CHAPTER IV

IMPACT OF PATENT LAW ON CONSUMERS OF

PHARMACEUTICAL PRODUCTS

Patent is a monopoly for commercial exploitation of an invention. It means an exclusive right to make use, exercise or sell an invention granted to a person for a limited period in consideration of the disclosure of the invention. The idea in conferring such exclusive right is that it stimulates technological progress by inducing the inventor to disclose his discoveries instead of keeping them as trade secrets. By rewarding the inventor, it encourages research. It also provides an inducement to invest capital in new lines of production which might not appear profitable if many competing producers embarked on them simultaneously. But at the same time it must be remembered that every monopoly is liable to be abused and patent monopoly is no exception. Therefore sufficient safeguards in law are required to ensure that patent inventions are properly worked in the country to protect the public interest. In case of patents on drugs and medicines which are essential to the life and health of the community, there is every need to prevent such abuse of monopoly rights. The law has to reconcile the conflicting interests of the holder of the patent and the interest of the public.

In this context the study on the impact of the patent law on consumers of pharmaceutical products become relevant. For this purpose, a brief survey of the provision of the Patents and Designs Act 1911 and the Patents Act 1970 dealing with pharmaceuticals is made. Analysis of these provisions would reveal the extent of protecting consumer interest in pharmaceutical products. Impact of the TRIPs incorporated in the Final Act of World Trades Organisation dealing with pharmaceuticals is also studied.

**Patent system in India**

The patent system in India is currently regulated by the Patent Act 1970. It replaced the Patents and Designs Act 1911. A study of some of the relevant provisions of the Act of 1911 bring out ambiguities and deficiencies in that Act which were fully exploited by the foreign owned pharmaceutical companies called Trans National Corporations (herein after referred to as TNCs) to the detriment of Indian interests. This analysis also helps to see how the Patent Act 1970 tried to rectify these lapses to protect the pharmaceutical consumers of India.

**Provisions of the Patents and Designs Act 1911**

Under this Act, the life of the patent was for 16 years. The Act says

"The term limited in every patent for the duration thereof shall, save as otherwise expressly provided by this Act, be sixteen years from its date".

This term could be extended to a maximum of another ten years. The patentee may present a petition to the Central Government praying for further

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3 Patents and Designs Act 1911. Section 14(1).
extension of term. The Central Government or the High Court when the petition is referred to it may extend the term of the patent for a further period not exceeding ten years if it appears to it that the patent has not been sufficiently remunerative. Thus, a patentee on an invention relating to a drug could enjoy exclusive monopoly rights of producing, selling and distributing for a period of 25 years on the whole.

In addition to this the Patents and Designs Act 1911 did not categorically state what was patentable. The interpretation followed by the Patent office was that any new process for manufacturing a drug, whether old or new, was patentable. A new drug was also patentable provided the process of manufacture was described in the patent. The process, however, in such a case was not required to be new. This was possible because the patentee, while patenting a new drug could describe all the known and possible processes. Hence the product patent for drugs was implicitly recognised under the Act. In practice the patent holders, most of them being transnational corporations, made maximum use of this lacuna in the Act to prevent the indigenous firms from developing a new process to manufacture an existing product. Even an old process, so specified by the patentees,

4 Id., "Section15(1) and 15(6) which reads : (1)The patentee may present a petition to the Central Government praying that his patent may be extended for a further term, (6)If it appears to the Central Government or to the High Court when the petition is referred to it, that the patent has not been sufficiently remunerative, the Central government or High Court as the case may be, may by order extend the term of the patent for a further term not exceeding five or in exceptional cases ten years....."


6 Supra. n.2 paras 20,34 and 36.
could not be used by the indigenous firms for at least 16 years. Indian firms were also forbidden from processing a potential drug into formulations or importing it.\footnote{Joint Committee on Patents Bill, Evidence, 1965, Vol.1 pp 149-150. For example, a TNC was importing a drug at Rs. 8 per 20 tablets. It sued an indigenous firm, CIPLA, when the latter started importing it at Rs. 2 per 40 tablets. Chloramphenicol and metronidazole are among the other drugs for which the TNCs took legal action to prevent the indigenous firms from formulating quoted by ibid. Also see Hathi Committee Report (1975), p. 92.}

Thus the TNCs holding the patents enjoyed a monopoly status for at least 16 years. Of course, the law permitted indigenous firms to manufacture a new drug if it could develop or use a process not mentioned in the patent. But there is ample evidence to show that these patentees could prevent or delay the use of these new processes developed through indigenous efforts even when these were not specifically covered in the patents of the patent holders.

