficient quantity and at reasonable prices, and at the same time ensure a reasonable return to the patentee on his invention. The patentee will have a period of 3 years from the date of the grant of the patent in which to establish production in the country and to take steps for making the patented products available to the public at a reasonable price. If this is done, there is no reason why anyone else should consider entering the same business in an attempt to compete with the patentee by securing a licence, even though one could be secured as a matter of right. In other words, it can be seen that the provision regarding the granting of licences under patents automatically endorsed will become really effective and advantageously utilized only if the patentee fails to discharge his obligation.

Royalties

Section 95(1) provides that in settling the terms and conditions of a compulsory licence, 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."

The above provision, which contains the guidelines to the Controller in the matter of fixing royalties and settling terms in granting a compulsory

34 BIRPI, *supra* note 30, at 67.

35 Sec. 116(2).

licence, corresponds to Section 39(1)(a) of the U.K. Patents Act of 1949 and Section 69 of the Canadian Act of 1935.[36]

However, in the case of patents relating to food, drugs and medicines, by reason of their importance to public health and welfare, the statute provides that the royalty and other remuneration reserved to the patentee under a licence (granted as of right) shall not exceed 4% of the net ex-factory sale price in bulk of the patented article.[37] Needless to say, 4% is only the ceiling or the maximum royalty allowable, and each case will be decided within this limit depending on its own merits. This statutory ceiling, however, as already indicated, is applicable only with respect to patents within this special field, *viz.*, food, drugs and medicines, and *does not apply to other categories of patents,* where the allowable royalty (in the case of a compulsory licence) will be determined in light of the provision in Section 95(1) of the Act.

I would like to point out one important aspect in this connection, namely, that the maximum rate of royalty, *viz.*, 4% for patents relating to food, drugs and medicines, is not arbitrary or without basis. The normal practice in connection with licences granted under Section 23CC (inventions relating to food, drugs or medicines) of the existing Indian Patents and Designs Act of 1911 has generally been to fix a royalty not exceeding 4% of the ex-factory wholesale price of the manufactured articles. Even in cases other than compulsory licensing, the royalties allowed generally were ranging between 2 and 5% of net sales in the field of medicines and pharmaceuticals.[38] It will, therefore, be appreciated that the statutory fixation of a ceiling on the royalty should not be a matter of concern to anyone, since what the new law does, in effect, is to give statutory effect to the existing practice, and then, too, only in the case of such essential items as food, drugs and medicines. This is intended to enable the prospective licensee to know his maximum liability as regards royalties and to assure a reasonable return to the patentee, while at the same time guarding against high prices of products in the sensitive fields of food, drugs and medicines.

Use of Patented Inventions by the Government

The provisions relating to Government use of patented inventions are contained in Section 100 of the Patents Act and are basically along the

36 The Patent Act, 1935, 25 & 26 Geo. 5, c. 32, §§ 66, 67.

37 Sec. 88(5).

38 *Report of the Reserve Bank of India on Foreign Collaboration in Indian Industry* (1968).

lines of the provisions in Section 46 of the U.K. Patents Act of 1949. Similar provisions are also to be found in Section 125 of the Australian Act.[39]

The use of a patented invention under this section is subject to the payment of royalties in an amount agreed upon by the Government, or its authority, and the patentee, or in the case of default of agreement, in an amount to be determined by the High Court under Section 103 of the Act. Thus, the interests of the patentee are fully safeguarded.

However, in the context of the responsibilities which a welfare state assumes, it is necessary to ensure that the existence of patent rights does not hamper its development programmes or its welfare activities. Therefore, for this purpose and in order to ensure that a scarcity of the patented article, including drugs and medicines, does not arise and lead to high prices, the Government is vested with powers of an enabling nature whereby it can make use of or exercise any patented invention merely for its own purpose. Under this provision (Section 47 of the Act) the Government can import patented drugs and medicines if they are merely for its own use or for distribution in any approved medical institution, with regard to the public service that such institution renders. It is the intention not to go beyond this limited use, even when the circumstances so warrant in the interest of the common good. Under this section it is also provided that use for experimental purposes of patented articles or processes, as well as the articles or products made by a patented process or a patented machine or apparatus, will be exempted from infringement actions.

In this connection, I may refer to the observations made by the U.N. Secretary General in his Report on the Role of Patents in the Transfer of Technology to Developing Countries. The report says —

> "In spheres of production vital to the national interest and the development of special resources, or to public health, limitations on patentability or provision for limiting the scope of the patent grant by special working or compulsory licensing in the public interest are natural, as is evidenced by the inclusion of such limitations in the legislation of many countries."[40]

Appeals

Under the provisions of the Indian Patents and Designs Act of 1911, appeals from decisions of the Controller were to lie in the majority of

39 Patents Act 1952 (Act 42 of 1952).

40 U.N. Secretary-General, *The Role of Patents in the Transfer of Technology to Under-Developed Countries* 22 (1964).

cases with the Central Government.[41] Under the new Act, however, in all cases appeals from the decisions, orders and directions of the Controller will lie only with the High Court, which is the highest court in each state in India.[42] The normal judicial process in accordance with the rule of law is thus assured to parties in all proceedings under the Act.

International Arrangements

As regards reciprocal or Convention arrangements, in the past such reciprocal arrangements for the mutual protection of inventions have been limited to only the United Kingdom and the Commonwealth countries.[43] The new Act has removed this limitation and enables the Government to conclude bilateral or multilateral arrangements or treaties with any other country or countries for the mutual protection of inventions.[44]

Conclusion

From what I have stated above, it should be clear that the main object of the Act is to promote research and inventions and to accelerate the indigenous industrial growth and, through a well-regulated patent system, to prevent the exploitation of a monopolistic patent position. The Act is also calculated to make our country free from continued external dependence as regards the supply of materials and machinery. As I have already clarified, the Act seeks to accord equal treatment to both nationals and non-nationals in all respects, and to provide to them or their licensees ample opportunities to commercially work their inventions within the country; and if they make the best use of these opportunities there should be no necessity to have recourse to any of the special provisions in the Act in order to ensure that patents are not used in such a way as to retard the economic development of the country.

The new Patents Act is the result of a detailed study of the economic conditions of the developed as well as the developing countries of the world with reference to their laws relating to patents, and has been designed to suit the special needs of our country. It has been the subject of careful consideration at various levels before enactment, including two expert committees, a Parliamentary Committee and the Parliament itself more than once. The enactment has been widely welcomed by different sections of the public and industry in India.

41 Secs. 5 (2), 9 (3), 16 (5), 17 (6), 43 (4).

42 Sec. 116 (2).

43 The Indian Patents and Designs Act, 1911, Sec. 78 (A).

44 Sec. 133 (1).

WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTÉ

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EXECUTIVE BOARD

OCCASIONAL PAPER NO 3.

Seventy-seventh Session

Provisional agenda item 14

POLICY ON PATENTS

Information paper on WHO patents policy

The Thirty-fifth World Health Assembly requested that progress in implementing the WHO policy on patents be reported periodically. WHO agreement forms have been adapted to facilitate the achievement of the objectives of the Organization in the most common funding situations. No significant change has occurred in the number of patents held or applied for, though WHO's use of its interests in patents held by research institutes is beginning to be reflected in concrete arrangements with industry for the making available of health-related products in the public interest.

1. Introduction

Pursuant to a recommendation of the sixty-ninth session of the Executive Board,[1] the Thirty-fifth World Health Assembly (May 1982), in resolution WHA35.14, decided that it should be the policy of WHO to obtain patent rights or interests in health technology developed through WHO-supported projects where such rights and interests are necessary to ensure development of the new technology, and to promote its wide availability in the public interest. This information paper updates a report on the early progress made in implementing the new policy, which was considered by the seventy-first session of the Executive Board[2] and the Thirty-sixth World Health Assembly.[3]

2. General provisions

2.1 The implementation of resolution WHA35.14 is being increasingly linked with the growing collaboration between WHO and industry, as partners in promoting the development and wide availability of health technology. In most cases, patent rights in themselves, that is to say the patents or other forms of industrial property and applications actually owned by WHO, are of little direct benefit to WHO, which lacks the facilities and resources to exploit them. On the other hand, they may be essential to an industrial enterprise interested in collaborating with WHO, in order to protect the often substantial investment required to develop and market useful technology.

2.2 Whenever a research project results in useful technology that may be patentable, the first question that has to be answered in accordance with resolution WHA35.14 is whether or not patent rights are necessary for the technology's development and wide availability. The basic answer is that, if the technology can be perfected and made widely available at a relatively low cost, patent rights may not be necessary and the interests of the Organization may best be served by placing the technology in the public domain. Where, however, development involves considerable investment and commercial risk, patent rights should be sought. Normally, this question cannot be answered at the outset, and the first steps in the patent protection process have to be taken in order for the rights to be safeguarded. The

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[1] Resolution EB69.R7.

[2] Document EB71/22.

[3] Document A36/6.

protected rights can be abandoned later before substantial costs are incurred or they can be continued, where necessary, until taken over by an appropriate non-profit entity or industrial partner.

2.3 The specific provisions agreed between WHO and collaborating enterprises vary from case to case, but they are designed to reconcile two general interests: the interest of the Organization in ensuring that the finished products of the technology, and in certain circumstances the technology needed to make that product, are available to the public health sector on preferential terms, particularly in developing countries, and the interest of the enterprise in obtaining a reasonable return on its investment.

2.4 The Organization has recently revised its standard "Technical Services Agreement" covering WHO-funded projects with research institutions. Previously there were two alternative forms of this agreement; one of them vested the patent rights initially in the Organization, and the other vested the rights initially in the research institution, with WHO retaining a patent interest in the form of free availability of the rights to it or its nominees. The Organization will continue to ensure that it retains patent rights in justified cases, particularly where it is providing most of the funds or intellectual input for the research; but, for other cases, the agreement no longer attempts to specify the patent interest to be accorded to the Organization if a useful invention should materialize. Instead, if and when the research results in an invention, the parties are placed under an obligation to negotiate an agreement covering the exercise of the intellectual property rights granted to the research institution. Such an agreement will be based on the attainment of the following objectives in the following order of priority:

(1) the general availability of products resulting from the project;

(2) the availability of those products to the public health sector on preferential terms, particularly in developing countries; and

(3) the grant to each party of additional benefits, including royalties, account being taken of the relative value of each party's financial, intellectual and other contribution to the research.

3. Patent rights

As of 15 October 1985, there have been 10 inventive efforts resulting in 16 patent applications filed by or on behalf of the Organization, of which four applications concern one particular invention and four other applications concern a related group of inventions. Of the 16 applications, one was rejected, six have been abandoned, six have been granted (one of which - a certificate of utility - has expired), and three are still pending. Of the five patents which the Organization currently holds, two concern inventions which are not actively being pursued (Drug delivery system and Tubal occlusion method); two involve the same invention, which is currently undergoing toxicology testing (Steroid synthesis); and one involves an invention (Long-acting esters) which is currently being tested and which is covered by a first-option agreement with a commercial enterprise, which contains provisions facilitating the making available of the product to the public sector. A list of WHO's patent rights is set forth in an annex to this information paper.

4. Patent interests

4.1 In addition to the Organization's patents and patent applications, WHO holds a considerable number of interests in patents obtained by research institutions funded by it. The term "patent interest" is used to refer to the right to demand a licence under a patent or the transfer to WHO of certain patent rights.

