

TRIPS and Changes in Pharmaceutical Patent Regime in India

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TRIPS and Changes in Pharmaceutical Patent Regime in India*

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Before the creation of the World Trade Organization in 1995, individual countries were free to have their own patents laws. India was one of the developing countries which took advantage of this freedom and replaced the British Patents and Designs Act, 1911 by the Patents Act, 1970 in 1972. The most striking feature of the new law was that it did not recognize product patent protection in drugs (and food). This (together with a few other policies) brought about significant structural changes and growth in the pharmaceutical industry in India. India became self-reliant in drugs. India also emerged as a major player in the global pharmaceutical industry. India has received world wide recognition as a low cost producer of quality drugs. The AIDs crisis has highlighted the benefits of the absence of product patent protection in pharmaceuticals in India. In the light of growing criticisms that the MNCs are charging exorbitant prices, a partnership (The Accelerating Access Initiative) was initiated in May 2000, between international organizations and pharmaceutical companies, which hold the product patents, to introduce voluntary price reductions to enhance access to antiretrovirals (ARVs) in selected developing countries. But despite the announcement of the initiative, price did not change. It was only after Cipla, a generic company from India offered in September 2000, to sell at US\$ 350 (per year) for the triple therapy (stavudine+lamivudine+nevirapine), that prices crashed. The originator company followed the Cipla offer by lowering its price from more than US\$ 10,000 to US\$ 931 by January 2001 and then to US\$ 727 by March 2001. Since then other generic companies from India (Hetero, Aurobindo, Ranbaxy) entered the ARV market and reduced prices further. By April 2003, against the originator company's price of US\$ 727, the triple therapy was available from Hetero at US\$ 201 (MSF 2003).

* This is a revised and updated version of a paper written after India's Second Patent Amendment in 2002 (Chaudhuri 2002 (b)). I have benefited immensely from discussions with Y K Hamied, N B Zaveri and N H Israni.

But the policy environment has now changed. One of the WTO agreements, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS),¹ binding on all member countries of WTO, basically aims at establishing strong minimum standards for intellectual property rights (IPRs). Apart from patents, intellectual property includes copyrights, trademarks, geographical indications, industrial designs, integrated circuits and trade secrets. Under TRIPS, all the WTO member countries will have to provide product patent protection in all products including pharmaceuticals, within the time specified.

All the agreements of WTO, including TRIPS, came into force on 1 January, 1995. But Article 65.2 of TRIPS permits developing countries, a transition period of five years to implement the provisions of TRIPS. In addition, if a country did not provide product patent protection in any field when TRIPS came into force, then under Article 65.4, she gets another five years (in addition to the five years permissible under Article 65.2) to introduce such protection. But Articles 70.8 and 70.9 of TRIPS put a limitation on the transition periods allowed under Articles 65 for two classes of products - pharmaceuticals and agricultural chemicals. Even though the developing countries, such as India had time till 1 January 2005 to introduce full product patents protection for pharmaceuticals and agricultural chemicals, they were required to introduce “mail box” and “exclusive marketing rights” provisions from 1 January, 1995.²

The protection of the rights of the patentees, however is not the sole concern of TRIPS. TRIPS provides flexibilities for governments to fine tune the protection granted in order to meet social and economic goals (WTO 2001, p. 2). Article 7 of TRIPS on *Objectives* speaks of the mutual advantage of both producers and users of technological knowledge and stresses the need for a balance of rights and obligations. TRIPS recognises in Article 7 that the protection and enforcement of IPRs should be “conducive to social and economic welfare.” Again Article 8 on *Principles*, empowers the member countries to adopt measures to “protect public health and nutrition, and to promote the public interest in sectors of vital importance ...” and “to prevent the abuse of intellectual property rights by right holders.” Such measures are however required to be consistent

¹ The text of TRIPS accessed the website of WTO: www.wto.org.

² For a discussion of these transitional arrangements under TRIPS, see Ganesan 1999 in the Indian context and UNCTAD-ICTSD 2003; 2004 in the general context.

with the provisions of TRIPS. The Preamble to the agreement recognises that IPRs are private rights. But it also recognises the underlying public policy objectives and the special needs of the developing countries to have flexibility in implementing the provisions of TRIPS. In the light of certain developments and apprehensions expressed, the Ministerial Conference at Doha adopted a special declaration on issues related to TRIPS and public health in November 2001. The Doha Declaration clarified and confirmed that member countries have the rights under TRIPS to take appropriate measures to protect public health.

To comply with TRIPS, India has started the process of amending her Patents Act. The basic objective of this paper is to examine whether the amendments have taken advantage of the provisions and flexibilities, which are promised in TRIPS, to strike a balance between the private rights of patentees and the socio-economic needs and objectives. In Section II, we will describe how TRIPS have been implemented in India through three patent amendments. Then in Sections III and IV we will examine to what extent India has adopted the public health related TRIPS flexibilities.

II: PATENT AMENDMENTS IN INDIA AFTER TRIPS

TRIPS provides a three-stage frame for countries such as India which did not grant product patent rights in pharmaceuticals, when TRIPS came into force on 1 January, 1995:

1. Introduction of a facility (“mail box”) from January 1, 1995 to receive and hold product patent applications in the fields of pharmaceuticals (and agricultural chemicals). Such applications will not be processed for the grant of a patent until the end of 2004. But Exclusive Marketing Rights (EMRs) can be obtained for that application if a patent has been granted in some other WTO member country and the application has not been rejected in the country as not being an invention.
2. Compliance, from January 1, 2000 with other obligations of TRIPS, namely, those related to rights of patentee, term of patent protection, compulsory licensing, reversal of burden of proof and so on, and

3. Introduction of full product patent protection in all fields including pharmaceuticals from January 1, 2005. All the product patent applications held in the mail box are also required to be taken up for examination from January 1, 2005.³

Compliance with the TRIPS requirements has taken substantial time in India.⁴ This reflects the significant opposition to TRIPS in India. An Ordinance was actually introduced a day before TRIPS came into effect. But the Ordinance lapsed because it could not be followed up with the necessary legislation within the stipulated time required. Then the government introduced a Bill and it was passed in the Lok Sabha (the Lower house of India's Parliament). But in the Rajya Sabha (the Upper house), where the opposition was in a majority, the Bill was stalled – the Bill was referred to a Parliamentary Select Committee and the report could not be submitted by the time the Parliament was dissolved in May 1996. USA and later the European Commission (EC) filed a dispute against India at the WTO alleging that India had not complied with the provisions of Articles 70.8 and 70.9 of TRIPS. The Panel set up by the Dispute Settlement Body (DSB) of the WTO ruled that India had not complied with its obligations. India appealed against this ruling, but the Appellate Body of the WTO rejected the appeal and asked India to comply with the requirements by April 1999. Again a Bill was introduced, and this time it was passed in the Rajya Sabha on 22 December 1998, but the Bill could not come up for consideration in the Lok Sabha. Ultimately an Ordinance was promulgated followed by an Act passed in March 1999.⁵ The Patents (Amendment) Act, 1999⁶ amended the Patents Act, 1970 with retrospective effect from 1 January, 1995 to implement mail box facilities and EMRs as mentioned in (1) above.