The facts of two cases decided by Bombay and Culcutta High Courts would disclose the coercive tactics adopted by the transnational pharmaceutical corporations to prevent the local industries from making use of the indegenously developed new process in the field of manufacturing drugs. In F.H.&B Corporation v. Unichem Laboratories\footnote{A.I.R. 1969 Bom. 255.}, Haffkin Institute, a public sector firm, worked out a process for manufacturing ‘tolbutamide’ from locally available raw materials. A patent was also obtained. Unichem Laboratories, an indigenous firm obtained a licence from it and started manufacturing the drug from 1961. Hoechst, a TNC filed a suit claiming
that 'tolbutamide' had been manufactured by Unichem on the basis of one of the formulae as mentioned in the Hoechst patent granted in 1956. The judgement of the Bombay High Court went in favour of Hoechst. What is important here is that Hoechst won the case despite the fact that its patent did not specifically mention Haffkine's process. What clinched the issue was that Hoechst's description was open-ended. One of the claims of the Hoechst was, in the opinion of Justice Vimadal,

"Wide enough to cover all methods of eliminating sulphur from thioureas whether desulphurisation is effected, by means of hydrogen peroxide or by the use of any other substance."9

It may appear to be strange but such widely worded claims were permitted under the Act of 1911.

The same patent was also sought to be used for preventing Bengal Chemicals and Pharmaceutical Works (BCPW), an indigenous firm, manufacturing another drug, chlorpropamide10. BCPW developed a new process for manufacturing it and obtained a patent in 1956. But in 1961, BCPW received a letter from Hoechst, alleging that BCPW had infringed upon the letters patent under which pfizer had been given a licence to produce it. BCPW sought legal action when it continued to receive such threats. Hoechst and pfizer on their part, filed a suit in the Calcutta High Court against BCPW. This time the judgement went in favour of the

9 Id. at p.264
10 In an unreported case of Calcutta High Court in Suit No.1124 of 1962. Quoted in supra n.5
indigenous firm. The judge concluded that BCPW’s patent was an independent one and it was not in any way influenced by Hoechst’s patent which in fact, did not relate to the manufacture of chlorpropamide at all.

These cases are quite revealing so far as the issues relating to development of indigenous technology and role of patent legislation are concerned. Hoechst’s patent did not refer to any specific drug. It was for the broad group of sulphonyl ureas. Nearly forty examples were given, but it was claimed that other compounds could be obtained easily from the general formula and chlorproparnide was one of them. Hoechst, however, failed to establish in the court that chlorpropamide could be or had been produced on the basis of the process described in their patent.

Even an expert witness appearing for Hoechst admitted\textsuperscript{11} that the information disclosed in the patent was not enough to carry out the experiment. Thus TNCs could enjoy product patent though such patenting was not explicitly provided under Act of 1911.

As has already been pointed out, one of the objectives behind the patent laws is to induce the inventors to disclose the inventions in return for the exclusive right of using the invention for a specified period so that knowledge may be diffused to facilitate further technological progress. The above mentioned cases illustrates how the TNCs used the then existing Indian patent law to suppress indigenous growth. Hoechst’s patent contained inadequate and misleading information which prevented and distorted the

\textsuperscript{11} \textit{Ibid.}
diffusion of knowledge. The patent was a general type, intended to cover a large and unspecified number of products and processes\textsuperscript{12}. Thus, other firms could be threatened with legal consequences even when their product was not at all connected with the patent. All the patent disputes are not fought out in a court of law. A mere threat may be enough deterrent in many cases\textsuperscript{13}.

A patentee may grant a licence voluntarily to any one on mutually acceptable terms. Compulsory licence is a licence granted by the Controller of Patents or by the Patentee as directed by the Controller to a non-patentee to use a patent on payment of royalties to the patentee. The Act of 1911 provided for the grant of compulsory licence in the case of misuse or abuse of patent rights\textsuperscript{14}. Under Section 22, a compulsory licence could be claimed if "the demand for a patented article in India is not being met to an adequate extent and on reasonable terms\textsuperscript{15}.

