Impact of Patent System in India on Indigenous Drug Firms

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A demand is often made by certain quarters to modify the Patents Act of 1970 to make its provisions less restrictive for the patentees. This paper examines the experience under the Patent and Designs Act of 1911 to argue that such a change will go against indigenous efforts to develop processes and manufacture drugs.

THE objective of this article is to briefly relate the experience of the indigenous drug firms with the Patents and Designs Act, 1911 in the context of the Patent Act, 1970 which replaced the former in 1972.

The Patent and Designs Act, 1911 did not categorically state what was patentable.[1] 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.[2] Under the Act of 1911, the indigenous firms have been legally prevented from manufacturing most of the new drugs introduced by the transnational corporations, during the life of the patent secured by the latter, i e, for 16 years, which could be extended to a maximum of another 10 years if the working of the patent had not hitherto been sufficiently remunerative to the patentee.[3] This had been possible because, as N R Ayyangar who was appointed by the Government of India to examine the patent law in India observed, the patentee, while patenting a new drug, could describe all the known and possible porcesses.[4] Actually the TNCs did so, as the experience of the indigenous firms suggests.[5] Even an old process, so specified by the TNCs, could not be used by the indigenous firms for at least 16 years. The latter were also forbidden from processing a patented drug into formulations or importing it.

The TNCs asserted their patent rights to proceed legally against firms which tried to manufacture or import the patented drug. Thus, Hindusthan Antibiotics Ltd (HAL), a public sector firm, e g, claimed that it has developed an indigenous process for manufacturing oxytetracyline Hcl. A plant, in fact, 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 had to suspend production as Pfizer took legal action alleging infringement of patent rights.[6] 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.[7] Chloramphenicol and metronidazole are among the other drugs for which the TNCs took legal action to prevent the indigenous firms from formulating.[8]

The manufacturing activities of the indigenous firms were restricted to the old drugs or those new drugs for which it could develop new processes of manufacture. We will now discuss two cases which will give an idea about how the TNCs 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 TNCs.

Haffkine 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 from 1961. Hoechst, a TNC, however filed a suit claiming that tolbutamide had been manufactured by Unichem on the basis of one of the formulas as mentioned in the former's patent granted earlier in 1956. The judgement of the Bombay High Court delivered in 1968 went in favour of Hoechst.[9] What is important to note 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 Hoechst was, in the interpretation of the judge:

> "Wide enough to cover all methods of eliminating sulphur from thioureas (to manufacture Tolbutamide) whether desulphurisation is effected by means of Hydrogen peroxide (as specifically mentioned by Haffkine) or by the use of any other substance[10] (phrases within brackets ours).

Strange as it may appear, such widely worded claims were permissible under the Act of 1911.

The same patent was also sought to be used for preventing Bengal Chemical and Pharmaceutical Works (BCPW), an indigenous firm, from manufacturing another drug, chlorpropamide. BCPW developed a new process for manufacturing it and obtained a patent in 1959. But in 1961, BCPW received a letter from Hoechst, alleging that the former had infringed upon the latter's patent under which Pfizer had been given a licence to produce it. Denying the allegation, BCPW sought legal action when it continued to receive such threats. Hoechst and Pfizer, on their part, filed a suit in 1962 in the Calcutta High Court against BCPW.[11] This time the judgement went in favour of the indigenous firm. The judge concluded that BCPW's patent was an independent one, not in any way influenced by Hoechst's patent which, in fact, did not relate to manufacture of chlorpropamide at all!

The case is quite revealing so far as the development of indigenous technology and the 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. Forty examples were given, but it was claimed that other compounds could be obtained easily from the general formula and chlorpropamide 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 that the information disclosed in the patent was not enough to carry out the experiment. But Hoechst could not give specific directions as to how to proceed. One of the specifications, in fact, was found to be chemically incorrect.[12] Significantly, out of the 40 examples provided, none referred to chlorpropamide.