4.2 In cases where there is a potential for further development of the subject of the patent into a useful health-related product, WHO has exercised its interest in the related intellectual property rights so as to ensure the wide availability of the product in the public interest, in particular for developing countries. Two cases in which WHO has recently exercised its interests are for a malaria vaccine and a fertility predictor. In the case of each enterprise selected by the research institute to develop the product concerned, WHO has concluded an agreement which contains provisions facilitating the making available of the product to the public health sector, in particular of developing countries.

5. Consultations with other international organizations

5.1 The Secretariat consults appropriate services of the World Intellectual Property Organization (WIPO) as the need arises on relevant issues of intellectual property law in order to best protect the interests of the Organization and the public sector. It also follows certain aspects of the work of WIPO which are of particular interest to the Organization, such as improving industrial property protection of biotechnological inventions.

5.2 The Secretariat also has provided information to the United Nations Industrial Development Organization (UNIDO), at its request, in order to assist that organization in developing its own patent policy.

ANNEX

LISTING OF WHO PATENTS AND PATENT APPLICATIONS

	Filing date and country	Inventor & programme	Subject	Current status
1.	10.4.1979 USA	Decker (HRP)[1]	Electro-coagulator	Rejected
2.	3.5.1979 USA	Heller (HRP)	Drug delivery system	Pat. No. 4 261 969
3.	20.7.1979 USA	Nakamura (HRP)	Spermicides	Abandoned
4.(a)	4.8.1979 France	Crabbé (HRP)	Steroid synthesis (anordrin)	Certificate of Utility No. 79-20926 expired
(b)	15.4.1980 USA	Crabbé (HRP)	Steroid synthesis (anordrin)	Pat. No. 4 309 565
(c)	29.7.1980 FRG	Crabbé (HRP)	Steroid synthesis (anordrin)	Abandoned
(d)	14.8.1980 UK	Crabbé (HRP)	Steroid synthesis (anordrin)	Pat. No. 2 061 278
5.	20.11.1979 USA	Buckles (HRP)	Barrier contraceptive	Abandoned
6.	16.12.1980 USA	Hoffman (HRP)	Improved tubal occlusion method	Pat. No. 4 359 454
7.(a)	29.1.1981 USA	Archer et al. (HRP)	Long-acting esters (certain cycloalkyl derivatives)	Abandoned, since covered by United States patent No. 4 507 290 on long-acting esters
(b)	7.4.1981 USA	Archer et al. (HRP)	Long-acting esters	Pat. No. 4 507 290
(c)	19.5.1983 UK	Archer et al. (HRP)	Long-acting esters	Abandoned, since now covered by EPA[2]
(d)	31.1.1984 EPA[2]	Archer et al. (HRP)	Long-acting esters	Pending
8.	3.12.1982 USA	Bone (CFNI[3]/ FHE[4])	Haemoglobin screening device	Abandoned
9.	20.12.1984 UK	Rickman & Reed (TDR)[5]	Microscope	Pending (original 20.12.83 filing allowed to lapse; immediately refiled)
10.	2.7.1985	Crabbé et al. (HRP)	Testosterone esters	Pending

[1] Special Programme of Research, Development and Research Training in Human Reproduction (HRP).

[2] "European patent application" (application submitted pursuant to the Convention on the Grant of European Patents, 1973).

[3] Caribbean Food and Nutrition Institute (CFNI).

[4] Division of Family Health.

[5] Special Programme for Research and Training in Tropical Diseases (TDR).

HOW THE WORLD EMINENT PERSONALITIES FEEL ABOUT THE PATENT SYSTEM

In the words of Sir William Holdsworth :

" The foreign patentee acts as a dog in the Manger, sends the patented articles to this country but does nothing to have the patented articles manufactured here. He commands the situation and so our industries are under our own law starved in the interest of the foreigner."

Sir Robert Reed was more outspoken :

" Nothing can be more absurb or more outrageous than that a foreign patentee can come here and get a patent and use it, not for the purpose of encouraging industries of this country but to prevent our people doing otherwise what they would do. To allow our laws to be used to give preference to foreign enterprise is to my mind ridiculous".

Speaking of the American Patent System, while giving evidence before the National Economic Committee Mr. Langer said :

" We are doing business abroad and we want to protect our article, so that German or English manufacturer is not able to copy it immediately and go into competition with us. In other words, it is a great selling point for our goods to have a protected export markets."

Patents were, therefore, admittendly taken by foreigners, not in the interests of the economy of the country granting patents or with a view to manufacture there, but with the main object of protecting an export market from competition from rival manufacturers.

In spite of this grossly apparent misuse and abuses of the Patent System, the system continues to exist, as Edith Penrose aptly puts it :

" partly because the custom is old and firmly established, partly because of the pressure of the vested interests and partly because the ideals of "International Co-operation", "non-discrimination" and similar laudable sentiments have been influential in shaping the thoughts of lawyers and Statesmen".

The exploitation and abuses of the patent system by foreigners, who do not work the patents commercially in the country of grant but use them merely as a means of ensuring a monopoly of importation, has not escaped criticism even in advanced and developed countries. Speaking of the position of patents in USA, Floyd L. Vaughan Says :

" It is a contravention of our patent law and an economic injustice to the American manufacturer to allow a foreigner to take out a patent in this country merely for the purpose of reserving the United States a market for his patented product which is manufactured abroad exclusively. It means the expulsion of all other would be inventors and competitors from the industry covered by the patent and at the same time the building up of the industry in other countries, all to the detriment of the United States".

IT WAS NATURAL THEREFORE, FOR INDIA TO SHAPE ITS POLICY ON SIMILAR LINES AND ADOPT ITS LEGISLATION IN ORDER TO COUNTER THIS TENDENCY OF FOREIGN PATENTEES.

Smt. Indira Gandhi at the World Health Assembly at Geneva on 6th May, 1981 said :

" My idea of a better ordered world is one in which Medical Discoveries would be free of Patents and there would be no profiteering from life or death".

PART II - POLICIES

TECHNOLOGY POLICY STATEMENT OF GOVERNMENT OF INDIA TO DEVELOP A SELF-RELIANT INDIA :

Extracts from Technology Policy Statement of Government of India 1983 :

" The Government of India's Technology Policy Statement 1983 declares that "Our own immediate needs in India for the attainment of technological self-reliance a swift and tangible improvement in the condition of the weakest sections of the population and the speedy development of backward regions". It further adds that "Our future depends on our ability to resist the imposition of technology which is obsolete or unrelated to our specific requirements and of policies which ties us to systems which serve the purpose of others rather than our own, and on the success in dealing with vested interest in our Organisations ; governmental, economic, social and even intellectual, which bind us to outmoded systems and institutions".

EXTRACT FROM WIPO DOCUMENT NO.WIPO/IPL/BM/4 DATED DECEMBER 3, 1985

In considering the role of industrial property in economic development, an initial clarification needs to be made concerning the nature of the industrial property system. The industrial property system does not exist in order simply to grant legal protection to various facets of technology. Rather, the industrial property system is more correctly perceived as an instrument of public policy whereby legal protection is granted to various facets of technology in order to promote certain social and economic objectives, which typically include the disclosure and dissemination of technology, the stimulation of investment of resources in technology, and the establishment of a framework for the development and exploitation of technology".

Tailoring Patents Law to Suit MNCs

BM

The prime minister's tirade against indigenous technology which is geared to import substitution serves advance notice that he is ready to fall into trap of the Paris Convention on patents and the GATT provision for protection of intellectual property.

CONCERNED scientists and technologists, legal luminaries and social workers and even some enlightened business interests have woken up to the grave and imminent danger that has emerged on the horizon to Indian R and D and the contribution that Indian scientists and technologists can and must make to socio-economic development with some measure of self-reliance. They had been watching helplessly but with considerable dismay for quite some time the unfolding of official policy which had tended more and more to strangulate Indian R and D, open the doors wide for foreign technology and capital to take up commanding positions in the Indian market and overwhelm step by step domestic production capabilities in several critical areas. What they had not still bargained for, however, was that the government led by Rajiv Gandhi was getting ready to revise the well-tested policy on patent protection and join the Paris Convention on patents which the government had so far rightly refused to do. It is being suggested that the government may take this 'bold' step by the middle of December this year. The ground for this, according to some well informed sources, is being prepared at a rather hectic pace. These apprehensions have been strengthened by the extension of the so-called Rajiv Gandhi-Reagan Science and Technology Initiative under which transfer of high technology to India from US is being regulated and managed. The seminar being organised by the Federation of Indian Chambers of Commerce and Industry in the last week of November this year with the active association and participation of the World Intellectual Property Organisation (WIPO) is also considered ominous in this context.

It is freely admitted by concerned high officials that, though the pressure on India for straightaway joining the Paris Convention on patents has been somewhat relaxed considering the sensitivity of the Indian public on this score, the pressure for amending the patent law of 1970, which had been adopted in the teeth of the opposition of multinational corporations and the developed countries has been greatly intensified. What is being demanded is that product patents in particular should be reintroduced across the board and the provisions in the Indian law on compulsory licensing and licence of right for manufacturing patented products by the application of processes developed in India should be diluted. This would amount to conforming with the Paris Convention on patents without formally joining it. It is quite on the cards that these demands on India will find strong articulation and support at the proposed FICCI-WIPO seminar. A committee appointed by the government last year to advice whether or not to join the Paris Convention is also about to submit its report and may well be expected to reinforce the demands and suggestions of WIPO for amending the Indian patents law of 1970. This is how the ground is meticulously being prepared to force India to accept the line laid down by WIPO on the patents issue.

The multinational corporations, on their part, have drawn up a comprehensive plan of concerted action on the patents issue in the wider frame of the protection of intellectual property rights through the Uruguay round of GATT. The round has on its agenda a specific GATT provision for the protection of intellectual property as an urgent and pressing issue.

The representatives of multinational corporations from the US, Japan and western Europe adopted in June this year a comprehensive working plan to achieve their aim in the GATT round. They have demanded the adoption of a code similar to the standards or subsidies codes under GATT auspices in order to sanction "effective deterrent to international trade in goods where there is an infringement of intellectual property provision". What they are seeking is an "effective enforcement mechanism" under GATT system for countries which do not join the Paris Convention on patents and do not amend their national patent laws and procedures to conform to the norms of the Paris Convention for the protection of intellectual property rights. The multinational corporations have come down particularly heavily on the provision for compulsory licensing for production of goods which enjoy patent protection but are not actually produced in the country. What is being demanded is that a patent will be deemed to have been worked by the patentholder by only exporting the patented product and not necessarily producing it in the concerned country. This demand goes beyond even the Paris Convention which allows licensing of production of a patented product to a third party in the event of the non-working of a patent. Multinational corporations are also seeking to further extend and refine the scope of patent protection to high-tech areas such as the 'layout design' of a semiconductor chip or biotechnology. These demands, if accepted and enforced through the GATT mechanism, will hit the developing countries, notably those, among them India, which have acquired and developed scientific and technological capability for finding alternative processes for the production of patented products. The import-substitution effort of the developing countries is sought to be choked through the patent system and the GATT provision on the protection of intellectual property. The multinational corporations are clamouring for concerted action by the signatories to the GATT code on protection of intellectual property against those who may choose not to become party to the code.