\textsuperscript{12} Significantly enough, in this case, before the hearing started, Hoechst approached BCPW in 1968 to settle the dispute outside the court which however BCPW refused.

\textsuperscript{13} For example Hindustan Antibiotic Ltd (HAL) a public sector firm, claimed that it had developed an indigenous process for manufacturing oxytetracycline (Hcl). A plant was set up and production began in 1961 without any external technical help. In the same year a TNC viz. Pfizer too started manufacturing the same drug HAL, however, unlike BCPW decided to suspend production rather than to contest Pfizer, which claimed infringement of their patent rights. See HAL, Annual Report, 1961 quoted in supra n. 5 at 1862.

\textsuperscript{14} Patents and Designs Act 1911, Section 22.

\textsuperscript{15} Id., Section 22 (2) (b).
It was pointed out\(^\text{16}\) that the foreign patentees did misuse or abuse their rights by importing the patented products rather than manufacturing it here in India and by fixing the prices at high levels, not allowing others to manufacture the product even when it was not itself engaged in the manufacture. It was also observed that the provisions regarding compulsory licences were "wholly inadequate to prevent misuse or abuse of patent rights, particularly by foreigners"\(^\text{17}\). It may be noted that not a single compulsory licence could be obtained because of the wording of the relevant provisions. The section unnecessarily demanded that it had to be proved that as a result of the misuse or abuse any trade or industry had been unfairly prejudiced. Obviously, it appeared very difficult to establish such a link\(^\text{18}\). Though these provisions were amended in 1950 and 1952 by adding Section 23 CC to deal specially with drugs, it appeared that the foreign patentees were still in a position to effectively prevent or delay the use of compulsory licence\(^\text{19}\).


\(^{17}\) Id. at p. 172.

\(^{18}\) Id. at p. 168.

Thus the need to change the patent law was felt immediately after independence. But it was not before the enactment of the Patents Act 1970 that the patent system could be changed\textsuperscript{20}.

**Provisions of the Patents Act of 1970**

Keeping these loopholes in mind Ayyangar Committee and other committees appointed by the Government recommended for substantial changes to the 1911 Act. After overcoming tremendous resistance India enacted the Patents Act 1970. The Patents Act 1970 introduced revolutionary changes in the Indian patent system and more particularly in the area of patents for inventions relating to drugs and medicines. It provided a stimulus to the indigenous pharmaceutical industry. A major departure was made from the patent systems of Great Britain, the U.S.A. and other Countries in certain crucial areas.

An important feature of the Act of 1970 is the special provisions regarding drugs and few other products. The life of the drug patents has been reduced from 16 years in the previous Act to a maximum period of seven years\textsuperscript{21}. A patent is sealed after it is granted.


\textsuperscript{21} Patents Act 1970, Section 53 states: “Term of Patent: (1) Subject to the provisions of this Act, the term of every patent granted under this Act shall - (a) in respect of an invention claiming the method or process of manufacture or a substance, where the substance is intended for use or is capable of being used, as food or as a medicine or drug, be five years from the date of sealing of the patent or seven years from the date of the patent which ever is shorter...”
The Act categorically states that drugs and those manufactured by chemical processes can be patented only for a new method or process of manufacture and not for products as such. Thus, any firm whether foreign or indigenous inventing a new drug could at best patent the process of manufacturing it, provided it is new. Unlike in the previous patent regime, it cannot patent all the processes known to it even if these are new for a particular drug. Only one method or process the best known to the applicant can be patented.

The Act practically eliminated the monopoly status enjoyed by the patentees till then. The indigenous firms could immediately manufacture the new drugs if it could use an old process or develop a new one not mentioned in the patent. Even when they can't, the period of monopoly of the patentee would be significantly shorter. Under the provisions of compulsory licensing, manufacturing by non patentees can begin even earlier.

Every patent relating to processes for manufacturing drugs has to be endorsed with the words 'licences of right' after three years of the date

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22 Section 5 reads: "S.5 Inventions where only methods or processes of manufacture patentable - In the case of invention -
(a) claiming substances intended for use or capable of being used as food or as medicine or drug.
(b)......no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable."