³ See "Amendments to the Patents Act, 1970: Background Note," Department of Industrial Policy and Promotion, Ministry of Commerce, New Delhi. See also the website of the Controller General of Patents, Designs and Trademarks, Government of India (www.patentoffice.nic.in).

⁴ But it has taken much less time than what it did to introduce the Patents Act, 1970. The task of changing the British Patents and Designs Act, 1911 was started immediately after India's independence in 1947. Several bills were presented to the parliament. But it was not before another two decades that the new patents act could be enacted (Peoples' Commission on Patent Laws in India 2003, pp.7-9). N H Israni, Ex-Managing Director of Pfizer India, told us during an interview (at Mumbai, 8 October, 2003) that they were directed by the Head Office to spend most of their time for lobbying to stall the change in the patent law.

⁵ For a discussion of the background and the delay, see Peoples' Commission on Patent Laws for India 2003, pp. 17-20.

⁶ The text was accessed from www.patentoffice.nic.in.

Another Bill was introduced in the Rajya Sabha in December, 1999 to bring about the other changes in the patent regime as mentioned under (2) above. This Bill too faced similar hurdles and could not be passed immediately. The Bill had to be referred to a joint parliamentary committee. This committee consulted a large number of people including, lawyers, economists, industry representatives, NGOs and others. Several objections were raised. Some of these were incorporated and the committee submitted a revised Bill in December, 2001 (Joint Committee 2001). This Bill with a few changes was approved by the Parliament in May, 2002. The amended Act (The Patents (Amendment) Act, 2002⁷) came into force on May 20, 2003.

The Patents (Amendment) Act, 2002 made 64 amendments to the Patents Act, 1970 relating to terms of patents (20 years), exceptions to exclusive rights, compulsory licensing and so on.⁸

A Third Amendment was necessary by the end of 2004 to replace the EMR system and to introduce product patent protection as mentioned under (3) above. A bill (The Patents (Amendment) Bill, 2003) was introduced in the parliament in December 2003. Though only two clauses were necessary to replace the EMR system and introduce product patents in all fields including pharmaceuticals, the bill actually included 70 other clauses. As Zaveri⁹ and others have argued, these clauses were not necessary under TRIPS. These were introduced to simplify the patent grant procedures so as to make it easier for the MNCs to get product patents.

Before this bill could be passed, Lok Sabha was dissolved. After the elections, the new government which came into power in May 2004, refereed the issue of the Third Amendment to a Group of Ministers (GoM). Many public interest groups and others demanded that the recommendations of the GoM should be made public and a debate be held before finalizing the amendments. But this was not done. In fact even without discussing it in the parliament, full fledged product patent regime has been introduced in India from 1 January, 2005 through a presidential decree (the Patents (Amendment) Ordinance, 2004) issued on December 26, 2004. The provisions of the ordinance are

⁷ The text was accessed from www.patentoffice.nic.in.

⁸ See Peoples' Commission on Patents Laws for India 2003, pp. 20-22 for the list of the 64 amendments made.

essentially the same as those of the Bill of 2003, with some modifications as we will discuss below.¹⁰

Contrary to widespread apprehensions, only a few applications for EMR have been filed in India.¹¹ But the one granted to an MNC, Novartis, for an anti-cancer drug, imatinib mesylate (Novartis' brand name: Gleevec) has created a controversy. Under Article 70(3) of TRIPS, a WTO member country has no obligation to provide protection (through patents or EMRs) for any subject matter which has fallen into the "public domain" before WTO came into being, i.e., before 1 January, 1995. Patent information published in the US FDA Orange Book shows that Novartis' patent for the new chemical entity, imatinib mesylate was granted in USA before 1995.¹² A number of Indian companies (Natco, Ranbaxy, Sun Pharma, Cipla, Emcure, Intas, Hetero) have been manufacturing and marketing generic versions before the EMR was granted to Novartis in November 2003. Compared to the price of Rs 120000 per month for the Novartis's product, generic versions cost between Rs 9000 and Rs 12000. The EMR sought and granted to Novartis is for modification of the crystal form of imatinib mesylate (beta-crystal form). Novartis' EMR relates to this modified form for which it got patent and marketing approval in Australia during 2001-03. While Natco has challenged the grant of EMR to Novartis in the Delhi High Court, Novartis filed suits against the other generic companies in the Madras High Court. The latter has passed an interim order restraining six Indian companies from manufacturing and marketing imatinib mesylate. What is basically being contested is whether secondary patents obtained after 1995 for a new chemical entity patented before 1995 can be used to prevent generic companies from producing the drug.¹³ This has implications for grant of patents to the mailbox applications as discussed below.

⁹ See, for example, N B Zaveri, "Patents (Amendment) Bill 2003: The Objectionable Features," July, 2004 (mimeo).

¹⁰ The text was accessed from www.patentoffice.nic.in

¹¹ According to the information obtained from the Office of the Controller of Patents and Designs in Calcutta, only 13 EMR applications were filed by August, 2004.

¹² Patent No 5521184 expires on May 28, 2013 and the patent term is 20 years (see www.fda.gov).

¹³ See "IPA wants immediate revocation of EMR on Glivec by Patent controller", in *Chronicle Pharmabiz*, December 19, 2003; "India cos to challenge Madras HC stay against imatinib manufacturing, marketing", in *Chronicle Pharmabiz*, January 29, 2004; "Natco now planning to move Kolkata HC to challenge grant of EMR for Glivec", in *Chronicle Pharmabiz*, April 7, 2004; "SC admits cancer patients' petition against granting EMR for Gleevec", in *Chronicle Pharmabiz*, August 11, 2004. *Chronicle Pharmabiz* is a

In contrast to the small number of EMR applications, more than 7000 applications for product patents for pharmaceutical and agro-chemical products are believed to have accumulated in the mail box.¹⁴ These will now (from 1 January, 2005) be considered for grant of patents. If and when a product patent is granted to any mailbox application, what will happen to the generic companies, which may be producing the product? The Bill of 2003 did not address this important issue. The Ordinance of 2004 has only partially dealt with it. As we will discuss below, TRIPS-consistent measures can be adopted to prevent the disruption of supplies and the negative impact on prices.

III: FLEXIBILITIES UNDER TRIPS

It is anticipated that with the introduction of full product patent protection in pharmaceuticals from 1 January, 2005, as the generic companies are prevented from introducing new drugs, the lack of competition will result in high prices. Supply of low cost new drugs to the Indian market and to other countries will be threatened. But TRIPS provides for some flexibilities to member countries of WTO to take action to tackle such negative consequences of product patent protection. We analyse here to what extent India has been able to do so.