What all this adds up to is that the multinational corporations backed by the governments of the developed countries are demanding that the developing countries strangulate their own R and D effort and dismantle their production capabilities which result in import substitution and which compete with multinational corporations and exports of the developed countries to the developing countries. The moves of the ruling establishment in India, encouraged and supported by compradore business interests and a section of the corrupt bureaucracy with close links with multinational corporations, to review and revise the patent law of 1970 have, therefore, caused grave apprehensions among Indian scientists and technologists and all those, among them some enlightened business interests, who stand for self-reliance and want to strive to break the foreign stranglehold on socio-economic and technological development of the country.

The public affirmation by the prime minister that the import substitution effort in technology has been "one of the biggest mistakes" has come as a shock to these sections. Coming in the midst of mounting pressure and open arm twisting by the developed countries, in particular the US the prime minister's stand portends ill for Indian R and D and technology. Rajiv Gandhi chose to deliver his dictum on technology policy and its aims in his characteristic hectoring style on the occasion, ironically enough, of presenting the 1987 Shanti Swarup Bhatnagar awards to Indian scientists. It is a pity that the Indian scientists present on the occasion did not have an opportunity to refute his extremely dangerous position on Indian technology and its tasks at the present stage of India's socio-economic development.

The prime minister's stand on technology policy and the reasoning behind it are strikingly supportive of the mobilisation of forces by the multinational corporations for incorporating a provision for the protection of intellectual property rights under the GATT charter. This will be a powerful in-

strument for enforcing what is called the Paris Convention on the protection of patents, designs and trade marks to cover not only industrial property, as orlginally conceived, but all intellectual property on a much broader basis. Rajiv Gandhi has actually argued that "we are always substituting third generation or fourth generation and we are never upfront when we are doing import substitution". Invariably, according to him, by the time we have a breakthrough in import-substituting, technology of the next generation or perhaps two generations ahead is already available to us readily and "that frustrates our scientists and technologists and our effort to go into production". What he thus made out is a case for unhindered import of patented goods and technologies with Indian scientists and technologists to act as hired hands of foreign interests.

India, after a great deal of tussle with the multinational corporations, which own 85 per cent of the patents registered in the world, enacted its patents law in 1970. The essence of this law is that it provides a solid and viable basis for Indian R and D to develop technologies for substituting the import of patented products and prevent their unhindered access to the Indian market. It challenged the monopoly of foreign business interests to export their patented products to India and gave a boost to Indian R and D and indigenous business enterprises to undertake domestic production of similar products. The Indian patents law permits not only product patents which alone are allowed under the Paris Convention but also process patents for food, medicines, drug and chemical substances. Agriculture products and processes for treatment of human beings or animals are not treated as inventions and, therefore, they are not patentable. Atomic energy inventions are also not patentable under the Indian law. As regards the period for patent protection, the Indian law provides $^{5}/_{7}$ years for food, medicine, drugs and chemical substances and 14 years for other products. The law, therefore, gives reasonable protection to those who invent new products and processes and the charge of the multinationals that it encourages imitators and production of counterfeit goods is totally misplaced.

The real point about the working of the Indian patents law is that it has helped to find substitutes for imported goods and services through R and D in India which has rightly concentrated its efforts not on finding brand new products but on finding new processes for undertaking domestic production to substitute import of goods produced abroad. This is due to the compelling reason that discovery of brand new products requires huge resources in skills and money which a developing country lacks. In the first stage of development, a developing country must conceptrate available resources to achieve optimal results which come by way of import substitution rather than production of new products. By adopting the import substitution route, Indian R and D has derived rich returns not only in terms of foreign exchange savings but directly for Indian consumers as regards assured supplies and reasonable prices. It has slashed the high monopoly profits which foreign goods could earlier extract from the Indian market. This has been most palpable in the case of pharmaceuticals and food products. This also explains the frantic lobbying by international drug firms to drag India into the Paris Convention on patents. Before the 1970 patents act came into force, finished drugs and exotic processed foods had free entry into the Indian market and the consumer was mulcted by their producers abroad in the absence of any competition from domestic producers. This could go on under the Paris Convention for as long as 20 years for each product. After 1970, however, Indian R and D developed cost-effective processes for a large number of basic chemicals, drugs and pesticides in India. These products are being sold to the Indian consumer at reasonable prices and even export outlets on a competitive basis are being found for them.

What the multinational corporations are clamouring for is what they call an "effective deterrent to international trade in goods where there is an infringement of intellectual property rights". They are demanding that for patent protected products, the production of an identical product should be prohibited. It is disconcerting in this context that with the policy of import liberalisation already seriously affecting domestic production of a variety of goods and services, particularly capital goods and the machine-making industries, and opening the Indian market for investment and marketing activities of foreign capital, the government has initiated moves to review its time-tested position on the Paris Convention on patents. The prime minister's tirade against technology which is geared to import substitution serves advance notice that he has been persuaded by interested quarters and is now ready to fall into trap of the Paris Convention on patents and the GATT provision for protection of intellectual property. Concerned scientists and technologists have to bestir themselves immediately and raise their voice to block this disastrous move.

A national working group headed by an eminent Indian scientist, Nityanand, has already been set up to campaign against the scuttling of the Indian patents law of 1970. It is proposed to hold a seminar, backed by well-documented studies, to enlighten public opinion on the important and far-reaching issues involved in the patent system and the designs of the multinational corporations. After the seminar, it is also proposed to institutionalise a 'National Alliance' for socio-economic development on the basis of self-reliance.

TECHNOLOGY

The Patent Question

THERE are reportedly significant differences within the Indian bureaucratic, political and business elites over the question of amendment of the Indian Patents Act, 1970. The nature of amendments that have been proposed are said to be in line with the Convention of the Union for the Protection of Industrial Property, in short, the Paris Convention or international patents convention. The proposal for amendment of the Patents Act came up at least three years back. There have been reports of pressures, most notably in the form of threat of trade sanctions, being exerted on the Indian government by the US. It is said that in the context of the Trade and Competitiveness Act (1988), Washington has identified countries, such as Brazil and India, which, according to it, do not extend adequate protection to the US patents and copyrights. Further, the US is now holding out the threat of trade sanctions to pressurise them to amend their patents acts in line with its proposal on trade related intellectual property rights that is reportedly being taken up at the Uruguay round of trade negotiations under the auspices of GATT.

The Indian Patents Act (1970), which superseded the 1911 colonial act, is based on the progressive (from a anti-imperialist viewpoint) recommendations of the Ayyangar Committee Report of 1959 on the Revision of Patent Laws. After a decade of concerted opposition to the Ayyangar Report's recommendations by TNCs as well as sections of Indian capital, Indira Gandhi's minority government, which was then dependent on the left for crucial support, and in the wake of a near-scandal over drug pricing, presided over the passage of the bill in parliament.

The progressive content of the present Patents Act includes the terms of patents, the scope of patent coverage, the grant of compulsory licences, licences of right and the right of the government to acquire and use a patent. In the case of foods, pharmaceuticals, pesticides and other agro-chemicals and veterinary products, the term of a patent is five years from the date of sealing of the patent or seven years from the filing of complete specifications, whichever is shorter. For products other than the above, the term is 14 years from the date of filing. The US proposal will mean a term of 20 years in general and at least 17 years for pharmaceuticals and agro-chemicals. For the products mentioned above, the 1970 Act gives protection to process patents only, explicitly excluding "product-by-process protection". The US proposal specifies patent protection for both processes and products. The 1970 Act does not grant patents in the areas of bio-technology and environmental pollution control. Adoption of the US proposal would imply amending this section. The Act has provisions for the grant of compulsory licences. Any aspiring manufacturer has a right to be granted a licence to manufacture a patented product if the patent holder does not exploit the patent within a stipulated period of time, on payment of royalty not exceeding a particular rate. The US government officials argue that grant of compulsory licences is detrimental to promoting transfer of technology. Indeed, according to the US administration, foreign firms are reluctant even to file patents in India because of the absence of adequate protection.

From the business opposition to the amendment of the 1970 Patents Act, it seems clear that it is the interests of the firms controlled by Indian business in the pharmaceutical and chemicals industry that are likely to be the most hard hit. The statement of the Indian Drug Manufacturers Association, communicated to the government on August 9, basically articulates the familiar anti-imperialist position, so convincingly and comprehensively argued and empirically validated by Constantine Vaitsos for the Latin American countries. The representatives of the Indian affiliates of transnational corporations in the pharmaceutical and pesticides industries who support the amendment of the 1970 Act also articulate the by-now familiar arguments which however have little empirical validity in the third world.

It may be useful to reiterate one point in the argument against patent protection for bio-technology in the third world. Bio-technology is a sort of umbrella term for processes, developed in the last decade or so, that produce proteins and other molecules by the artificial manipulation of genetic material. It has vast potential in the areas of agriculture and medicine. The basic technology of hybrid seeds, for instance, is the monopoly of a few transnational corporations who also control proprietary/patented agro-chemicals that form part of the technology package for their application in crop cultivation. These TNCs have, by and large, genetically upgraded crops by freely obtaining the germ plasms from the third world and now want patent protection.

TNCs in the bio-technology field are demanding patent protection not only for micro-biological processes and products but even for the plant and animal varieties, freely taken from the third world, that they have genetically upgraded. Even Western European patent rules on bio-technology do not concede some of these demands.

The US seems particularly concerned about the import of generic pharmaceuticals (after the expiry of US patents) from Brazil and India. Brazilian patent law, it is said, does not provide for patent protection of pharmaceutical products since 1945 and pharmaceutical process patent protection since 1969. US administration officials say "the piracy of intellectual property" will no longer be tolerated. There is a period of protracted negotiations and hard bargaining ahead. India and Brazil will no doubt use important related issues as leverages in the negotiations.

THE TIMES OF INDIA

BOMBAY: THURSDAY, NOVEMBER 27, 1986

I-Right To Health As A Basic Right

By V. R. KRISHNA IYER

TWO great imperatives, one Indian and the other international, should impel the Indian state to shape its drug policy so as to provide health for all by the turn of the century. The right to a free and healthy life, central to all human rights, is a constitutional fundamental of our republic.

The right to life (article 21 of the constitution), expanded by other provisions like equal protection of the laws (article 14) and freedom of movement and speech (article 19) and seen in the light of the state's duty to reach public assistance in cases of old age and gender handicap (part IV), is a guarantee of positive health free from disease and disablement.

Article 38 mandates the state to create a social order without economic disabilities and disparities and with social justice in respect of health. The equal, actual right of the littlest Indian to free health care at least by 2000 A.D. is a creative though belated response by the state to egalitarian call of the constitution.

The right to medical care for the humblest citizen is integral to evolving an international health order. The alma ata declaration (1979), in which 134 nations including India pledged urgent action to protect and promote health and the resolution of the 38th world health assembly in 1985, sponsored by India and other countries, to give this promise practical shape, are some of the international instruments to secure good health for all humanity.

The WHO has also enumerated guidelines for establishing a national programme for essential drugs for developing countries. These international instruments are the sinews of a maturing world health order and supportive global jurisprudence.

The centre's statement on the national health policy in 1982, following the Hathi committee report of 1975, and the latest restructuring of the 20 point programme, could become the foundation of programmes that would grant equal access to those curative pharmaceutical advances which are now cornered only by the dominant section of our society.