23 Supra n.10.

24 Patents Act 1970, Section 10 (5).

25 Id., Sections 84 & 85.
of sealing. This implied that anyone is automatically entitled to a licence from the patentee for using the patent on payment of royalties, the maximum rate being fixed at four per cent of the ex-factory sales.

Even before expiry of three years from the date of sealing, the controller is empowered to grant a compulsory licence and fix the rates of royalties if "it is necessary or expedient in the public interest." There is also a special provision in the Act regarding the use of patents by the Government. Anytime, a patent may be used for official purposes, including those of public undertakings. The maximum royalty payable for such a use in case of drugs has been fixed at four per cent of the ex-factory sales.

Impact of the Act on the pharmaceuticals

The indigenous firms were quick to respond to the favourable provisions in the Act of 1970. The complete elimination of product patent brought about significant changes in the pharmaceutical industry in India. The result is summed up in the words of I.A. Modi, Managing director of Cadila Laboratories:

"The real turn for us and for the Indian drug industry came in 1970 when the Indian Patent Act was implemented. Until then we were prevented by the old

26 Id., Section 87.
27 See id., Section 88.
28 Id., Section 97 (1).
29 See id., Sections 99 and 100.
British Act from manufacturing a patented product. The Government introduced a process patent instead: the industry was allowed to market products with a different process.

"With our new-found freedom, Cadila developed its own processes for any product introduced in the world market...."30

Thus new drugs began to be manufactured in India much earlier compared to the previous regime31. Moreover, the competition that followed among the foreign multinational companies and the indigenous firms reduced drug prices in India below the international levels32.

Impact of the Patent Act 1970 on Prices

30 I.A. Modi, Managing Director of Cadila Laboratories, Minutes of the Director’s Meet (1993) quoted in supra n.5

31 Glaxo, TNC introduced abroad an anti-ulcer drug, ranitidine (Glaxo brand, Zantac) in 1981. By 1985 an Indian Company Ranbaxy put the drug in the Indian Market followed by many other Indian firms - Dr. Reddy’s Laboratories, Lyka, Albert David etc. Other examples of drugs which were introduced by Indian Companies in India within 4 years are Sulbutamol (anti-asthmatic) mebendazole (anti-helmenthic), naproxen (anti-rheumatic), Captopril (anti-hypertensive) norfloxacin (anti-bacterial). See Tables in Annexure I.

32 See Tables in Annexure II. This is revealed in a comparison of the prices of a sample of drug products in India with those countries, where per-capita income and wage costs are similar to India’s. Prices were lower in India for drugs considered in the annexure. See also Prasad & Bhut, "Strengthening India’s Patent systems: Implications for pharmaceutical sector", Economic and Political Weekly, May 22, 1993 p.1037.
In the prices of drugs and pharmaceuticals there had been substantial reduction after the enactment of 1970. A committee of the US Senate had commented in 1959 that prices of certain drugs and antibiotics in India were amongst the highest in the world. This was before the enactment of the Patent Act 1970. It is noteworthy that prices of drugs in India are now amongst the lowest in the world. In most countries which followed product patents, the prices are high.

The tables in Annexure show that the prices of important drugs in India have risen in 1992 compared to 1986 though marginally in many cases. If we compare the prices of some drugs in India and other countries, we can notice that drug prices are comparatively lower in India. Among the Asian countries Indonesia and Srilanka joined Paris Convention in 1950 and 1952 respectively. Indonesia, under its liberalised policy has accepted product patents in pharmaceuticals. Interestingly the prices of important drugs in that country, are very much higher compared to prices in India. It may be due to product patents introduced in that country.

Impact on Exports

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34 Supra n.33.

35 Ibid.

36 Ibid.
The dynamism witnessed among the indigenous firms following the introduction of the Patent Act 1970 is also indicated in the sharp rise in the exports of drugs and pharmaceuticals in 1970's and 1980's. In fact India is now a net exporter of drugs and pharmaceuticals. But for the Patent Law of countries like U.S., and Germany, which recognise product patents, India's exports would have been even higher. These countries do not allow imports of patented drugs from India. India exports drugs to these countries after the expiry of the patents.