Within the scope of TRIPS, the following are the main flexibilities which developing countries can use:

1. Provide exemptions from grant of patents in certain cases
2. Provide exceptions to product patent rights in certain cases
3. Limit data protection
4. Provide for government use and
5. Provide compulsory licenses to non-patentees.

Let us elaborate. We will discuss government use and compulsory licensing in the next section. Others are discussed in this section.

pharmaceutical news weekly published from Mumbai. We have consulted the subscribed internet edition accessed from www.pharmabiz.com.

¹⁴ The 7000 figure is what the Indian Drug Manufacturers Association believes to be the number of mailbox applications (see the Memorandum presented by IDMA to the Secretary, Department of Industrial Policy and Promotion, Government of India, 22 March 2004). According to other estimates, the number

Exemptions from grant of patents

Under Article 27(1) of TRIPS, patents will have to be provided for inventions, which are “new, involve an inventive step and are capable of industrial application” The agreement however does not define these terms. This provides some flexibility. It has been suggested that a developing country can interpret these terms so as to restrict the number of patents (Correa 2000; Abbott 2001; CIPR 2002).

Developed countries, for example, USA follow very liberal patent standards. Patents are granted not only for new chemical entities (NCEs) involved in the new drugs. Secondary patents can also be taken for new formulations, new combinations and new uses of existing NCEs. As a recent research report in USA has found, most of these new products provide no clinical benefits (NIHCM 2002). But these secondary patents can be taken later and since these would be valid even after the expiry of the patents on NCEs, the entry of generics can be delayed (Federal Trade Commission 2002). WHO (2001) in fact has warned that if the patentability standards are too broad, so that the terms “new”, “inventive” are defined to include all the new forms of the same NCE, then effectively the patent life can be extended beyond the 20-year period. WHO has advised governments to exercise discretion in this regard. CIPR (2002, p. 49) has pointed out that there is no compulsion under TRIPS for the developing countries to follow the liberal patent standards of developed countries. The aim should be to ensure that patents are granted for true technical contributions and not for blocking innovation and legitimate competition by generic producers (Correa 2000, p. 110).

Chapter II (Sections 3 to 5) of the Patents Act, 1970 deals with “inventions not patentable.” It was hoped that the third amendment would provide the qualification that product patents will be granted only for new drugs which represent significant therapeutic advances. It has been the demand of not only the generic pharmaceutical industry, but also of Indian scientists, lawyers and others that patents may not be granted for “a new molecular modification or a salt or ester or a derivative or a formulation or dosage form of

exceed 10,000 even 12,000 (see P T Jyothi Datta, “Day 1 of product patent regime,” in *The Hindu Business Line*, January 3, 2005.

a known new chemical entity having the same or similar pharmaceutical activity” or new uses or new combinations of existing NCEs (Peoples’ Commission on Patent Laws in India 2003, pp. 62, 76). One of the arguments in favour of product patent protection in pharmaceuticals is that the development of new drugs is a costly business and hence there must be enough financial incentive to continue to do so. But as the NIHCM (2002) study shows, most of the new drugs are unnecessary combinations of existing drugs or simple modifications of existing drugs, which represent practically no therapeutic advance. There is no reason why developing countries should subsidise such wasteful expenditure by providing patents for these products.

But the Patent Ordinance of 2004 is silent on these issues of patentability. It does not forbid secondary patents on drugs which represent no therapeutic advance. What it does, makes the situation worse. Before 1 January, 2005, when mailbox applications were accepted, new uses of a drug were excluded from patentability because under the then existing Section 3 of Patents Act, 1970, “new use for a known substance” was not a patentable subject matter. The Patent Ordinance has amended Section 3(d) by replacing the words “new use” by “mere new use.” This widens the scope of patentability by providing an opportunity to an applicant to patent a new use even when the substance is known.¹⁵

Stricter patentability criteria are important not only to prevent the MNCs from “evergreening,” i.e., extending the life of patents. It can also prevent them from taking action to stop the generic companies from producing drugs covered by mailbox applications.

It has been reported¹⁶ that Indian generic companies are producing and marketing a number of drug products for which MNCs have filed mailbox applications. Since the Bill of 2003 was silent on this issue, apprehensions were expressed that if and when the MNCs get patents on these applications, the generic companies may not only have to suspend operations but also hauled up for patent infringement. But the new Section 11a(7) of the Patent Ordinance has spelt out that for mailbox applications, patent rights will accrue only from the date of grant of patent and that patent infringement cases cannot be filed before

¹⁵ See G. Srinivasan, “Patent ordinance and reality check,” in *The Hindu Business Line*, 5 January, 2005 and M Safiyuddin and A Shaw, “Patent Ordinance 2004,” in *The Hindu Business Line*, 11 January, 2005

¹⁶ See, for example, “Indian drug cos may have to withdraw several brands of 36 molecules before 2005”, in *Chronicle Pharmabiz*, December 24, 2003.

the grant of patent. Thus Indian generic companies will not be required to immediately suspend production and will not face any penalty for their past manufacturing and marketing activities.¹⁷ But they will have to suspend production in future, if and when the mailbox applications are processed and patents granted. TRIPS consistent measures however are possible to prevent such disruption of supplies and adverse impact on competition in future.

Compared to more than 7000 mailbox applications, the number of NCEs approved by US FDA during the period 1995 to 2003 is only 274.¹⁸ Thus it is clear that most of the mailbox applications relate to secondary patents. If such secondary patents are permitted, then the MNCs can use these to prevent the generic companies from producing not only the NCEs patented after 1995. As in the case of Novartis' EMR, they can use these for preventing generic companies from producing also those drugs relating to NCEs patented before 1995. But if secondary patents on NCEs are not permitted, then for any NCE patented before 1995, generic companies can continue to produce the drugs after 1995. The MNCs cannot take recourse to post-1995 secondary patents on the pre-1995 NCEs to stop the generic companies from producing.

The full list of mailbox applications is not available with us. We considered the incomplete list of about 30 drugs for which mailbox applications are pending but are currently produced by Indian generic companies.¹⁹ After consulting the US FDA Orange Book, it was found that patents for the NCEs for these drugs have mostly been granted in USA before 1995²⁰ and hence if secondary patents are not recognized as suggested above,

¹⁷ It has been said that since India's Patent Offices lack adequate resources and expertise, there may be a delay in processing mailbox applications. And since the generic companies can continue to produce till the patent is granted, this goes against the interests of the mailbox applicants. But because of the inadequacies in the patent offices, patentees may also gain - a patent may be granted wrongly and in that case the generic companies will have to suspend production even though they are not supposed to do so. In such cases it is only after a lengthy and difficult legal process that the generic companies can get back their rights.