The main recommendations of the Hathi committee were nationalisation of multinational drug companies; establishment of national drug authority; priority production of 116 essential drugs; abolition of brand names and introduction of generic names; revision and updating of the Indian national formulary; strengthening of quality control; and elimination of irrational drug combinations.

Life-saving Drugs

A decade has distressingly passed, governments have come and gone, Mr. Hathi is dead, NAM's drugs deliverance resolutions have become more strident. But India's penurious millions are daily dying without life-saving drugs. "Health for all", as a lollipop slogan, is noisomely publicised by state media and yet not a single proposal of the Hathi committee or UNCTAD, WHO or NAM guidelines has become part of a practical national policy.

The battle for "health for all" is a struggle for pharmaceutical swaraj against medical imperialism. A developmental plan of 'health for all' must organise integrated approach to the many systems like ayurveda, unani, siddha, homeopathy, Chinese and, of course, modern medicine.

A holistic health strategy relevant to the third world countries, where nutritional disasters, pharmaceutical privations, and endemic-epidemic diseases are common, calls for a cultural revolution in health care.

The dominant diseases that stalk the third world — infectious, parasite and respiratory — are more or less absent in the west. The socialist countries have developed a socially sensitised medical system where, at a nominal cost, Medicines and hospital facilities are available to the common people. The scenario in the developing countries is sombre. The WHO estimates that 80 per cent of illnesses are preventible.

In India 1.5 million children die annually from diarrhoeal diseases caused by polluted water. Half of the world's TB patients live in India, but we produce only a third of our TB drugs requirement.

More than 40,000 children in India become blind each year for want of vitamin A; yet vitamin A is in short supply. Over 60 million people in India suffer from endemic goitre only for want of iodised salt.

Evidently, for drug corporate power, with its control board abroad, profits, not people, matter. This power affects the drug policy of India too.

Even the courts, beguiled by MNC's submissions through leading advocates, grant stay of orders which control prices or sale of banned drugs. Judicial pharmacopoeia knows the letter of the law, not the goal of curing people at a reasonable cost.

Forty eight per cent of Indians live below the poverty line and it is estimated that only 20 per cent of the people have access to modern medicine. Leprosy, curable at cheap cost, rages among tribals. Many thousands of children die of diarrhoea although oralirehydration therapy at little cost can save most of them.

WHO estimates that 60 to 80 per cent of the people in the third world have for all practical purposes no access to medical services. What aggravates the agonising situation is the absence of the right drug at the right time at the right cost and with the right information.

A social audit will record the colossal waste of scarce resources on about 60,000 drug formulations, many of which are hazardous and irrational. The philosophy of "health for all" will remain a grand illusion unless a humanist national drug policy reverses these perversities.

Undeniably, India has advanced after independence in the field of health and medicine. Smallpox, plague, cholera and a few other diehard diseases have been banished, while malaria and filaria have been controlled to some extent.

Medical Colleges

A network of dispensaries, hospitals and specialised institutions has been developed and, thanks to medical colleges and allied institutions, doctors and paramedics have become available. There has also been an impressive improvement in the indigenous capacity for the production of drugs, pharmaceuticals, vaccines and hospital equipment.

Nevertheless, the country's health picture causes concern. To quote a recent report: "the mortality rates for women and children are still distressingly high....total deaths occur among children below the age of five years; ... infant mortality is around 129 per thousand live births ... the severity of malnutrition continues to be exceptionally high. Communicable and non-communicable diseases will have to be brought under effective control and eradicated".

Preventive medicine is neglected, social medicine is laughed at. The Indian medical industry, given the opportunity, has the capability to develop and meet the national needs for essential drugs and instruments.

Our medical pluralism, as a great heritage of the science of healing and health, suffers the status of a Cinderalla. Alas, "health for all" is sacrificed at the altar of western medical sophistry!

For whom is sophisticated medicine meant and for whom is life a brief candle? who matters? India (private) limited or India's poor unlimited?

Sixty foreign drug companies control 80 per cent of India's drug production, and market their astronomically priced products and formulations with flavoured advertisements. India's major national health adversary remains "pharmaceutical imperialism".

The first charge of the state must be to offer pharmaceutical rescue shelters to the marginalised, malnourished categories. This basic proposition takes us to the stranglehold of pharmaceutical multinationals and their quislings in our country capitalising on human suffering, importing phoney formulations, exporting huge profits, glamorising the cult of "west is best" and crushing the impressive capabilities of the national sector, public and private.

The Central government has not surrendered before them until now, but pharmaceutical patriotism, if entrusted to new committe and bureaucracies within the field of influence of foreign firms, may well genuflect before transnationals inc. the MNCs are now influencing the colonially brainwashed oligarchy to accede to the Paris convention and unwittingly sign the death warrant on the indigenous drug industry.

A powerful lobby of political professionals, subsidised intellectuals, call-girl academics, misled medicos and pharmaceutical mercenaries have put pressure on the Union government to join the Paris convention. These are strong words. But we shall show that accession to the convention will accelerate the Indian drug industry's defeat in the war against disease and against the west's monopoly patents.

II — Drug Policy And Right To Health

By V. R. KRISHNA IYER

THE Alma Ata declaration of the global goal of "Health for all" by 2000 A.D. pledged urgent action by WHO member-states keeping in view the specific problems of the third world and the poor availability of essential drugs at realistic prices. The negation of the citizen's fundamental right to life (Article 21) is the inevitable consequence of the *de facto* denial of the humar right to health reaffirmed at Alma Ata.

If India's accession to the Paris Convention leads to this consequence in terms of drug availability, it would be at once unjust, arbitrary and unreasonable (Maneka Gandhi's case) and unconstitutional.

A nationalist drug policy, geared to medicinal self-reliance and modern technology, is a basic condition of health *swaraj*. But in a world dominated by pharmaceutical transnationals manipulating soft states whose administrators and experts are willing to fall victim to their brandishments and bullying, a patriotic policy cannot be sustained without a degree of radicalism.

A revolution in health care is the human essence of the Alma Ata declaration. National self-sufficiency in drug manufacture, the use of generic against brand names, elimination of the confusing profusion of formulations, control of inflated pricing, barricading infiltration into our medical bureaucracy, elevating the public sector to the commanding heights of the pharmaceuticals economy and strengthening the Indian sector in general are some of the preconditions for such a revolution. All this demands a battle against the high-tech baloney spread by MNCs that they have a monopoly of research capability and a passion to catalyze indigenous R and D to develop new drugs adpated to our social conditions.

Indian drug manufacturers contend that, given the proper atmosphere and stimuli, they can beat foreign corporations in cost, quantity and quality. The Indian Patent Act, 1970, has been a boon for indigenous drug companies and Indian consumers. It has promoted the introduction of a host of new drugs by Indian companies and eliminated the monopoly position enjoyed by the transnationals.

Our patent law, based on Indian realities, has stimulated a competitive Indian drug industry. The resultant local competition substantially reduced the lead time between the discovery of a drug elsewhere and its manufacture in India. Prices have also dropped in many cases. MNCs are not interested in essential drugs or generic products. They have been guilty of aggressive promotion of brand names, sale of drugs at outrageous prices and even of marketing formulations banned in their home countries.

The corrupting force of MNCs has led to many therapeutically irrational, but lushly profitable formulations. The concentration of foreign industrial might in the drug sector is disturbing. In 1973-74, 60 firms with foreign shares accounted for 70 per cent of the country's total drug sales. The remaining 30 per cent was shared by 116 large and 2,500 small manufacturing companies. Foreign companies, which started here as marketing subsidiaries of their giant parents, are not interested in the production of bulk drugs. They have been forced by circumstances into manufacturing activity. But this mainly consists of importing bulk drugs from parent companies and merely mixing them together in various promotions to make various formulations with particular brand names.

National Needs

The national sector has proved to be equal to the national needs and many people are asking for self-reliance in pharmaceuticals. Social action groups and even official committees have endorsed this demand. Meanwhile the MNCs are getting exposed. In a last-ditch battle, they are readying to use their final weapon — the Paris Convention. The convention represents the pharmaceutical cemetery of the Indian drug industry and an obituary for the plan of "Health for all".

The Paris Convention holds that industrial property is private property and whoever acquires rights thereto in a country is entitled to enforce those rights for his own benefit; he may prevent any other person from making use of the industrial property, including process, not only in the country in which it is registered but in all countries which are signatories to the convention. At the same time the holder of industrial property undertakes no obligations incidental to or flowing from his rights. The grant of a right to industrial property imposes no corresponding obligations upon the holder and he is entitled to claim protection against invasion of his rights against the action of a member-state even if that state regards that it is necessary to invade those rights in the larger public interest or as a matter of over-riding necessity. The owners' rights shall be enforceable in all countries of the Union and enforcement of those rights will be governed by the law of the state in which the right to industrial property is recognised or registered and not by the substantive laws of the country in which it is sought to be enforced.

Article 5A(4) of the Paris Convention provides for compulsory licensing of patents in some specified contingencies but grants no real protection against abuse of the patent. Independent studies have revealed that compulsory licensing is of no value whatever because the time lag involved in obtaining a compulsory license is too long when viewed in the context of ensuring the public good. Finally, signatory-countries are obliged to ensure protection against unfair competition in respect of all commercial activity. Whether competition is unfair will be determined according to the law of the country in which the patent is registered.

A perusal of the convention reveals a striking contrast between the precision with which the rights and privileges of the owner of industrial property are defined and the insignificant protection afforded to the rights of the state or of the nationals of the state which accords these privileges. The convention may therefore be fairly described as a charter of rights of the holder of industrial property in the international field.

The Paris Convention is inspired by the ideology of defending industrial (intellectual) property of advanced countries wanting to operate in developing countries. Its philosophy is maximum freedom for big business to make profits while excluding rivals in the field, undertaking no duty to produce drugs and enjoying the privilege of importing products heedless of the needs of the third world. This privatisation of medical relief based on profiteering from suffering is anathema for our constitution.

Drug MNCs with a pathological addiction to profits will enjoy complete freedom in India to secure patents under the Paris Convention if we sign it. Moreover, the patents can be claimed for products, not merely for processes. The Indian researcher is thus inhibited from making the same products by innovative processes. Against these, MNCs are entitled to patents under the convention but are under no obligation to produce the patented drugs. As Mr. Justice Chandrachud has observed: "This becomes possible only because one country takes out a large number of patents for exploitation in the other member countries. The foreign patent holder has no interest in the greater industrialisation of underdeveloped countries. He utilises those countries as a dumping ground to which he can, in the name of his patent, export his patented goods. What is worse, he can obtain a patent and not use it at all for manufacturing the patented goods. What he achieves thereby, which is a most nefarious form of trading practice, is to prevent the producers in underdeveloped and developing countries from manufacturing those goods. It is a dog-in-the-manger policy".

Similar Views

Similar views have been expressed by Mr. Justice J. C. Shah and Mr. M. Hidayatullah and other jurists. Mr. Justice Rajagopala Ayyangar in his report on the revision of our patent law opposed accession to the Paris Convention as injurious to the development of industrial capability. It is a shame that the nation should surrender to transnational pharmaceutical terrorism on the ground that without accession we may be condemned to pharmaceutical primitivism.