Pressure brought on India to change the patent laws

In the 1980s the developed countries started taking concrete steps to force India to modify its patent laws. India as a member of General Agreement on Tariffs and Trade (here in after referred to as GATT) was bound by its principles and rules. The role of GATT was traditionally restricted to international trade in goods. It did not extend to intellectual property like patents, copy rights and trade marks, or services. Hence the Patents Act, 1970 in no way violated the GATT principles. In 1986, a new round of trade talks started at Punta del Este in Uruguay.

37 India exports a large number of bulk drugs - ampicillin, chlorpropamide, pyrazinamide, trimethoprim, diazepam, ethambutol, nifedipine etc. See Annual report of IDMA 1992. (IDMA stands for Indian Drugs Manufactures Association)


The developed countries proposed and succeeded in including Trade Related Aspects of Intellectual Property Rights (hereinafter referred to as TRIPS) as part of the Uruguay Round of Multilateral Trade Negotiations.

It was alleged that the provisions on TRIPS closely resemble the submissions made by the American, Japanese and European business communities to the negotiating committee\(^4\). The developed countries were fighting among themselves on some issues like farm subsidies. But they unanimously supported TRIPS. These countries attached tremendous importance to TRIPS in the Uruguay Round of talks\(^4\).

The Uruguay trade talks were over in December, 1993. Countries like India who initially opposed TRIPS have been subjected to different kinds of pressures. The U.S. in particular had threatened India with retaliatory action unless India revises her patent laws\(^4\). Under the Special 301 intellectual property provisions of the Omnibus Trade and Competitiveness Act of 1988, the U.S. Government is empowered to take retaliatory action against any country which deny adequate and effective intellectual property protection. The US National

\(^{40}\) Id., at pp. 28-29.


\(^{42}\) In April 1992, the U.S. President suspended the duty free benefits under Generalised System of Preferences (GSP) to imports of pharmaceutical and chemical products from India on the ground that India has failed to provide effective protection to American Intellectual Property. Quoted from Sudhip Chowdhuri. "Dunkel Draft on Drug Patents", Economic and Political weekly, September 4, 1993, p.1861.
Trade Estimates Report of Foreign Trade Barries 1991 states that India's patent protection is weak and has especially adverse effect on US pharmaceutical and chemical firms. According to its report many US invented drugs are widely reproduced since patent protection is not available. The United States Trade Representative too alleged that "as a result of total lack of protection for certain classes of investigations, particularly pharmaceuticals, many US patented products are widely pirated."

The pressures exerted by U.S. ultimately might have worked. India accepted the TRIPS, though there is strong and articulate popular opinion in the country against the terms set by the developed countries through TRIPS.

**Provisions of the TRIPS Agreement**

The aim of this agreement is to enforce globally tough standards in respect of several forms of intellectual property including patents. Out of all the provisions of the Final Act, the agreement on TRIPS is considered to be the most contentious part. A critical study of these provisions would reveal that health related needs of the developing countries were totally ignored in formulating these provisions.

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44 Ibid.
45 Supra n. 39 at pp. 24 & 25.

There was also strong demand that the GATT issues be examined by a Joint Parliamentary Committee before the Government takes a stand on them. See also Ammu Balachandran, "Patenting a product", *The Hindu*, July 4, 1993 at Sunday Magazine.
The preamble of the TRIPS Agreement “recognises the need for multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods.”46 The preamble also explicitly “recognises the underlying public policy objectives of national system for the protection of intellectual property including developmental and technological objectives.”47 Article 7 of the TRIPS agreement provides that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and transfer and dissemination of technology, to the mutual advantage of the producers and users of technological knowledge in a manner conducive to social and economic welfare and to balance of rights and obligations.”48 Similarly, the Agreement also provides that “Member may, in formulating or amending their laws and regulations adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development provided that such measures are consistent with the provisions of TRIPS agreement”49.

These are laudable objectives and principles. In spite of these provisions, substantive provisions in the Agreement do not provide for any obligations on the patent holder to be able to safeguard these national

46 TRIPS, Preamble. TRIPS stands for Trade Related aspects of Intellectual Property Rights, herein after referred to as TRIPS.
47 Ibid.
48 Id., Article 7, (Emphasis is added).
49 Id., Article 8.
interests mentioned in the preamble and Articles 7 and 8. According to Article 27, “the patents shall be available for any invention *whether products or processes* in all fields of technologies provided that they are new, involve an inventive step and are capable of industrial application*50.