¹⁸ Calculated from information accessed from the FDA website, www.fda.gov. Assuming that the number of NCEs approved during 2004 will be around the average figure for the period 1995 to 2003, the total number of NCEs during 1995 to 2004 would be around 300.

¹⁹ See, for example, "Indian drug cos may have to withdraw several brands of 36 molecules before 2005", in *Chronicle Pharmabiz*, December 24, 2003 and "Pandora's box set to open for drug majors," in *The Financial Express*, net edition, 6 December, 2004.

²⁰ Consider, for example rosuvastatin (AstraZeneca's brand: Crestor), the cholesterol lowering drug. The earliest patent (typically that of the NCE) expires on June 12, 2012. A patent term of 20 years implies that the patent was taken before 1995. But two other patents (secondary) are listed which expire on August 4,

mailbox applicants will not be eligible for patents and hence the generic companies will not be required to stop production even in future. But what happens if an MNC gets a product patent for an NCE developed after 1995, when mailbox applications are taken up for consideration? As per the Patent Ordinance, if and when such a patent is granted, Indian generic companies will have to suspend production. As suggested by IDMA, the Third amendment could have provided for the continuation of such production either by granting compulsory licenses or by making an exception to patent rights as provided under Article 30.²¹

It is also important to put in place a proper procedure to scrutinize the 7000 patent applications already made and those which will be made in future. The Indian Patents Act, 1970 provides a detailed procedure under Sections 2 to 26 to avoid wrongful claims. First the patent examiners scrutinize the claims and are given adequate time not exceeding 18 months to do so; the complete specifications are made open for public inspection; any interested person can oppose the grant of patent on specified grounds; and finally a patent is granted only after entertaining such opposition. The advantage of such a procedure is that any wrongful claims can be detected before the patent is granted. For example, if only NCEs are eligible to get patents, then the pre-grant scrutiny can detect applications for secondary patents and protection can be denied. The Patent Ordinance has diluted such pre-grant opposition provisions. Full scale proceedings for opposition to grant of patents can start only after the patent is granted. The Ordinance lists 11 grounds on which a patent can be opposed, but only after the patent has been granted. Before the grant of the patent, opposition is restricted to only two grounds: “(a) Patentability, including novelty, inventive step and industrial applicability or (ii) non-disclosure or wrongful mentioning in complete specification, source and geographical origin of biological material used in invention and anticipation of invention by the knowledge, oral or otherwise available within any local or indigenous community in India or elsewhere” (Section 25). Moreover, the Patent Rules²² issued to implement the Ordinance specify time limits on entertaining such opposition.

2020 and December 23, 2019, implying that these were taken after 1995 and hence for which applications may have been made in the mailbox. (See www.fda.gov).

²¹ Discussion with N H Israni, Chairman, IPR Committee, IDMA, Mumbai, 5 August, 2004.

²² The Patent Rules 2003 were updated on December 28, 2004 through a notification. Text of the Rules accessed from www.patentoffice.nic.in.

Representation for opposition will have to be made within three months of the date of publication of the patent application. The applicant will have to reply to the notice, if issued by the Controller within one month. The Controller of Patents will have to decide about the refusal/grant of patent ordinarily within one month from the completion of proceedings, which may include hearing, if requested (Rule 55).

Thus unlike as under the Patents Act, 1970, a patent can be granted even when it is not convincingly settled that it can be granted. This obviously will speed up the process of grant of patents and that seems to be the objective.²³ But this favours the patentees. Since MNCs are the main innovators of new drugs, this favours the MNCs. They can continue to enjoy exclusive rights even when these are wrongfully claimed and granted, till the post-grant scrutiny establishes it and this may take years. With much greater access to financial resources, the MNCs can delay or influence the proceedings. To enjoy such monopoly power and charge high prices is obviously an abuse of patent rights. Since TRIPS does not impose any restrictions on what procedures WTO member countries can adopt, there is no need and justification for India to change the procedure of pre-grant scrutiny as provided in the Act of 1970.²⁴

Exceptions to exclusive rights

Patents basically confer on the patentee the right to prevent others from using the invention. But such rights are not absolute. All patent laws usually provide some qualifications to such exclusive rights.

Article 30 of TRIPS permits member countries to “provide limited exceptions to the exclusive rights conferred by a patent ... ” This article does not list the specific acts for which exceptions can be provided. What it says is that such exceptions should satisfy

²³ It was stated in the “Statement of Objects and Reasons” of the Patents (Amendment) Bill, 2003 (on which the Patent Ordinance is based) that “While considering amendments to the Act, efforts have been made to make the law not only TRIPS compliant but also to simplify and rationalize the procedure governing grant of patents so as to make the system more user-friendly.” The text of the Bill was accessed from www.patentoffice.nic.in.

²⁴ For a discussion on the pre-grant procedures under the Patents Act, 1970 and the implications of diluting it, see N B Zaveri, “Patents (Amendment) Bill, 2003: The Objectionable Features”, 13 July, 2004, mimeo. See also the representation from IDMA dated 22 June, 2004 to Minister of Commerce and Industry and Industry.

certain conditions that it does not “unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties”. TRIPS does not contain any other explanation about the terms, “limited exceptions”, “unreasonably conflict”, “legitimate interests” and hence the use of this provision depends on the interpretation of these conditions. The following three are the most significant and common exceptions which the national laws in many countries provided when TRIPS came into effect:

1. Early working
2. Parallel imports and
3. Research and experimental use.²⁵

It is generally understood that individual countries have some flexibility in interpreting these terms and incorporating some exceptions to exclusive rights of the patentees in national patent laws. But under TRIPS , in the absence of clear guidance, any such use by a country (for example Canada, as we discuss below) can be contested by any other country and in that case the former cannot use it unless the dispute is resolved in its favour.

Early working

The “early working” provision is popularly referred to as the “Bolar” provision or exception, as it is known in USA. It is important to understand the background of the Bolar provision.

Patents provide a monopoly to the innovator companies for a specified period of time. After the expiry of the patents, others can also produce and market the products. But it was found that before 1984, the entry of generic products was very slow in USA. Food and Drug Administration (FDA) estimated that by 1984, about 150 off-patent brand name drugs had no generic equivalents in the market.²⁶ There were two reasons for this:

- FDA approval process and.

²⁵ See, UNCTAD-ICTSD 2004, p. 95.

²⁶ This discussion on the problems of generic entry before 1984 in USA is based on Federal Trade Commission 2002.

- Patent law.