It is sheer lunacy to practice reverse discrimination in favour of powerful MNCs without even imposing on them the duty to make essential drugs in our country.

The right to life (Article 21) rests on the right to medicine and if this right is crushed by accession to the Paris Convention, the action would violate Article 21. Foreign monopolies will acquire the exclusive right to manufacture and import drugs covered by their patents. India, if it accedes, will be bound to grant such patents. This is a procedure obnoxious and unreasonable and violative of Article 21. The Indian manufacturer may justly complain of violation of his right under Article 19(1)(G) and (6). Surely, the directive principles of Part IV, under Article 39(B) and (C), interdict the concentration of means of production to the common detriment.

It is also plain that the existing laws like the Patent Act, Trade and Merchandise Marks Acts, FERA and the Atomic Energy Act will have to be sacrificed in vital aspects to propitiate the clauses of the convention. Even our nuclear programme will be exposed to the competition of multinationals. There is no partial membership.

An intensive and detailed national debate on the dangerous implications of the Paris Convention is imperative before we cross the rubicon by acceding to it.

When a poor patient pleads for survival and his disease can be controlled or conquered by a life-saving drug, it is diabolical to deny him that medicine on account of state policy which vests a patented monopoly for its manufacture in a profiteering enterprise without putting the latter under a duty to produce and distribute essential drugs on reasonable terms while preventing others from making them. And yet India's accession to the Paris Convention will have this very impact on millions of poor people.

I hope the Prime Minister will remember Gandhiji who once observed: "Whenever you are in doubt... apply the following test. Recall the face of the poorest and the weakest man whom you may have seen, and ask yourself if the step you contemplate is going to be of any use to him".

(Concluded)

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India should not join the Paris convention

THE question whether India should join the Paris Convention has been the subject of consideration and review from time to time for nearly four decades. The question appears to be again a live issue and, therefore, merits serious attention.

Industrial property consists of patents, trade marks, knowhow etc. With reference to patents India has enacted a legislation in 1970 replacing the Act of 1911, on the basis of the recommendations of Mr. Justice Rajagopala Iyengar, then of the Madras High Court and later of the Supreme Court. He has submitted a comprehensive report in September, 1959 pointing out the deficiencies in the then existing Statute. He drafted a bill which took a decade to be adopted as a Statute, with such modifications as were necessary. The Act came into force in 1972.

The basic purpose of a patent system is to encourage innovation and the improvement of industrial techniques. In return for the disclosure of his invention by registering it in the patent registry, the inventor is given a monopoly in the use of it for a specified period of years, thereafter it becomes public property. Britain was the earliest to have a Statute regarding patents right from 1623. The latest law in that country was enacted in 1977.

Other European countries too appear to have had similar protective legislation even in the last century. In order to have uniformity in the protection of inventions, ten countries of Europe and the U.S.A. evolved what is known as the Paris Convention of 1883. Three more countries joined the convention next year and now there are 96 countries which are signatories to the convention. China and India among others, have not yet become its signatories. Out of the 96 countries, more than 62 are developing countries or countries whose industrial development is behind the advanced ones.

One of the basic provisions of this convention is that any amendment of its articles has to be by unanimity among the members. Other international conventions require only a 2/3rd majority. The result is that over a century there have been only six amendments to this convention.

No discrimination

The essential features of the convention are as follows.

There should be no discrimination between a national and one belonging to other member countries in the matter of protection of industrial property rights. On the basis of the first application in any one of the member countries, a person can file an application for protection of his patent in any other member country and he gets a right of priority over others in those member countries. The priority date is from his first application in any one of the member countries. An application for a patent in any of the member countries is treated as an independent one, so that even if the application is rejected in one country it can be registered in any other member country with obvious consequences.

The patentee can import his goods, manufactured abroad and any statutory provision for forfeiture of the patent for not working it in any of the countries cannot be resorted to. The forfeiture clause in any patent legislation is designed to discourage such imports and to encourage local manufacture. This object cannot be pursued when once a foreign patent is registered in the convention country. The provisions of the convention are thus heavily loaded in favour of the inventor or patentee, and there is little or no recognition of the public interest of the other member countries.

In fact even in a country like Britain great jurists have spoken against the exploitation by foreign interests by cutting patents registered in Britain. For instance, Sir William Worldsworth observed; "the foreign patentee acts as a dog in the manger, sends the patented article of this country (UK), does nothing to have the patented articles manufactured here (UK), He commands a situation and so our industries are under own law starved in the interests of the foreigners."

Sir Robert Reid (later Lord Reid) expressed himself more emphatically when he said: "Nothing can be more absurd or more outrageous than that a foreign patentee can come here and get a patent and use it, not for the purpose of encouraging industries of this country, but to prevent our people doing otherwise what they would do. To allow our laws to be used to give preference to foreign enterprise is to my mind ridiculous". Sir Robert Finlay (later Lord Finlay) has also observed "a patent is supposed to be granted for the encouragement of manufacture in this country, but under the existing laws, a large number of patents are taken out by foreigners solely for the purpose of preventing encouragement of manufacture in this country". These observations came to be made more than 70 years ago and are still valid.

Exploitation

Eighty per cent of the patents have been granted to multi-nationals of only five developed countries. The number of patents obtained by Indian inventors is infinitesimally small, though India is said to have the third largest reservoir of scientific talent. More than half the population of the world is outside the convention. The main reason for this feature is that in the absence of any compulsory requirement to manufacture the goods patented in any particular country, the tendency is to import the manufactured goods and sell them at the best possible price, resulting in the process of economic exploitation of the less developed or under-developed countries.

India, with a large potential market and as a leading member of the Third World is wooed and coaxed into joining the convention by holding out all baits. It is suggested that India need not even amend its laws so as to be in conformity with the convention! This is a strange bait and by Article 25 of the convention every member joining it undertakes to adopt the measures necessary to ensure the application of the convention. There is no authority to excuse any country from honouring the commitment following the joining of this convention.

How this commitment is to be enforced by the convention countries is a matter of procedure. But that the provisions of the Indian law will have to be amended in accordance with Article 25, is indisputable.

The Senate Committee of the U.S.A. pointed out in 1961, before the 1970 Act of India was enacted, that India which granted patents on drug products ranked among the highest priced nations of the world, a case of inverse relationship between per capita income and the level of drug prices. The statutory changes of 1970 have resulted in bringing down the drug prices far below even of Britain, where comparatively speaking, among the developed countries' drugs are cheaper. This is the result arrived at by an official study in India of the prevailing drug prices between the two countries.

Even now one gets reports in newspapers of manufactured products, sometimes life-saving drugs routed through one or more countries, and after being imported into India being sold at fantastically high prices. The Paris convention would further this tendency on the part of the multinationals and monopolists. They would manufacture the goods abroad and sell them at high prices here. The power to ban such imports cannot be exercised as it will be inconsistent with the obligations arising under the convention.

Act will be useless

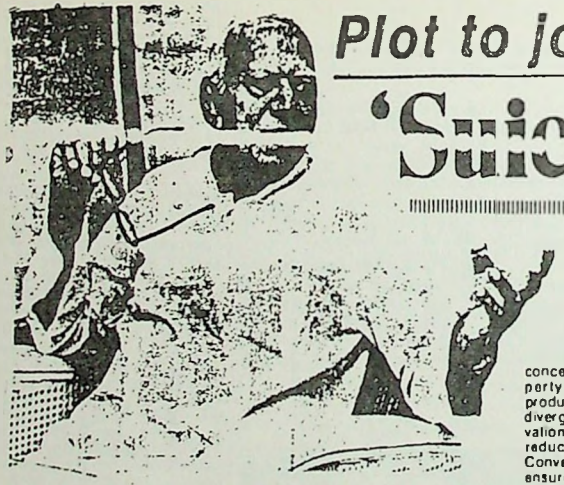
The M.R.T.P.Act designed to end the exploitation of consumers by Indian industrialists would be powerless to regulate foreign business interests. The foreign patentee would not manufacture the goods in India and will not allow it to be manufactured here relying on his patent. In order to see that these tactics did not succeed, the present Act contains provision for compulsory licensing, endorsement of licences of right, etc.

There is a school of thought that even the present law, is inadequate to deal with the situation, as the foreign patentee has a long period of six years at the minimum when he can dump his goods in India and stifle Indian business interests during that period. Our talks of socialism and helping the weaker sections will cease to have any meaning when India bends before the provisions of this convention by joining it.

An Indian industrialist is now getting the knowhow of patented process in technical collaboration agreements which are subject to Government approval. They are permitted for short periods. This kind of arrangement gives a fillip to Indian industries. By India entering into the Paris Convention, there will be a disincentive to enter into such agreements on the part of foreigners and the development of Indian industries would suffer thereby.

The former Prime Minister, Mrs. Gandhi, had spoken in no uncertain terms about resisting this kind of exploitation. Let us hope that the foreign overtures would be resisted. Mr. Justice Iyengar, who recommended the desirability of joining the international convention in relation to trade marks, has taken a different view in regard to patents. In paragraph 307 of his report, he has recommended certain safeguards by way of revocation to suit Indian interests and points out that those provisions would be inconsistent with Article 5-A(iii) of the Convention. It is hoped that our Government would not venture into what is distinctly adverse to Indian interests. In Parliament there was a disclaimer recently on joining this Convention. This disclaimer would have to continue to govern the official attitude to the foreign approaches.

V. Seturaman
Retired Judge, Madras High Court



Plot to join Paris Convention...

'Suicidal, a betrayal... a subversion'

—V.R. KRISHNA IYER

■ *Six years after his retirement, former Supreme Court Judge V.R. Krishna Iyer continues to apply his razor-sharp intellect to issues of national interest. Here, we reproduce excerpts of his comments to* BLITZ *on the Paris Convention for the Protection of Industrial Property, and the disastrous consequences that would follow if India were to join it.*

This journal has repeatedly warned that such a move would ring the death knell of India's industry (see BLITZ *Nov. 30, 1985, and Sept. 20, 1986). We had earlier prominently featured the views of former Chief Justices of India, Hidayatullah and Chandrachud. Here we carry further brief comments from them (see box) together with a comment by Justice Shah, another distinguished former Supreme Court judge, to illustrate the amazing judicial consensus on this issue.*

I WOULD describe India's joining the Paris Convention as an act of abdication of government's responsibility to defend the people against multinational invasion of their right to health and freedom from sickness, their right to what I would call 'pharmaceutical swaraj'. Pharmaceutical multinationals hungry for markets in the Third World are utilising the Paris Convention on Patents as an instrument to gain a strangle-hold.

The provisions of the Convention are obviously detrimental: for one thing, it ensures the Indian producers will never be able to compete with the multinational giants. Secondly it ensures they will be unable to manufacture once patents are applied for by the multinationals—and they will do that the day you enter the Convention. There will be a flood of foreign companies getting patents by applications in India.

An obnoxious aspect of the Paris Convention is that it gives patents not only for products, but also for processes. In our country, the existing patents law, while it concedes private intellectual property through patentization of products, always encourages better, divergent processes so that innovations may be made. And that will reduce the cost also. But the Convention does not do that. It ensures there will be no competition as far as these foreign firms are concerned. We cannot allow that.

Treaty will violate existing law

Further, the Convention does not obligate the multinationals to manufacture here. The result is that they will quietly import what actually you can manufacture here and save on foreign exchange. So you will be the loser in several ways. And there is also no obligation for them to give you the know-how.