TRIPS agreement has totally changed the aspect of ‘working of the patent’. ‘Imports’ are generally not regarded as ‘working of the patent’ in the Indian patent law. The patent holder had an obligation to work the patent in the country which grants the patent. It was considered as an important element of the patent system. The TRIPS Agreement however, provided that “patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and *whether products are imported or locally produced*”51. The implication of this is that patent holders will have no obligation towards the country conferring the patent rights under the new system to produce the patented product in that country. There will thus be free flow of imports of patented products.

Of course, the TRIPS provides for authorisation for uses of patented product by the country granting patent. Article 31 of TRIPS deals with other use without authorisation of the right holder52. It could be extended to measures necessary to protect health and nutrition and to promote the public

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50 Id., Article 27 (1), (Emphasis added).
51 Ibid. (Emphasis is added).
52 Id., Article 31.
interest in sectors of vital importance to their socio economic and technological development, provided that such measures are consistant with provisions of TRIPS Agreement. These provisions are considered to be in no way comparable to the usual provisions of ‘compulsory licensing’ or ‘licence of right’ provided under Indian patent laws for nonworking of the patent.

Under the TRIPS agreement period of protection, “shall not end before the expiration of a period of twenty years counted from the date of filing”. Since the patentability extends to products and processes, it may be pointed out that the term would be applied for twenty years for product patent in the chemical field, including drugs and pharmaceuticals.

The agreement also provides for reversal of burden of proof during process patent regime for civil proceedings in respect of infringement of the rights of the patent owner. The onus of proving that the process used by enterprise is totally different from the patented process would lie with the defendant and he will have to prove that he is not guilty of infringement.

A general grace period of one year from the beginning of 1995 to all countries for applying the provisions of TRIPS Agreement is recognised. The developing countries have been allowed further four years to implement

53 Ibid.
54 Id., Article 33.
55 Id., Article 34(1).
56 Id., Article 65(1).
the Agreement. However, the developing countries who do not extend product patent protection will have further period of five years to recognise product patent in their national laws. Thus countries like India will have a period of ten years to apply product patent for chemical based products including pharmaceuticals.

However, there is an obligation under TRIPS to receive applications immediately from 1995 for product patents for pharmaceuticals and agrochemicals if product patent is not available in the domestic laws of a country. It also provides for another obligation for grant of exclusive marketing rights to the applicants of product patents for pharmaceuticals and agrochemicals.

It provides that the new World Trade Organisation (WTO) dispute settlement procedures will apply to the TRIPS Agreement. However, during the first five years commencing from 1995 the Council for TRIPS will examine scope and modalities for complaints.

Critique of TRIPS Agreement

TRIPs when implemented will bring about drastic changes, among others, in

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57 Id., Article 65 (2).
58 Id., Article 65 (3).
59 Id., Article 70 (8).
60 Id., Article 70 (9).
61 Id., Article 64 (3).
the pharmaceutical industry in India. The gains from the Patents Act 1970 will be negated. The situation in fact will be worse than that under 1911 Act. TRIPS takes away the sovereign right of the countries to enact laws to suit the needs of its people. It categorically states that they will have to implement the provisions of the agreement in their own legal system and practice. It will force India to change its Patent Act 1970 beyond recognition. Already many studies indicated that the different aspects of TRIPS will adversely affect the interest of the developing countries.

**Longevity of patent rights**

India will now have to recognise and grant product patents. The patent holder will have not only the sole right to produce but also to import. Thus when a foreign firm introduces a new drug abroad and gets a patent for it, indigenous firms will be prevented from manufacturing for domestic market or for exports or importing it. This prohibition lasts for 20 years i.e. during the life of the patents as agreed in TRIPS even if they can develop their own processes of manufacturing it. This is in sharp contrast to the present situation. As pointed out earlier, the non-

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62 *Id.* Article 1 (1)

at least had the right to manufacture a new drug under the provisions of 1911 Act, provided it could use or develop a process not mentioned in the patent.