Under the Federal Food, Drug, and Cosmetic Act, innovator companies seeking approval for a new drug are required to conduct tests including those on humans (“clinical trials”) and to submit those results to the FDA with their new drug application (NDA). Before 1984, the generic producers also had to conduct their own studies and submit data about the safety and the efficacy of the product. The generic producers hardly had the resources to undertake such time consuming and costly studies. Moreover, under the then existing patent law, they could start the process of testing and submitting data to FDA only after the patents have expired.

The *Drug Price Competition and Patent Term Restoration Act 1984* (commonly known as the Hatch-Waxman Act) - amended in 1984, the Patent Act of 1952 (35 USC) and the Federal Food, Drug, and Cosmetic Act (21 USC) to take care of both the problems. Under the Bolar²⁷ provision of the Patent Act, non-patentees could start using the patented product for regulatory purposes even before the expiration of the patents. Moreover, generic applicants were no longer required to repeat the clinical studies to prove the efficacy and the safety of the product. They were permitted to rely on the innovator company’s safety and efficacy data and could file only an *Abbreviated* New Drug Application (ANDA). The generic applicants were required to demonstrate that the generic drug product has the same active ingredient, route of administration, dosage form and strength and is bioequivalent (the rate at which the drug becomes available for absorption in the patient) to the relevant brand-name product.

The Bolar provision is very important for generic entry. It permits generic entry soon after the patents expire and hence allows the consumers to benefit from competition and lower prices without delay. In the absence of it, generic companies will have to wait till the patents actually expire before they can start the tests necessary for getting regulatory approval. During the several months or even years it may take to get such

²⁷ It is known as Bolar provision after the court case involving Roche, an MNC and Bolar Pharmaceuticals, a generic company. The US court denied Bolar the right to develop and submit a generic product for regulatory approval before the expiry of the patent. The Hatch-Waxman Act basically overrules this court ruling (see Raghavan 2000).

approvals, the patentee will effectively enjoy monopoly status even though there are no legal barriers to entry.

While reforming her patent law, Canada introduced two provisions that it will not be an infringement of the patent right, if the patent is used for (i) submitting information for regulatory approval (essentially the Bolar exception) and (ii) for manufacturing and storing the product in the period immediately preceding the expiry of patent (the stockpiling exception) (subsections 55.2(1) and (2) of the patent Act). The EU lodged a complaint with the WTO alleging that these exceptions to patent rights are not permissible under Article 30. The issue basically boiled down to whether these two provisions of the Canadian law are “limited exceptions” as provided under Article 30. The WTO dispute panel upheld the use of the Bolar exception as conforming with TRIPS. But the stockpiling exception was struck down.²⁸

Not surprisingly, after the very clear ruling in the EC-Canada case, the amended patents Act in India provides for Bolar exception. Under Section 107A(a), use of a patent for development and submission of information for regulatory approval will not be considered as an infringement of the patent right. Thus in the new patent regime, as innovator companies introduce new drugs in India and enjoy exclusive patent rights, such Bolar provisions can be used to introduce generics immediately after the expiry of patents.

Parallel imports

Under Article 28 of TRIPS, the patent owner has the exclusive right to prevent others not only from making, using or selling the invented product or process in the country, but also importing from other countries. This is however subject to Article 6 on “exhaustion.” What it basically means is that the patent holder in a country cannot legally stop imports of patented products offered for sale in another country. Such imports of patented products

²⁸ Thus generic companies can be ready with regulatory approvals, but can start production only after the patents actually expire. For a discussion of the Canada-EC dispute see, UNCTAD-ICTSD 2002, pp. 96-100; for the report of the dispute panel, see *Report of the Panel: Canada-Patent Protection of Pharmaceutical Products*, WTO Document No WT/DS114/R dated 17 March 2000 (accessed from www.wto.org).

without the consent of the patent holder in the importing country are known as parallel imports. This is very important in the pharmaceutical industry because the same patented medicine is often sold at different prices in different countries and hence parallel imports permit a country to shop around for the lowest price. The underlying justification of allowing parallel imports is that since the innovator has been rewarded through the first sale of the product, its patent rights have been “exhausted” and hence it should have no say over the subsequent re-sale. Under Article 6 of TRIPS as clarified by the Doha Declaration (paragraph 5(d)), each country is “free to establish its own regime for such exhaustion without challenge.”²⁹

Under the original 1970 Act, importing was not mentioned as an exclusive right. This has been amended (in Section 48) to conform to TRIPS. But unlike Article 28 of TRIPS, Section 48 of India’s amended patents Act provides no qualification about exhaustion of patent rights. Instead another section (107A(b)) has been inserted which says that “importation of patented products by any person from a person who is duly authorised by the patentee to sell or distribute the product shall not be considered as an infringement of patent rights.” This does permit parallel imports but only in some cases. As the Indian Drug Manufacturers Association (IDMA)³⁰ has pointed out, the phrase “duly authorised by the patentee” may cause delay and difficulty. In accordance with the spirit of Article 28 of TRIPS, any import from any legitimate source even if not specifically authorized should be permitted

Research and experimental use

Section 47 of the Patents Act, 1970, which has not been deleted in the recent amendments, provides other exceptions. The patented product/process may be made or used by any person for the “purpose merely of experiment or research including the imparting of instructions to pupils.” As UNCTAD-ICTSD 2002 (p. 101) has pointed out, the exception can not only be for scientific research with no commercial intent. It is also possible to exempt acts of experimentation even if made with commercial purposes. To avoid any

²⁹ See Correa 2000, pp. 71-80 for a discussion on the theory and practice of parallel imports.

³⁰ Letter to Secretary, Ministry of Industrial Policy and Promotion, 28 July, 2003, p. 25

ambiguity, it should be clearly understood that the non-patentees can experiment with the patented product and develop their own processes of manufacturing for commercial purposes, (though they may not be able to actually use these unless they are authorised to do so). As the Doha Declaration has affirmed, “the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles”. Such possibilities of experimentation will help realise the *objectives* mentioned in Article 7, viz., promotion of technological innovation and transfer and dissemination of technology. This is also important for maintaining and developing efficient alternatives to protect public health and to prevent patentees from abusing patent rights (Article 8 on *Principles*). R&D is a continuous process. If the indigenous sector is asked once in a while to develop a process, it is possible that they may not be able to do so. The opportunity of using the patented product for R&D purposes, will enable the indigenous firms to be ready with efficient processes and use these whenever they are permitted to do so. Article 66.2 obliges the developed countries to provide incentives to developing countries to promote technology transfer. A number of studies have shown that the single most important factor determining the success of technology transfer is the existence of indigenous technological capacity (CIPR 2002, p. 11).

Limiting data protection

As we have mentioned above, to get marketing approval for a new drug developed, innovator companies are required to submit test and clinical data relating to safety and efficacy to national health authorities. The current practice is that when generic companies apply for approval of their drug, they are not required to conduct their own studies and submit independent data. They can rely on the safety and efficacy data submitted by the innovator company and get marketing approval for their products. But if the law of a country provides for data exclusivity, i.e., grants exclusive rights to the innovator company to prevent subsequent applicants from using the data submitted, then generic companies cannot use such data till the data exclusivity period ends.