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 case illustrates

how the TNCs used the Indian patent law existing then to suppress indigenous growth. It is not only that Hoechst's patent contained inadequate and misleading information which prevents and distorts the diffusion of knowledge. The patent was of a general type, supposed to cover a large and unspecified number of products/processes. 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 deterrant in many cases. Significantly enough, in 1968, before the court hearing started, Hoechst approached BCPW to settle the dispute ouside the court, which however the latter refused.[13]

Compulsory licence: An indigenous firm intending to manufacture a drug is required to obtain a licence from the patentee concerned, if the process of manufacture to be used is covered by the patent. Under the Act of 1911, this was the requirement even if the process in question was well known (but even so had been mentioned in the patent as in the case of new drugs discussed above) or additional technical data were necessary to implement the process and these had been developed by, or obtained from, other sources. Obviously, a patentee may grant a licence voluntarily to anyone on mutually acceptable terms. Compulsory licence is a licence granted by the Controller of Patents (or by the patentee as directed by the Controller) or 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 case of misuse or abuse of patent rights.[14]

The Patents Enquiry Committee reported in 1950 that the foreign patentees did misuse or abuse their rights, e g, by importing the patented product rather than manufacturing it here, fixing the prices at high levels, not allowing others to manufacture the product even when it was not itself engaged in manufacture.[15] But, as the Committee observed, the provisions regarding compulsory licences were "wholly inadequate to prevent misuse or abuse of patent rights, particularly by foreigners".[16] The Panel on Fine Chemicals, Drugs and Pharmaceuticals, appointed by the government also reported earlier in 1946 that not a single compulsory licence could be obtained because of the wording of the relevant provisions.[17] For example, under Section 22, a compulsory licence could be claimed if "the demand for a patented article is not being met to an adequate extent and on reasonable terms". As the Patents Enquiry Committee commented, the Section unnecessarily also demanded that it has to be proved that as a result any trade or industry had been 'unfairly prejudiced'. Obviously, in practice it appeared very difficult to establish such a link.[18]

The provisions regarding compulsory licence (Sections 22 and 23) were amended in 1950, following the recommendations made by the Patents Enquiry Committee in its interim report submitted in 1949.[19] In 1952, an entirely new Section (23 CC) dealing specifically with drugs (and food, insecticide, germicide, fungicide, surgical or curative devices) was added. Under this section, the Controller of Patents was empowered to grant a compulsory licence to any applicant at any time unless there are 'good reasons' for refusing. The foreign patentees, however, were still in a position to effectively prevent or delay the use of compulsory licence.

The Haffkine Institute, e g, applied for a complusory licence, but the foreign patentee offered to give the licence voluntarily on the basis of royalties to be fixed through negotiations. They demanded an absurdly high rate of royalty of 25 per cent. It took more than four years to reduce it to 10 per cent, which however was still higher than the limit of 5 per cent stipulated by the Reserve Bank of India. By that time the Haffkine Institute decided to abandon the scheme.[21] Again, another indigenous firm Neo Pharma Industries entered into a technical collaboration agreement with an Italian firm for the technology to manufacture chloramphenicol.

A licence was sought from Parke Davis, which held the relevant patent in India. But whereas the subsidiary company in India pointed out that the matter was beyond its jurisdiction, the parent company in the USA insisted that Neo Pharma should first discuss with the local company. It took more than two years to decide as to who would negotiate. At last when the negotiations started with the parent company, they did not formally refuse to grant a licence but simply sat over the proposal. Finally, when a compulsory licence was sought for and was granted, Parke Davis went to the court and obtained a stay order.[22]