I cannot see a single advantage from the pharmaceutical angle, from the health angle of the people, to have these foreign companies hold our people's health to ransom and I say this for another reason: our people are poor. And we cannot afford to buy the high-cost products which they will bring here from outside.

You will be surprised to see that while I disagree even on fundamentals with certain Judges like, shall I say, Justice Shah or Justice Hidayatullah—they and I are not necessarily on the same wavelength as regards our value system—there is nevertheless such a consensus on this issue that that by itself is a guarantee that the juristic and the judicial view is against our entry into the Paris Convention.

Accession to the Convention would violate the existing patents act and a number of other legislations, especially done by Executive action (as is being presently contemplated. Ed.). It will be contrary to these laws and, therefore, invalid. Without an amendment in Parliament of all these enactments, they cannot do this.

However, neither the Cabinet nor the Parliament can get rid of the Indian Constitution which gives everybody a right under Art. 19 to become a manufacturer, freedom of trade, freedom of business, freedom of calling, all these things are in Art. 19. So any individual has a right to manufacture these pharmaceuticals. Even the Parliament cannot overturn that.

The only justification would be if there were grounds for a reasonable restriction. To my mind it is obviously an unreasonable restriction to stifle, muzzle and silence the producers in India in favour of manufacturers from abroad. It is grossly unreasonable, unfair and unjust, and, therefore, plainly violative of Art. 19.

From another angle it is violative of Art. 21 which says the right to life cannot be deprived of, except by those procedures established by law. My right to life as an Indian depends on my being able to buy medicines to cure myself of my maladies. But if the remedies are not available for a reasonable price on account of a Convention that gives foreign manufacturers free rein, then that is definitely violative of my right to life.

As Justice Chandrachud has said, the right to livelihood is implied in the right to life. I would say that the right to health is implicit in the right to life.

'A betrayal of the Indian people'

Art. 14 of the Constitution guarantees equality before the law and equal protection of the law. "A" must stand on the same footing as "B". But here what is happening is that the Indian manufacturer is discriminated against vis-a-vis a foreign manufacturer. Therefore, it would be violative of Art. 14. Thus, all these three articles of the Constitution are violated by accession to the Paris Convention.

I have no doubt that this would be a very perilous step on the part of the government, and a betrayal of the health interests of the common millions. That any government should consider appointing a committee to go into whether we should enter the Paris Convention at all, seems to me a violation of all previous statements of pharmaceutical policy in this country.

hold upon the markets of countries like India.

India today is able to produce, from the pharmaceutical angle, many of the items which it needs. The Hathi Committee report, which outlines the parameters of our nationalist pharmaceutical policy, had gone to the extent of recommending nationalisation of the foreign drug manufacturers. The report emphasized that we do not need these thousands of foreign brand names presently being dumped on the Indian market.

What we really need are the basic drugs, a very limited number, life-saving or otherwise essential drugs which will meet the needs of the people. These brand names now circulating are not only not those of life-saving or essential drugs, but also of unnecessary things which are made attractive by propaganda. But the elimination of the Indian competitor can only be achieved by legal processes, and they have hit upon the Convention as just such a process.

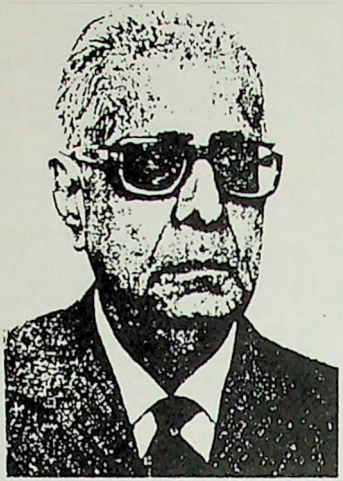
Patented path to disaster

Accession to the Convention of Paris means acceptance of various obligations under it. One of those obligations: that there must be free access to patentization by the multinationals which have their patents elsewhere and can make an application here. Under the Convention they would automatically get patents here.

So the entire pharmaceutical industry will suffer privatization through patentization, monopolization through patentization, foreign control through patentization, and total exclusion of the Indian industry through patentization. This is the stratgem being adopted by these multinationals. Do we want it?

I say this is sabotage of health swaraj. After having entered the Alma Ata Convention which has Health for All as its objective, what you are doing (by joining the Convention) is suicidal, what you are doing is a betrayal, what you are doing is a subversion of the very constitutional foundation which guarantees in its articles, equal right to health for every Indian.

Amazing legal consensus



M. HIDAYATULLAH

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INDIA will suffer if she joins the Paris Convention. Once she joins she cannot get out of it...for six years. During this period of six years, the (Convention's) baneful effects will flow and may well destroy many of our industries.

The Convention is an inflexible document. Framed in 1883, it has been revised only six times in 100 years. It cares little for the need for social change which is the crying need of the developing countries and does not speak in terms of public interest....we have to protect ourselves and not seek to be with those who need no protection!

I hope that India will not learn the hard way. Learning by experience is proverbially costly.

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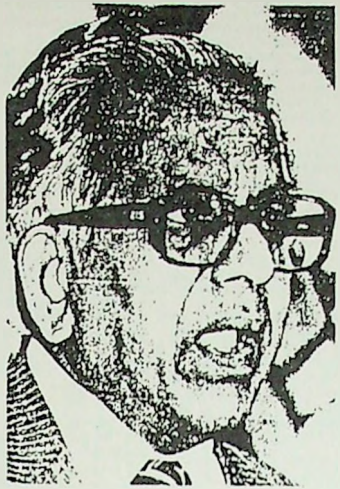

Y. V. CHANDRACHUD

"

IF India joins the Paris Convention, the monopoly of foreign patent-holders is bound to increase...the foreign patent-holder has no interest in the greater industrialisation of underdeveloped countries. He utilises these countries as a dumping ground to which he can export his patented goods.

What is worse, he can obtain a patent and not use it at all for making the patented goods...thus the monopolist patent-holder intensifies his stranglehold on the producers in underdeveloped countries by pursuing a policy which is wholly detrimental to the needs of such countries.

Accession to the Convention is fraught with grave peril to the Indian manufacturer and will not serve any public interest.

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J. C. SHAH

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IN my opinion, in signing the instruments of accession India will be signing a bond of slavery in favour of other developed countries whose industrialists are anxious to prevent any further development of the industrial base in India and simultaneously to destroy whatever has been achieved during the last two decades as a result of the protection afforded by the Indian Patents Act...

Subscribing to the Convention by India, apart from involving prejudicial consequences to the Indian economy, is open to the objection that it is contrary to the injunction contained in Art. 39(b) and Art. 39(c) of the Constitution.

"

Paris convention is the last straw: IDMA

Financial Express Bureau

BOMBAY, Aug. 9. – The Indian Drug Manufacturers Association has expressed alarm over the pressures mounted on the Government by the US Government to compel India to join the Paris Convention.

In a communication to the Government, IDMA today expressed its fears that "any amendment to Indian Patent Act 1970 will mean deathknell of the national pharmaceutical industry and in future years India will no longer be a country having low priced medicines..."

In fact, the prices of drugs and medicines will go up five to ten times within a few years as a result of the monopoly of import of essential and life-saving drugs by a single manufacturer and the removal of all competitive forces from the market, IDMA said. The convention bestows exclusive right of importation, manufacture and marketing to the patent holder.

A majority of new drug introductions in the last ten years have been effected by the national sector of the industry and many of them have been manufactured as bulk raw material in the country, IDMA observed. Some of these are already being exported to the Western world.

Export of pharmaceuticals has increased by 63 per cent in 1985-86 and the trend is likely to be accelerated in the future. Amendment of the patent act will slow down exports on the one hand and increase the price of drugs to the consumer on the other hand. As such, any amendment to the Indian Patent Act will cause long-term irreparable damage to the national interest and national priorities.

IDMA invited the Government's attention to the fact that India is a signatory to the Alma Ata declaration of Health for All by 2000 AD. The Government is playing a significant role in achieving this objective and there will be a substantial outflow of Government funds for the purpose. "The Government can ill-afford at this point to disturb the price structure which is operating within the country in competitive environment and take the risk of creating a monopoly situation of imported patented drugs by multinationals."

The association pointed out the following specific fallouts if India signed the convention: 1. Prices of drugs and medicines would go up and in a few years would match the western price because of the monopoly of imports allowed to multinationals. 2. Indigenous development of technology by the national sector will decelerates. 3. There will be an increase in the imports of costly substitutes and the value of such imports would go up to the extent of 300 to 500 in less than five years. 4. The export effort mounted by national companies for bulk drugs and pharamaceuticals will receive a severe setback and this will be matched by increased imports.

The letter pointed out that the industry today has reached a situation where the gap between export and import is minimum and it has not increased over the last ten years. On the contrary, it is showing a declining trend. The gap between imports and exports will widen if India signed the convention.

Many of the new discoveries of the world have been introduced in India in three-four years time after the enactment of the 1970 Act. The pre-1970 gap for introduction of new drugs was, on an average, eight to 10 years. The Indian consumer will be denied the availability of new drugs fast enough after its introduction in the western world at a reasonable price if India succumbed, IDMA said.

The price of pharmaceuticals are the lowest in the world and comparative products in the rest of the world, especially in the west, are 10 to 12 times higher where the Patent Act provides market monopoly to manufacturers, it said.

Also, the CSIR and other research institutes are on record that the Indian Patent Act has in fact stimulated indigenous research and development and have to fact contributed to technological upgradations and innovations during the last 18 years.

This has also been recognised in recent years by various ministries and special committees appointed to study the need for joining Paris Convention.

DECCAN HERALD
Bangalore, Saturday, July 30, 1988

Thought for the day

THEY are doing things on the screen these days that the French don't even put on postcards. — *Bob Hope*

Turning the screws

THE UNITED STATES estimates that it suffers an annual loss of $ 50 billion from patent violations across the world. This is no small amount for a country running an annual trade deficit of around $ 150 billion. So it is not surprising that the US has been working on a world wide agreement that would give more protection to US products. Senior US officials are currently in India to try to convince the Government to agree to a more rigorous protection of "intellectual property." The violation of US patents is not very significant in India; the phenomenon is more common in East Asia and Latin America. But India is one of the developing countries that until recently has been in the forefront of opposition to the international convention on patents.

The issue is a difficult one to resolve. The considerable expenditure that goes into research and development requires that the inventor of a product or process should be given some protection so that he can earn a reasonable return. However, such protection invariably also leads to a higher price which, especially in an area like drugs and pharmaceuticals, means a conflict between private gain and public interest. The issue is even more complicated in developing countries whose past experience has been that less than 5 per cent of patents granted to foreign companies have been exploited for domestic production. Clearly, patents here are used to pre-empt domestic production, the patentee preferring to meet demand through imports.

It is on this issue that developing countries have on the whole been opposed to the existing Paris Convention on patents. The convention was first signed in 1893, has been revised only six times since then, and, while supposedly according equality to all signatories, in actual practice discriminates heavily in favour of countries holding the most patents. It is not that the developing countries do not have any patent laws. These laws are, however, less stringent than those of the US and Western Europe and encourage local production rather than imports.