Data exclusivity provisions have implications for generic entry and hence competition and prices (IIFT 2003). A patent is taken immediately after a new drug (new chemical entity) is developed. But usually it takes several years of clinical trials and other testing and drug development before a drug is approved for marketing. Thus a drug discovered and patented in 1995 may actually be approved for marketing in 2005. In developing countries, it may be introduced even later, for example in 2010. With a 20 year patent term under TRIPS, the monopoly patent rights are supposed to expire in 2015 and generic companies can enter the market. But if the developing country provides for data exclusivity for 10 years, then generic companies cannot use the test data before 2020 because generic companies typically do not have the resources to conduct such time consuming and costly studies.³¹ As a result data exclusivity effectively extends the monopoly beyond the patent term.³²

Article 39.3 of TRIPS is being interpreted by the MNCs and some developed countries, particularly USA to mean that WTO member countries are required to grant data exclusivity for a specified period of time. Article 39.3 does require governments to provide protection to marketing approval data under certain conditions. But tracing the negotiating history and the text of Article 39, Watal (2001) and Correa (2002(a)) have concluded that the protection need not be in the form of data exclusivity. Watal 2001 (a) has pointed out that if that were the intention then the terms “exclusive rights” would have been used as in Article 70.9 (p. 204). Article 39.3 requires countries to protect data against “unfair commercial use.” And as Correa has argued, countries have the discretion to do so not through data exclusivity but by proscribing situations where a competitor obtains the results of testing data through fraud, breach of confidence or other “dishonest” practices and derive a commercial advantage.

Again data protection to be provided under Article 39.3 is subject to certain qualifications. Protection is not necessary if regulatory authorities do not require the submission of such data for marketing approval or if the data are already public. Protection is required only for new chemical entities. Countries have considerable

³¹ As we have mentioned above, the entry of generics in USA was very slow before 1984 when they were required to conduct their own studies.

discretion in defining what is “new,” and may exclude the different formulations based on the same chemicals. Thus even if test data are required to justify a new formulation, Article 39.3 does not require any protection of such data.

India’s Drug and Cosmetics Act, 1940, which regulates the marketing approval of new drugs as well as the Patents Act, 1970, the three amendments (including the Ordinance of 2004) carried out till date to comply with TRIPS do not contain any provisions relating to test data protection. Thus India has been able to use an important TRIPS flexibility with positive implications for generic competition and prices. But India has been under tremendous pressure from MNCs and the US government to introduce data exclusivity provisions. Government officials admit that it is not a TRIPS obligation but feel that a re-consideration by India may be necessary.³³ In the USTR 2004 report, India as been targeted as a “priority watch list” and points out that “...the United States is encouraged by the Indian Government's recent statements concerning implementation of data exclusivity regulations ...”³⁴ It is significant to note that in a public speech few days after the Patent Ordinance was issued, the Commerce and Industry Minister has announced that the government is looking at the possibility of enacting a “holistic” piece of legislation on data protection.³⁵

IV: COMPULSORY LICENSING AND GOVERNMENT USE

As different studies and reports have highlighted, in a product patent regime, a proper compulsory licensing system is of vital importance to deal with the negative implications of

³² Similarly data exclusivity provisions can adversely effect the entry of competing companies in cases of products for which the innovator companies are not eligible to take patents under TRIPS, see Watal, 2001 (a), p. 203.

³³ Director, Department of Industrial Policy & Promotion, Ministry of Commerce & Industry, told Express Pharma Pulse that “the magnitude of pressure on India is such that even though the government want to exploit all flexibilities under TRIPS, we cannot predict anything now.” See *Express Pharma Pulse* (a pharmaceutical weekly), 3 October, 2002 (accessed from www.Expressphramapulse.com). See also “Govt to consider data protection”, in *The Economic Times*, 29 November, 2003 (accessed from www.economictimes.indiatimes.com).

³⁴ See *2004 Special 301 Report* (accessed from www.ustr.gov/reports/2004-301/special301-pw1.htm#india).

³⁵ As reported in *The Hindu Business Line*, December 28, 2004.

product patent protection on prices. If generic companies are given licenses to produce a patented drug on payment of royalty, then competition among manufacturers would drive down prices, but the royalty paid to the innovators would continue to provide funds and the incentive for R&D (CIPR 2002, p. 42; Correa 2000, p. 91).³⁶ In fact as WHO and WTO (2001, p. 99) point out, compulsory licensing is one of the ways in which TRIPS attempts to strike a balance between promoting access to existing drugs and promoting R&D into new drugs. International NGOs such as Medecins Sans Frontieres/Doctors Without Borders (MSF), Consumer Project on Technology, Health Action International have been drawing attention to compulsory licensing provisions of TRIPS to enhance access (t' Hoen 2003, p. 46). After analysing the costs and benefits of the patent system, what Penrose (1951, p. 231) concluded more than fifty years back is valid and relevant even today:

“The second method of reducing the cost of the patent monopoly is that of compulsory licensing. This is by far the most effective and flexible method and enables the state to prevent most of the more serious restrictions on industry. It could be used very effectively to undermine the monopoly power of several of the more powerful international cartels whose position is largely based on their control of the patent rights to industrial processes in the larger industrial countries; and it could be used to ensure that patented new techniques developed abroad are available to domestic industries wishing to use them.” (Footnotes excluded).³⁷

Ever since compulsory licensing was adopted in the UK under the Patents Act of 1883, compulsory licenses have become a common feature of patent laws world wide. By the time TRIPS came into effect, around one hundred countries provided for compulsory licenses (Correa 1999, pp. 3-4). Compulsory licensing has been used in a number of developed countries. As we will see below, USA has been opposed to easy to use compulsory licensing in developing countries. But USA has a rich experience of granting compulsory licenses particularly under its antitrust legislation to remedy anticompetitive

³⁶ As Y K Hamied, the chief of Cipla, the reputed generic company from India has pointed out, they are not against product patents. They are against monopolies in vital areas of food and medicine and hence wants an easy to use compulsory licensing system. (Interview with Y K Hamied, Mumbai, 22 August, 2002; see also his interview published in *Pharma Bioworld*, February-April, 2004, reproduced in *IDMA Bulletin*, 30 April, 2004).