In fact, going to the court is a simple device the foreign patentees could employ. Even if ultimately the judgement goes against the patentee, the applicant would normally be prevented from using the compulsory licence during the period of the court case. The longer the time taken to settle a case, the smaller will be the relative benefit to the applicant for compulsory licence, because in any case after the expiry of the patent (normally 16 years) anybody was free to use the patent. The hazards of obtaining a compulsory licence, which include legal battles, perhaps explain why so few applications for compulsory licence were made under Section 23 CC. Till 1972, i e, when a new Act came into force, there were only five applications for compulsory licence, made by Hindustan Antibiotics Ltd (in 1959), Alembic Chemical Works (1963), Dey's Medical Stores (Manufacturing) (1960), Raptakos Brett and Co (1957) and Neo Pharma Industries (1961).[23] The applications were ultimately withdrawn in the first two cases. Compulsory licence was refused by the Controller of Patents in the third case.[24] The controller granted compulsory licences in the last two cases.

Patent System under Act of 1970

An important feature of the new Act, 1970[25] is the special provisions regarding drugs and a few other products. The life of the drug (and food) patents has been reduced from at least 16 years in the previous Act to five years from the date of sealing,[26] or seven years from the date of filing of complete specifications, whichever is shorter (sections 45 and 53), i e, for a maximum period of seven years. For other patents, the duration is 14 years. The new Act categorically states that drugs (and food and those manufactured by chemical processes) can now be patented only for a new method or process of manufacture, not for the products as such (section 5). Hence in contrast to the previous situation, the indigenous firms can manufacture new drugs by old processes without violating the Act. Obviously, as before it can continue to manufacture old drugs. Even in cases where new drugs cannot be manufactured by known processes, and so a new process is required, the indigenous firms are expected

to face less restrictions in developing such new processes. This is because the firm discovering/inventing a drug can no longer 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 (Sections 5 and 10).[27]

Under Section 87 of the Patents Act, 1970, every patent relating to processes for manufacturing drugs (or food or chemical substances) has to be endorsed with the words "Licences of right" after three years of the date of sealing. This implies 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 (Section 88). Even before expiry of three years from the date of sealing, the controller is empowered to grant a compulsory licence (and fix the rate of royalties) if "it is necessary or expedient in the public interest" (Section 97). There is also a special provision in the Act of 1970 regarding the use of patents by the government. Any time, 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 (and food) has been fixed at 4 per cent of the ex-factory sales (Sections 99 and 100).

It must be pointed out, however, that the actual use of a patent by a non-patentee still remains hazardous. For example, under Section 87, as mentioned above, while the right to obtain a licence automatically accrues after three years from the date of sealing of a patent, it cannot actually be used till the royalties are fixed either mutually or at the intervention of the controller. As before, the patentees can continue to prevent or delay the use of their patents by others by refusing to negotiate and then proceeding to the court in case of any intervening action by the controller. This has, in fact, happened in the case of each of the applications made to the controller till now by three firms for fixation of royalties. Incidentally, all these cases relate to products other than drugs. In the case of the application made in March 1976 by Catalyst and Chemical India (West Asia), the controller fixed the rate of royalty tentatively as per Section 88(4). The patentee (ICI), however, went to the court and by the time the case came up for final hearing (July 1977) the patent was about to expire (in August 1977). In the remaining two cases, as the patentees approached the court, interim injunction was granted and the Patent Office was directed not to proceed with the applications of Titanium Equipment and Anode Manufacturing Co and Coromandel Indag Products made in September 1980 and July 1981 respectively. The two patents in which Titanium was interested expired in February 1983 while the court case was still pending. Regarding Coromandel, too, while the case is yet to be settled, one of the patents has already expired in March 1982, while the other is due to expire in February 1986.[28]

Despite such hazards, the Patents Act, 1970 appears, on the whole, to be an improvement from the point of view of the development of indigenous science and technology, compared to the previous situation. A demand is often made by certain quarters to modify the present Act and make the provisions less restrictive for the patentees. If the experience under the Act of 1911 is any guide, then such a change will go against the indigenous efforts to develop processes and manufacturing drugs.

Notes

[This paper was written in 1984 and hence does not contain any references to later events.]