Under US pressure, intellectual property (along with services) was put on the agenda of the Uruguay Round of trade discussions. In the meanwhile, however, the US has continued to force individual countries to provide stricter protection to foreign products and processes. Under the threat of trade retaliation, this has worked to some extent in East Asia. The pressure is now being put on India. The US strategy appears to be to make a new international agreement a more attainable proposition through pressure on individual countries. The terms of this new agreement will ultimately depend as much on a common Third World platform as on the intensity of US pressure.

Generic drug market

US firms resent Indian inroads

By Shyam Kumar

BOMBAY, Aug. 4. – India's growing penetration of the United States' generic drug market has sparked off resentment among American manufacturers, some of whom have approached the US Administration asking for revocation of duty-free status for Indian exports.

The demand, coinciding with US Government's pressure on India to sign the Paris Convention on patents, has aroused fears that the most lucrative export market may become out-of-bounds for the Indian industry.

Ethyl Corporation, a bulk drug and chemical unit based in Richmond, Virginia, has filed a petition with the US Trade Representative, Mr. Clayton Yeutter, asking for revocation of duty-free status for ibuprofen.

The company justified its demand with the claim that "the flood of Indian ibuprofen into the US market is undercutting the price of US production." Some other manufacturers have also complained of dumping by Indian companies.

Ethyl Corporation in its petition said: "We believe ibuprofen industry in India, perhaps the whole pharmaceutical industry, is as developed and as competitive worldwide as is the industry in the US or any other country where ibuprofen is produced."

This claim may be true, but charges of dumping by Indian firms are unfair, according to industry sources here. They said India was quoting the same price for ibuprofen in the US as it did in Europe, and no European manufacturer has complained as yet. If the drug costs more for American manufacturers, Indian suppliers ought not to be blamed, they said.

Cheminor Drugs Pvt. Ltd., a Hyderabad-based company belonging to Dr. Reddy's group of companies, is the largest producer of ibuprofen in India, and has obtained the approval of the US Food and Drug Administration (FDA) to the US. It began its production of the drug in 1985 and produced 212 tonnes last year. More than 80 per cent of the drug is exported to the US, USSR, Japan, China, UK and other countries. Exports of ibuprofen has earned more than Rs. 25 crores for the company.

Industry sources said that the most attractive market for the industry is the generic market in Europe and the US and a host of Indian companies have turned to export of those bulk drugs and formulations whose international patents have either expired or are about to expire in the near future.

India has already earned a name in the world market as a leader in the manufacture of a number of bulk drugs like ethambutol, metranidazole, methyldopa, ibuprofen, mebendazole and sulfaxethazole. Drugs whose patents have already expired in the US and produced in India include chlorpropamide, lurazepam, methyldopa, tolnaftate, danazol, diazepam, ibuprofen, clonidine, metaproterenol, ampicillin, cephalexin, sulfamethoxazole and trimethoprim.

This year, patents for nalidixic acid and piroxicam are expiring, two other drugs produced in India. Other drugs whose patents are expiring in the near future include the following already made in India: albuterol, amoxicillin, miconazole, nifedipine, naproxen, alprazolam, atenolol, metoprolol, cimetidine, terbutaline, captopril and cisplatin.

Last year, out of the $30 billion US pharma market, generic drugs constituted $ four billion. It is estimated that this segment will grow to $11 billion by 1998. More than 40 drug formulations are also due to come off patent by 1992. This represents perhaps the biggest marketing opportunity for the Indian industry.

Everyone acknowledges the fact that the most important factor, which enabled India to penetrate the US market was the enactment of the Indian Patents and Design Act of 1970. Any move to amend the act will prove detrimental to Indian exports, industry sources said.

Apart from the quality of the drug concerned, US FDA officials inspect the production facilities for good manufacturing practices before approving it for imports. More than 15 Indian companies have already been approved by the US agency and applications of many more are pending. Approvals once granted are valid only for three years, and have to be renewed.

WORLD MARKETS

IMPORTANT PRESS CLIPPINGS
FOREIGN PRESS
OCCASIONAL PAPER NO-6.

NATIONAL LABORATORIES ATTACK NEW ARGENTINE PATENT PROPOSALS

If current Argentine patent legislation is modified to allow patents for pharmaceutical compounds, national laboratories will be prevented from utilising 70% of their compounds, since these will become subject to patent protection, says CILFA, the association representing the national industry, in a press release aimed at increasing public awareness of the consequences of the proposed changes for the national drug industry.

At present, the legislation stipulates that pharmaceutical compounds cannot be patented, but manufacturing processes can. Proposed changes in the patent law would permit patents for both pharmaceutical compounds and manufacturing processes.

According to CILFA, the national industry has been "obstructed, checked and many times prevented" from manufacturing drugs as a result of the co-ordinated actions of multinational enterprises. By a massive patenting of manufacturing processes, multinationals have, it says, been able to protect and monopolise virtually all drug intermediates on the world market. As soon as a national laboratory has started to manufacture a drug using its own or imported intermediates, multinationals have immediately threatened legal action on the pretext of patent infringement of manufacturing procedures.

The argument that patent protection would encourage multinational companies to invest in local production facilities is, according to CILFA, a complete fallacy – as witnessed by the fact that 430 drugs are already manufactured locally by multinational companies. CILFA points to the literature published in recent years on the technological problems experienced in developing countries as evidence that a patent system does not provide an effective instrument for the development of a national industry. It also cites the case of Brazil where, although patents are prohibited for both products and manufacturing processes, there has been a substantial increase in the local production of drugs.

The main objective of any change in the legislation, CILFA maintains, should be a strengthening of the national industry – in which case the legislation should make it "absolutely and completely clear" that no patents should be granted for either pharmaceutical compounds or manufacturing processes on the grounds that such products are indispensable to health. The introduction of patent protection for drugs would, it says, result in a loss of control over public health and a "total dependence on monopolistic interests."

ARGENTINA: NATIONAL COMPANIES CONTROL 50 PER CENT OF THE MARKET

The importance of the local pharmaceutical industry in Argentina has been emphasised by Sr Antonio Arguelles, president of CILFA (Centro Industrial de Laboratorios Argentinos), the pharmaceutical manufacturers association representing the interests of the country's national laboratories.

In an interview with the newspaper "La Nacion," Sr Antonio Arguelles pointed out that although the local pharmaceutical industry operates in competition with leading multinational companies, it has still managed to control 50 per cent of the market. This compares with Brazil, where national companies account for only 18 per cent of the market, and Mexico where they control scarcely 12 per cent. Furthermore, the local industry exports finished products to Paraguay and Bolivia and has established subsidiaries in Uruguay and Chile.

The general economic recession had a less serious effect on the pharmaceutical industry than on other sectors, Sr Antonio Arguelles said. The demand for drugs had fallen by only 9 per cent and most companies had been able to continue operating at full strength. However, he added, in order for the industry to continue working at its present rate, it was necessary for price levels to be governed by free market conditions rather than by political criteria. "Otherwise, chaos would destroy the industry and the general public would be deprived of any progress made within the pharmaceutical field."

. . . maintenance of antipatent law essential

Sr Antonio Arguelles also stressed the importance of preserving the country's antipatent ruling which stipulates that pharmaceutical compounds are not subject to patent protection on the grounds that they are indispensable for the preservation of health. "It is essential that the government adheres to this principle when drawing up its new legal instrument on patents," he said. Another important factor was the maintenance of an open drug compendium. Plans by the PAMI, the health insurance agency for pensioners, to implement a drug formulary containing only 341 products would go against the interests of PAMI beneficiaries and would also have a serious effect on the industry's level of production.

Finally, Sr Antonio Arguelles suggested that adequate credit facilities should be made available to the industry for the installation of new plant and equipment for the manufacture of drug intermediates as well as finished products.

NO PHARMACEUTICAL PRODUCT PATENTS IN DENMARK AS NEW LEGISLATION DEFEATED

The bill to amend the Danish patent law (1968) so as to permit ratification of four patent conventions, including the European patent convention (see Scrip No308, p5), fell unexpectedly at its second reading on May 24th, following a switch of the 24-seat Progress Party from support to opposition. Since the bill, which would have introduced amongst other things a pharmaceutical product patent, implied some relinquishment of Danish sovereignty, it required a vote in favour by five-sixths of the house.

In consequence, the conventions will not now be ratified and the bill's third reading on June 2nd concentrated on minor domestic issues, without the ratification clauses, and was passed uneventfully. This is not, however, necessarily the end for Danish pharmaceutical products. Under the 1968 Act the Secretary for Commerce has the authority to grant blanket permission for product patents to be introduced in particular industrial sectors. During the second reading he did not respond to a challenge from the Progress Party that he should renounce this power for the pharmaceutical industry.

The major criterion for use of this authority, that other countries in Scandinavia should have introduced such patents, has already been met. The government is believed to be embarrassed that Danish patent law has, for the first time in years, failed to keep in step with Swedish law (which introduced product patents on June 1st), and may thus favour the exercise of ministerial prerogative.

Some Danish industrial sources have suggested that vigorous lobbying by two companies, Dumex A/S and A/S GEA, played a part in changing the vote of the Progress Party. Others suggest that the lobby from the Handvoerker-Radet, the craftsmen's council representing some 40-50 thousand small businesses, was very much more influential. The two industry associations, the domestic manufacturers MEFA and the importers MEDIF, both supported the bill.

WORLD NEWS IN BRIEF

■ "No! to the proposed changes in the patent law," is the slogan of CILFA, the Industrial Centre of Argentine Pharmaceutical Laboratories, in its efforts to counteract the campaign initiated by foreign laboratories which is aimed at persuading the government to introduce modifications to existing legislation which prevents the patenting of pharmaceutical products. CILFA is warning that the success of the multi-nationals' campaign would result in "the destruction of the national pharmaceutical industry."

NO PATENTABILITY OF DRUGS IN NEW YUGOSLAV BILL

It is expected that a new Yugoslav Patent, Trademark, Models & Designs Law will be passed by parliament by the end of the year to take effect virtually immediately. Earlier reports had indicated that under the new law patents would give no rights to their owners to oppose imitation by Yugoslav companies, but would simply entitle the holders to low royalty payments. The latest reports are even more pessimistic: according to article 19 of the draft bill currently being considered by the authorities, there would be neither substance nor process protection for pharmaceutical products, agrochemicals (fungicides, insecticides & pesticides), synthetic fertilisers and alloys.

It is understood that an earlier version of this bill had been rejected by parliament, but that chances of passage of the new version are high. This is yet another blow to foreign pharmaceutical companies which had until now, co-operated with Yugoslav pharmaceutical firms, and provides another reason for them to pull out of Yugoslavia and stop co-operating with Yugoslav firms.

SPANISH INDUSTRIAL PHARMACISTS SAY NO TO DRUG SUBSTANCE PATENTS

The Spanish association of industrial pharmacists, AEFI, met in Barcelona on September 27th to consider the European patent system and its consequences for the Spanish pharmaceutical industry. The meeting, which was also attended by the Director-General of Pharmacy & Drugs, Dr A Lopez Casero, his deputy, Dr F Ferrandiz Garcia, and the Director-General of Chemical & Textile Industries, Dr J Angulo, reached a number of conclusions which confirmed that there is little enthusiasm among Spanish-owned pharmaceutical companies for patent protection of drug substances.