³⁷ The other method mentioned by Penrose (1951, pp. 230-31) is compulsory working of patents for inventions developed abroad. This she considered as ineffective.

practices. More than one hundred such licenses have been granted in USA.³⁸ Under its patent law, USA has also made extensive use of compulsory licensing to facilitate public non-commercial uses by the government and those authorized by it. While most of these pertain to national defense, this legal tool has also been used to bring down prices of medicines (Reichman and Hasenzahl 2002 (a), p. 19). A number of countries (Canada, United Kingdom, France, Irish Republic, South Africa, among others), provided for separate compulsory licensing provisions for pharmaceuticals (Scherer 1977, p. 40). Between 1953 and 1971, UK granted compulsory licenses in 20 cases relating to such important products as Chloromycetin, Librium and Valium (Scherer and Watal 2002, p. 918).

But the country which has made the most effective use of compulsory licensing in pharmaceuticals is Canada. Until 1987, Canada granted patent protection for medicines (and food) for processes for manufacturing and not for products as such. But it was found that the companies which patented new drugs, also tried to take patents for each of the possible processes by which it could be produced and hence make it difficult for others to enter the market (McFertridge 1998, p. 81). In 1923, Canada introduced special provisions for compulsory licensing of patented processes for food and medicines. But till the 1969 reforms, compulsory licensing was not widely used in Canada. This was because of the restriction that the active ingredients had to be produced in Canada. The generic producers were hesitant to undertake investments for basic manufacturing because of the relatively small size of the Canadian market.³⁹ The patent amendments of 1969 eliminated the local manufacturing restriction. Anyone could get a compulsory license not only to produce, but also to import any medicine produced with a patented process. As Eastman *et al* (1985, pp. 348-53) found, the 1969 patent reforms brought about significant changes in the pharmaceutical industry in Canada. The generic sector grew in number and size and the number of compulsory licenses and market competition increased. Compared to only 22 cases between 1923 and 1969, compulsory licenses were granted in 613 cases between

³⁸ See Correa 1999, pp. 14-15, who cites evidence from different sources.

³⁹ Horton 1993 citing a study by Paul K Gorecki, Economic Council of Canada, Ottawa, 1982.

Box 1 Compulsory Licensing for Pharmaceuticals in Canada, 1969-1992

One of the main reasons for the very successful compulsory licensing experience of Canada between 1969 and 1992 (see text) was the simple and easy to use procedure. The main features were:

(i) Any one could apply for a compulsory license – the applicant was not required to prove that he or she is capable or competent to exploit the license and handle the pharmaceutical products

(ii) To prevent delays, time limits were specified: The Commissioner of Patents would notify the patentee about the application and the latter would have two months to file a counterstatement and affidavit; the Commissioner would take at most 18 months after the date of notification to decide whether or not to grant a compulsory license. Six months after submitting the application, the applicant could petition the Commissioner for a six month interim license pending the final decision. This was rarely denied.

(iii) The Commissioner had to check whether there was any good reason not to grant a compulsory license. But apart from bankruptcy and false statements, nearly all other arguments were rejected. The compulsory licenses were available almost for the asking as a matter of right. The Commissioner seemed to take the view that a compulsory license enhances competition and reduces price and that is why the law provides for it and this forms the conclusive evidence of the fact that normally the grant of compulsory license was in public interest.

(iv) As in all laws, appeals against the decision of the commissioner granting compulsory licenses were permitted. But, the Federal Court of Appeal never set aside the Commissioner's decision and invariably took the view that it would not interfere with the compulsory licensing decisions of the Commissioner.

(v) In the very first case, the Commissioner fixed a royalty of 4% of the net selling price. This was routinely applied in virtually all subsequent cases.

Sources: Torremans 1996, pp. 316-19; Reichman and Hasenzahl 2002 (a), pp. 33-38.

1969 and 1992 (when the special regime of compulsory licensing for pharmaceuticals was abolished subsequent to Canada joining NAFTA and in anticipation of TRIPS)⁴⁰ (McFertridge 1998, pp. 81-82). For a sample of 32 drugs under compulsory licensing in Canada but patented in the United States, Eastman *et al* (1985, Table 7.7) estimated the cost in Canada as a percentage of the cost in the US to be 41.2% in 1983.⁴¹

In the context of our discussion on India below, what is particularly notable about the Canadian experience during this period is that the practice and the procedures were such as to make it very simple to get compulsory licenses (see Box 1). Since the 1990s, however, Canada has hardly used compulsory licenses and after having used it to her advantage, has been advocating caution in the use of such licenses by other countries (Reichman and Hasenzahl 2002 (b), p. 18).

Compulsory licensing in TRIPS

TRIPS does not use the term “compulsory license.” Article 31 refers to “use without authorization of the right holder,” and includes both use by third parties (what is usually referred to as compulsory licenses) and use by government.

Article 31 of TRIPS dealing with compulsory licensing⁴², does not place any restriction on the grounds under which a compulsory licenses can be given. In case there were any doubt, the Doha Declaration has made it clear that “Each member has the right to grant compulsory license and the freedom to determine the grounds upon which such licenses are granted.” The problem is that certain conditions listed in the Article will have to be satisfied. These include: (i) that authorization of such use will have to be considered on its individual merits, (ii) that before permitting such use (except in such cases as situations of national emergencies, extreme urgency, public non-commercial use), the proposed user will have to make efforts over a reasonable period of time to get a voluntary license on reasonable commercial terms, (iii) that the legal validity of the

⁴⁰ The Patents Amendment Act of 1992 took effect from March 1993. Earlier in 1987, when Canada amended her patent laws and recognized product patents, the special provisions for compulsory licenses in pharmaceuticals were retained but diluted - see Reichman and Hasenzahl 2002 (a), pp. 39-44.

⁴¹ Scherer and Watal (2002, p. 919) have cited several other studies which show the significant savings made by the Canadian consumers because of compulsory licensing.

compulsory licensing decision and the remuneration will be subject to judicial or other independent review, (iv) the compulsory licenses can be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. However as several commentators including, Watal (2001) and Love (2001), have argued, the grounds and the procedure can be so specified as to make these conditions less onerous than what these appear to be. For example the ground can be as it is in China, that any qualified entity who fails to get a license from the patentee on reasonable terms and within a reasonable period of time can apply for and be granted a compulsory license. Guidelines can be issued for “reasonable terms”. The maximum time period can also be stipulated. In this case, the procedure can be very simple. If the qualified entity does not get a voluntary license within that time and on these terms, it can be given a compulsory license. To find this out would be the consideration of “individual merit”. If this is the way the wording of the ground for compulsory licensing is done, then so long as the patentee does not give a voluntary license on reasonable terms, the non-patentee will continue to enjoy the compulsory license. And if the patentee does give a voluntary license on reasonable terms then obviously the need for giving a compulsory license will not arise. Of course the patentee can ask for a review of the compulsory licensing decision. TRIPS allows the review to be non-judicial. This can be a simple administrative process.

Has the amended Act in India taken advantage of the compulsory licensing as provided under TRIPS? We first examine the general provisions for compulsory licensing and then government use and the special compulsory licensing applicable in cases of national emergency or other circumstances of extreme urgency.