In the case of medicines it seems patents are available in USA for usage form, dosage form and combinations and the same would be extended to other countries on implementation of TRIPS provisions. The table gives an idea of new combinations for which patents have been taken in USA even when the product patent on the basic drug expired long back.

**Procedural implications**

The provisions dealing with burden of proof in the TRIPS would also be vulnerable for misuse by powerful foreign pharmaceutical industries to curb competition from others particularly the small companies, even when their process may be different.

**Adverse impact on prices**

With no one to compete against them, the TNCs can afford to charge higher prices. Official price control measures are unlikely to be effective. The TNC's may not be interested in manufacturing the drugs in India but try to import to India. They may also refuse to import to India unless their terms including exemption from price controls are met. Such threats will in all likelihood force the Government to yield to any price particularly if drugs are of life saving nature. Under the 1970 Act, a

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64 Ibid.

65 see the table in the Annexure III.
patent can be revoked if "the demand for the patented article is not being met to an adequate extent or on reasonable terms from manufacture in India." No such safeguards have been provided in the TRIPS. In TRIPS, failure to provide the product on reasonable terms is not cited as a justification for punitive action.

The decision of the patentees about the extent of manufacturing, imports and exports from a particular country, especially when a patentee is a TNC, depends on their global strategy of operations. It will not depend on the needs of the country granting patent rights.

**Transitional Concession: An Empty Shell**

The Agreement provides for transitional period of 5 to 10 years for developing countries for implementing the TRIPS agreement. This provision for transitional period has been virtually invalidated by the provisions in Article 70.8 of the TRIPS agreement which insists member countries to provide for means for acceptance of product patent applications with immediate effect. According to Article 33, the term of the protection, i.e. the patent rights, are available to the holder from the date of filing of the patent application. The composite interpretation of these Articles would virtually exclude domestic enterprises from developing process technologies.

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66 Patents Act 1970, section 90 (a) (ii).
67 See *Supra* n. 55 to 57.
68 See *supra* n. 54.
for any new product from the date of the agreement. Thus, there is a clear distortion in providing for transitional period until the establishment of product patent regime.

**Working of patent: a non-issue**

It may be stated that this agreement is a "Charter of Rights" for the patent holders and there are no specific obligations towards the country conferring patent rights. The element of 'public interest' is totally absent in the Agreement. The interest of the consumer which is the primary obligation of the patent system has been ignored. There is provision for allowing the patent rights without discriminating 'imports' against domestic production. This is completely contrary to the provisions of the present patent law which states that patents "are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article." Apart from this there is no provision for 'compulsory licensing' for 'commercial purposes'. Unless there is such provision, public interest would not be served at all and there would be no way to ensure easy availability of the patented product through commercial channels.

The member countries have to fulfill the obligations immediately from the date of entry of WTO. India became a member of WTO on 1st January 1995. To satisfy the requirements, the Government immediately introduced the Patents (Amendment) Bill, 1995 which was

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69 See *supra* n. 23.

passed by the Lok Sabha. It lapsed in the Rajya Sabha due to the
dissolution of 11th Lok Sabha. However, a study of the provisions of the
Bill is relevant to enable one to forecast the prospective legislation that may
come into existence at any time.

**Salient features of the Patent (Amendment) Bill 1995**

From the Preamble of the Bill it is clear that the Bill sought to
achieve three objectives.

(a) to make the Patent Act 1970 to be in conformity with obligations
under the TRIPS agreement,

(b) to adopt measures consistent with the TRIPs Agreement, and

(c) to take steps to protect public health and nutrition and to promote
public interest in sectors of vital importance to the socio-economic and
technological development.

A provision was made in the form of amendment to section 5 of the
Act of 1970 to incorporate patent rights for pharmaceutical products. It
provided -

"a claim for patent of an invention for a substance itself
intended for use, or capable of being used, as medicine or
drug."\(^71\)

\(^71\) The whole Section 5 of the 1970 Act was re-numbered as subsection (1) of section 5 and the
amended provisions are re-named as sub-section 2 of section 5. S. 5 (2) reads;

"Notwithstanding anything contained in sub-section (1), a claim for patent of an invention for a
substance itself intended for use or capable of being used, as medicine or drug may be made and
shall be dealt without prejudice to the other provisions of this Act, in the manner provided in
chapter IV A." For the text of the Bill, see (1995) 2 Comp. L.J. 33 (Statutes)
The controller of the patents is empowered "to grant exclusive right to sell or distribute the article or substance"\textsuperscript{72} after being satisfied that the applicant complied with the patentability requirements of the Act.