The participants, who included representatives of all major and many medium-size Spanish pharmaceutical companies, and some multinational companies, reached a majority opinion that, if Spain were to sign the European Patent Convention and the Community Patent Convention, "the Spanish balance of royalty income from patents, which is already negative, would deteriorate considerably as a result of the enforcement in Spain of many European patents." This would "seriously damage" Spanish-owned companies, they said.

. . . attitude to CPC

The participants agreed that, as long as the Community Patent Convention had not been ratified by all member states, signing the Convention was not a prerequisite for Spain's entry into the EEC: as long as Spain could avoid signing it, it should do so. If signing the CPC became a necessity, then the Spanish government should negotiate, as part of an overall package for joining the EEC, provisions that would make Spanish (Castillan) the fourth official language for Community Patents.

. . . and EPC

The participants also agreed that, since there was no obligation for Spain to join the European Patent Convention (EPC), it should abstain from doing so, since this would "seriously damage" manufacturers in Spain. If signing the EPC became unavoidable, care should be taken that this was not done simultaneously with the CPC, and that the use of Spanish as an official language should be approved. If Spain was to join the EPC, she should make specific reservations as per article 162.1.a of the EPC regarding any contradiction between the EPC and Spanish legislation on the protection of chemical, pharmaceutical and food substances, the participants said.

NO DRUG SUBSTANCE PROTECTION IN NEW FINNISH PATENT BILL

The proposed new Finnish patent legislation, which is now being discussed by a parliamentary committee and should become law in March, 1980, will provide process but not substance protection for pharmaceuticals. This is generally regretted by the non-Finnish international companies, although they welcome the extension of patent life to 20 years.

The new Finnish law, which has been drawn up with the advice of other Nordic countries and follows the principles of the European Patent Convention, does, however, contain a transition rule which would at some future date allow the authorities to change to pharmaceutical substance protection by ministerial order. According to observers, there is no chance of the transition rule being used for this purpose in the immediate future, but the chances of it happening at some time are not being ruled out. It is noted that the Finnish national pharmaceutical companies, which have benefited from the process-only protection, are no longer talking of never having a substance patent but about when it will come.

Under the bill Finland will be able to join the Patent Cobperation Treaty.

GREEK LAW SAID TO HAVE CANADIAN-TYPE COMPULSORY LICENCE PROVISIONS

First reports on the new Greek patent law passed by parliament last week indicate that a late amendment provides for compulsory licences for importing pharmaceutical products, probably similar to the Canadian system. This is causing serious concern in international pharmaceutical industry circles, since: (1) the variety of reasons for granting a compulsory licence for importing a drug patented in Greece is believed to be such that virtually all products and all Greek manufacturers would be eligible; (2) Greek manufacturers benefiting from a compulsory licence could re-export and compete with the original manufacturer in foreign markets where patent protection is lacking.

The situation is viewed as at least as serious as the one in Yugoslavia, since Greece, although not having the pharmaceutical manufacturing capacity and capabilities of Yugoslavia, is now a member of the EEC, with the membership agreement coming into force next year. The new Greek Patent Act, in respect of its compulsory licensing provision, is seen by international pharmaceutical industry circles as contravening the European Patent Convention, which should be ratified by Greece because of its EEC membership.

NEW THAI PATENT ACT PROVOKES OUTCRY FROM MANUFACTURERS

The recent passing of a Patent Act by the Thai National Legislative Assembly has provoked an outcry from multinational pharmaceutical companies because of the absence of a provision in the Act to cover the patentability of pharmaceuticals.

According to Mr Tim Anscomb, director of the Pharmaceutical Products Association (PPA), which represents the research-based manufacturers in Thailand, the absence of patent protection for medicines is discouraging the introduction of new medicines and hindering efforts to improve health care. The enactment of an effective patent law is the key issue affecting end-users of pharmaceuticals and the pharmaceutical industry in Thailand as a whole. Research-based companies are obviously reluctant to introduce new medicines when they can be legally imitated and marketed at lower, yet profitable, prices, Mr Anscomb declared.

The emphasis among non-research based companies on low price rather than quality has tarnished the image of the Thai pharmaceutical industry, said Mr Anscomb. Furthermore, far from benefiting consumers, copy products could lead to a slower return to full health as their formulation and effectiveness was often inferior to the original product.

In an interview with the Thai magazine, WEEK, Mr San Singhapakdi, acting secretary-general of the Thai Food and Drug Administration, acknowledged that imitated drugs were inferior to brandname products, particularly in terms of weight-accuracy, uniformity and bioavailability. Nevertheless, he added, the number of drugs currently available in Thailand was sufficient to meet the country's basic needs and the introduction of newly-developed drugs was not essential to the nation's health.

The acting secretary-general also pointed out that, because of their low price, Thai-produced drugs could compete effectively on the world market and were exported regularly to South America, the Middle East, Malaysia, Singapore, Indonesia, Hong Kong and Taiwan.

■ **The governments of Thailand and the United States have** signed an agreement under which the USAID will provide a loan of $4 million and a grant of $500,000 to the Thai Ministry of Public Health for a campaign to eradicate yellow fever. Both the loan and the grant will be used by the Health Ministry to finance the health improvement project during 1980-82, particularly in areas infested by yellow fever.

LEAVE PATENT ACT ALONE SAY CANADIAN GENERIC COMPANIES

In its position paper on changing the pharmaceutical patent laws, the Canadian Drug Manufacturers Association (CDMA), which represents Canadian-owned companies in the English-speaking provinces, has recommended that the section of the Patent Act dealing with pharmaceuticals should not be changed, but that multinational companies which show a commitment to engaging in research and development, raw material synthesis or export activities should be offered special incentives.

Replying to the suggestion put forward by the Pharmaceutical Manufacturers Association of Canada (PMAC) that there be a ten-year period of exclusivity for new drugs, the CDMA points out that once a compulsory licence is obtained, it takes an additional three years to obtain HPB approval for a copy/generic drug – thus the PMAC's concept would place research-based companies "in a virtual monopolistic market position for a period of 13 years . . . The public would gain little or nothing by allowing the multinationals 13 years of virtual monopoly to set drug prices," the CDMA declares.

The financial impact of generic competition on multinational companies is exaggerated, the CDMA claims, with the total sales of drugs under compulsory licences hardly exceeding Can$10 million ($8.6 million) per year, compared with total estimated pharmaceutical sales of Can$715 million ($614 million) in 1978. If the multinational companies feel they are suffering financial hardship because of generic competition, then, the CDMA suggests, they should come forward and submit their financial statements of the past five years, together with those of their parent companies, to the proper government authorities.

**Copies of the CDMA's position paper on changing the pharmaceutical patent laws are available through Scrip's Reader Service, Ref Can. 0 6. Price: £5.00.*

EFFECTIVE US PATENT LIFE ON NEW DRUGS AVERAGES ONLY 9½ YEARS

The average effective patent life on the 13 new drugs approved by the US FDA during 1979 was only 9.5 years, the lowest since at least 1966, according to private correspondence between Dr Martin Eisman, of the University of Rochester's Centre for the Study of Drug Development, and the US PMA

Dr Eisman prepared the following table for the PMA:

Year	Patented NCEs	Av Effect Patent Life (Yrs)	Year	Patented NCEs	Av Effect Patent Life (Yrs)
1966	10	13.6	1973	12	12.1
1967	16	14.4	1974	15	13.0
1968	10	13.5	1975	11	11.4
1969	8	12.7	1976	15	11.3
1970	14	14.4	1977	15	9.6
1971	12	12.2	1978	14	10.5
1972	6	10.9	1979	13	9.5

The PMA announced Dr Eisman's findings in a press release which highlighted seven of the 13 new drugs introduced in 1979 (Merrell-National's ritodrine hydrochloride, Yutopar; Upjohn's 25 hydroxyvitamin D_3, Calderol; Parke-Davis' meclofenamate sodium, Meclomen; Pfizer's prazosin HCl/polythiazide, Minizide; Abbott's continuous ambulatory peritoneal dialysis, Inpersol; Ortho's meclocycline sulfosalicylate, Meclan; and Lilly's fenoprofen calcium, Nalfon 200).

Commenting on Dr Eisman's findings, the PMA president, Mr Lewis A Engman, said "One doesn't have to be an economist to see the dampening influence this has on the industry's inclination to accept risk . . . Obviously, no firm can afford to commit itself to such large research costs if competitors are free to copy the resultant product before those costs can be recovered."

Scrip's Washington correspondent reports that the PMA's release and Dr Eisman's study both coincide with a new, strong wave of Congressional sympathy for the drug industry's patent-life predicament. This makes it all but inevitable that rapid action will be taken in early 1981 to extend drug patent lives, our correspondent says.

United States

VARIABLE DRUG PATENT TERMS MAY BE AN OPTION, SEMINAR TOLD

One option facing the new Congress in its effort to overhaul US drug patent laws is the possible establishment of variable lengths of patent protection, depending upon the cost and duration of R&D and regulatory approval procedures. This was suggested to the first 1980-81 Roche Foresight Seminar in Washington on November 12th by Dr Henry Grabowski, of the University of Rochester, New York.

Dr Grabowski pointed out that anti-infectives have about half the average R&D cost of other pharmaceuticals, and this fact could argue for their being given half the patent protection. Since the purpose of patents is to encourage innovation, Dr Grabowski suggested another option may be to grant extended patent lives to drugs that save the most money in cost of therapy. In Dr Grabowski's audience at the seminar were many legislative aides of senators and congressmen who have an interest in reforming the drug patent laws. It is generally expected that major legislative efforts will definitely be made in this direction during 1981.

Dr Grabowski pointed to recent statistics compiled by his university's Centre for the Study of Drug Development, showing that the average effective life of a US drug patent has fallen from 14.4 years to 9.5 since 1967. This will have a "nontrivial" adverse effect on the US industry, Dr Grabowski predicted. He referred his audience to UK data showing that, in terms of measured impact on R&D, drug patents are far more crucial than patents on most other products. For example, Dr Grabowski said, the UK studies had rated patents as affecting 64% of drug R&D, 25% of pesticide R&D, and a "negligible" amount of electronics R&D. Drugs, once developed, are simply too easy to copy, he said.

Dr Grabowski was sceptical, however, about the remedial effects of extending drug patent lives. This would not deter the flow of drug R&D overseas, nor would it have any impact on the development of orphan drugs – he recommended that reform of regulatory procedures in the FDA drug approval process still be viewed as the first priority in improving incentives to innovate.

Mr Alan Lourie, senior patent attorney at Smith Kline & French, told the seminar that if patent terms continue to diminish at their current rate, "compounds just won't be developed". He reminded his audience that the current 17-year patent term was set in the Congress of 1970, when regulatory premarket approval was not a factor. The US Supreme Court's recent strengthening of "method of use" patents generally would be a great help to the pharmaceutical industry, Mr Lourie predicted.

NATIONAL WORKING GROUP ON PATENT LAWS

OBJECTIVES

To discuss issues relavant and related to the Patent Laws and Paris Convention ;

To arrange for research and publication of papers relating to these issues ;

To help create a better understanding of these issues by organising meetings, seminars and public debates ;

To represent to the Government and those concerned with the formulation of policy on agreed views of the Group :

Publicise and organise publicity ;

in respect of India's and international patent and related laws and policies.

To forge a National Alliance of various Organisations/Forum/ Associations, etc.to work towards and campaign for patent laws and policy best suited for India's interests.