1. *Report of the Patents Enquiry Committee (1948-50)* (Delhi, GOI, Ministry of Industry and Supply, 1950), p 64; N Rajagopala Ayyangar, *Report on the Revision of the Patents Law* (Delhi, GOI, 1959), p 20.
2. Ayyangar, *Report*, pp 20, 34, 36.
3. See Section 14 and 15, "The Indian Patent and Designs Act 1911", reproduced in *Patent Office Hand Book* (Delhi, GOI, 13th ed, 1966).
4. Ayyangar, *Report*, pp 34, 36.
5. See the evidence of K A Hamied of Chemical, Industrial and Pharmaceutical Laboratories (CIPLA), *Joint Committee on the Patents Bill, 1965: Evidence* (New Delhi, Lok Sabha Secretariat, 1966), Vol 1, p 154 and of S G Somani of All India Manufacturers Association, *Joint Committee on the Patents Bill, 1967: Evidence* (New Delhi, Lok Sabha Secretariat, 1969), Vol 1, p 294.
6. *HAL, Annual Report, 1961.*
7. Evidence of K A Hamied of CIPLA, *Joint Committee on the Patents Bill, 1965: Evidence,* Vol I, pp 149-50.
8. *Report of the Committee on Drugs and Pharmaceutical Indu* (Hathi Committee) (New Delhi, GOI, Ministry of Petroleum Chemicals, 1975), p 92.
9. For the text of the judgement, which also provides the background of the case, see, *The All India Reporter* (Nagpur, AIR Ltd, 1969), Bombay Section, Vol 56, pp 258-73.
10. Ibid p 264.
11. Information on this Patent case has been obtained from the judgement of the Calcutta High Court (Suit No 1124 of 1962); the plaint; the written Statement submitted by BCPW (all available at the Calcutta High Court) and the BCPW Assistant Secretary's Note placed at the BCPW Board of Directors meeting held on 27 July, 1970.
12. Hoechst's patent mentions alkalation with primary amides which is chemically impossible. See Ibid.
13. Minutes of the meeting of the directors of BCPW, Calcutta, 5 December, 1968.
14. *Report of the Patents Enquiry Committee (1948-50)*, p 71.
15. Ibid, p 162.
16. Ibid, p 172.
17. *Report of the Panel on Fine Chemicals, Drugs and Pharmaceuticals* (New Delhi, GOI, Department of Industries and Supplies, 1947), p 15.
18. *Report of the Patents Enquiry Committee (1948-50)*, p 168.
19. Ayyangar, *Report*, p 1.
20. *Patent Office Hand Book*, p 32.
21. Evidence of C V Deliwala of the Haffkine Institute, *Joint Committee on the Patents Bill, 1967: Evidence*, Vol I, pp 451-52.
22. Evidence of N L I Mathias and A C Mitra of Neo Pharma Industries, *Joint Committee on the Patents Bill, 1965: Evidence*, Vol II, pp 487-88, 493-94.
23. Information obtained from the Patent Office, Calcutta. Apparently, the application by the Haffkine Institute, referred to earlier in the text, was made before Section 23 CC was added in 1952.
24. According to Rule 32B (inserted in 1953) of the Indian Patent and Design Rules, 1933, the Controller shall refuse the application, if "the Controller is not satisfied that a *prima facie* case has been made out for the making of an Order" (*Patent Office Hand Book*, pp 71-72).
25. For the provisions, see *The Patents Act, 1970* (New Delhi, GOI, Ministry of Law, Justice and Company Affairs, 1973).
26. A patent is sealed after it is granted.
27. For a discussion of the important provisions regarding drugs in the Act of 1970 vis-a-vis the Act of 1911, see S K Borkar, "Patent Act, 1970 and Its Effect on Drug Industry in the Country", in *Annual Publication* (Bombay, Indian Drug Manufacturers Association, 1974).
28. "Applications Filed for Licences of Right under Section 88(2) and 88(4) of the Patents Act, 1970", in *Journal of Patent Office Technical Society*, Vol 16, 1982, pp 80-81.