The exclusive right of the applicant or his agents or licensees to sell or distribute any such article or substance used as drug, whether the invention has been made in India or outside is recognised. But to claim such exclusive marketing rights in India, the right of patent must have been approved by such other countries where an application has been made claiming for such rights\textsuperscript{73}. Implication of this provision is that if in any other country in which such claim has been made and rejected for identical article or substance, he cannot claim such exclusive rights in India.

Compulsory licences, can be given only when the patented drug is not available either by indigenous production or by importing. The provisions of the Bill says, "working of the invention shall be deemed to be selling or distributing of the article or substance"\textsuperscript{74}. 'Patented article' means an article for which exclusive right to sell or distribute has been granted. By implication, it means working of the invention need not be by way of manufacturing in India.

\textsuperscript{72} Id., section 24 A (3).

\textsuperscript{73} See id., section 24 B.

\textsuperscript{74} See id., section 24 C.
The Central Government can authorise persons other than the person to whom exclusive marketing rights have been granted to sell the same article or substance if it is satisfied and thought it expedient in public interest. The Bill also enables the Central government to direct that such substance or article for sale and distribution of which rights have been granted “be sold at a price determined” by the authority specified by it.75

**Patent Bill 1995: A critique**

The foregoing discussion reveals that the Bill was one of the most ill drafted legislations. The whole objective provided in the preamble of the legislation appears to be not to satisfy the requirements of the people of this vast country but to suit demands of international big brothers who coerced India to sign TRIPs.

A critical analysis of some of the provisions of the Bill reveals that it will not be able to protect the interests of the large number of consumers of pharmaceutical products. These provisions have been incorporated obviously in pursuance of Article 70.8 of the TRIPS agreement. Section 24 C in the Bill would negate the spirit of Section 90 of 1970 Act dealing with compulsory licensing. With this new section, the only ground on which a compulsory licence can be granted is non availability of products at reasonable price. This will be beneficial only if the products are manufactured in India. If the products are

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75 See Id., section 24 D.
made available by way of import, such licence will be of no use and naturally any one would hesitate to apply for compulsory licence.76

The price control mechanism contemplated in Section 24-D (2) of the Bill also appears to have the same fate.77 If the product is not manufactured in India, the imposition of price control may cause its withdrawal from the market since the Government has no control on the manufacture. Since the working of the invention is not mandatory the possibility of technology development which is the enshrined objective of TRIPS in pursuance of which this Bill had been introduced, will also become difficult. Only by the licensing process our industry can develop the product. In that case industry has to pay high royalty for such products and it will be difficult for them to make the drug available at reasonable price. The net result is that domestic industry will face major setback and the consumer will have to pay increased prices for drugs.

The provisions of the Bill and new the Drugs Policy clearly indicate the limitations of the country to legislate for the nation according to the needs of its people.

It appears that all these developments are part of the globalisation process. This globalisation intends to allow the big business gaints like TNCS to have unrestricted business operations in the developing countries. General Agreement on Tariff and Trade (GATT) and the WTO are the

77 Id. at p.7.
platforms used by them through which they have been attempting to impose the terms of globalisation. Few big business interests with collaborative arrangements with foreign corporate giants may favour these provisions, but informed popular opinion in the country is against to the terms imposed by the developed countries through TRIPS. These provisions come into conflict with not only the existing laws including those dealing with protection to the consumers of pharmaceutical products but also with India's fundamental law, the Constitution itself.

India's dependence on other countries for technology is shown as one of the main reason which has put pressure on India to such changes in our patent laws. This dependence was considered to have far reaching implications in today's unipolar world. Apart from the dependence on foreign technology the political and economic weaknesses in India have made her vulnerable for such pressures to change patent regime.

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78 Ammu Balachandran, 'Patenting a Product', The Hindu, July 4, 1993 (Sunday magazine).
80 Ibid. The fall of Soviet Union has made the world a unipolar world with the U.S. as the only superpower.