Compulsory Licensing in India's Patent Act: General Provisions

The Patents Act, 1970 had a clear strategy – to eliminate the monopoly of the MNCs and remove the bottlenecks in the previous regime which prevented the indigenous firms from producing patented drugs. And it was done through a very simple process of abolishing product patent protection in drugs. The Act of 1970 also had provisions for compulsory

⁴² As Scherer and Watal (2002, p. 915) have pointed out, compulsory licenses can be also be granted under Article 40 of TRIPS in case of an adverse impact on competition in the relevant market.

licensing for pharmaceutical processes. In fact under Section 87 of the 1970 Act, any process patent related to pharmaceuticals were to be endorsed with the words “Licenses of right” within three years of the sealing of the patent. In such cases, anyone could ask for a license from the patent owner to use the patented process on mutually agreed terms. But a compulsory license was redundant in the previous regime. Being free to produce the patented drugs, the indigenous firms could develop their own processes and they indeed did so, as we have mentioned above. But in the product patent regime being introduced in India, the indigenous firms will not be able to produce a patented drug even if they develop the processes of manufacturing it, unless they get a compulsory license. Hence it is of fundamental importance to have a simple and easy to administer compulsory licensing system. TRIPS does not prohibit this as we have mentioned above and the Canadian experience (Box 1) shows how it is possible to have such a system.

But this has not been done. The basic problem with the amended Act is that it lacks any positive strategy. It appears that adequate attention has not been devoted to design the law to take advantage of the flexibilities which TRIPS provides. The entire amendment has been carried out very mechanically. It starts with the relevant text of the Patents Act, 1970 and then makes some changes to make it TRIPS compliant. This has been done by deleting some clauses of the 1970 Act (for example abolition of special license of right compulsory licensing provisions relating to pharmaceutical processes) and lifting some clauses from TRIPS and inserting these in the amended Act. In the process many negative aspects have remained in the amended Act, which could have been tackled without violating TRIPS,

As Article 1 of TRIPS has made it clear, member countries are “not obliged to implement in their laws more extensive protection than is required by this Agreement ...” But the government has adopted a stricter compulsory licensing regime than what is required under TRIPS.

In the amended Act, an application for a compulsory license can be made under two sets of circumstances: under Section 84, three years after the sealing of the patent and under Section 92, anytime after the sealing of the patent with respect to a patent notified by the government as eligible for a compulsory license. We discuss here the general provisions. The special provisions will be discussed in the next sub-section.

The amended Act has elaborate provisions on compulsory licensing in Chapter XVI (Sections 82 to 94).⁴³ The “general principles” sound very impressive. In fact these are more elaborate than what we find in the Act of 1970. The general principles note that patents are granted to encourage inventions and to make the benefit of patented invention available at “reasonably affordable prices to the public,” to secure that these are worked in India, and not to enable patentees to enjoy monopoly power by importing. That the patent right is not abused by the patentee and the patentee does not “resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology” (Section 83). Entire Article 7 of TRIPS agreement on *Objectives* and the entire Article 8 on *Principles* are listed here. Para 4 of the Doha Declaration relating to the right of the governments to take measures to protect public health, is also incorporated here. The Amended Act also specifies the “general purposes” to be followed while granting compulsory licenses, for example that “the patented inventions are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable” (Section 89).

An application for a compulsory license can be made under Section 84 on the following grounds: that the “reasonable requirements of the public” have not been satisfied, or that the product is not available at a “reasonably affordable price”, or that the patented invention is “not worked in the territory of India”. Thus under the Indian law, if a patentee does not exploit locally the patented inventions, then compulsory licenses can be asked for. For a similar feature in the Brazilian patent law, USA lodged a complaint with the WTO. USA withdrew its complaint later. But Brazil has agreed to hold talks with USA before using such a provision. It remains to be seen how Brazil, India or any other country will or can use this provision.

As CIPR 2002 (p. 44), for example has stressed, what is often crucial for an effective compulsory licensing system is to have straightforward, transparent and fast procedures. A patent holder will naturally be opposed to any compulsory licenses. The pre-1993 Canadian experience shows how the practice and the procedures can be such that the

⁴³ It provides details of general principles applicable to working of patented inventions; grounds for grant of compulsory licenses; matters to be taken into account by the Controller of patents while considering applications for compulsory licenses; the procedure for dealing with compulsory licensing applications; general purposes for granting compulsory licenses; terms and conditions of compulsory licenses.

patentees have no opportunity to delay or prevent the grant of compulsory licenses. But in India that has not been the case. The wording of the grounds for granting compulsory licenses in Section 84 is not amenable to easy interpretation and is not operationally useful and the procedure specified is cumbersome. The procedure is open-ended without any time limit imposed for the grant of compulsory licenses. The copy of the compulsory licensing application will have to be advertised in the official gazette, though this is not required under TRIPS. The patentee or any other person may oppose the application and will have to be given adequate time for doing so.⁴⁴ The Controller will decide only after giving both the parties an opportunity to be heard.⁴⁵ A compulsory license granted by the Controller can be opposed. Such appeals will be considered by an Appellate Board before a compulsory license is ultimately permitted. Whether a patent is worked in India or not, can perhaps be objectively assessed. But the grounds of “reasonable requirements of the public” or “reasonably affordable price” can easily be challenged by the patentees. Then arguments and counter-arguments will follow. After all these are heard by the Controller and then by the Appellate Board,⁴⁶ in case of an appeal, it may be years before a compulsory license is granted, if at all. The entire process is excessively legalistic and provides the patentees the opportunity to buy time through litigation. The huge legal expenses involved in fighting the MNCs holding the patents may dissuade the generic companies from applying for licenses in the first place. These are not mere theoretical possibilities. This is precisely what happened in India under the Patent and Designs Act of 1911, which was in force till the Patents Act, 1970 replaced it (Chaudhuri 1984). It may not be irrelevant here to refer to the experience under the Act of 1911.

⁴⁴ The Patent Rules, 2003 (Chapter XIII (98)) issued for administering the amended act specifies a time limit of two months. Time limit has not been specified at any other stage. (The text of the Patent Rules, 2003 accessed from www.patentoffice.nic.in).

⁴⁵ TRIPS does not prevent governments from specifying the maximum time permissible at each stage. Peoples’ Commission on Patent Laws for India (2003, pp. 120-24) has suggested: that under Section 84, before applying for a compulsory license, an applicant may not wait for more than 150 days to get a voluntary license from the patent holder and that under Section 87(4), the Controller of Patents may not take more than 100 days to hear the opposition to the grant for a compulsory license and decide the case.

⁴⁶ One change introduced in the amended Act is that the appeals will be referred to a separate Appellate Board rather than to High Courts as was done under the Acts of 1970 and 1911. But the structure is basically judicial. It is possible that compared to High Courts, the specialized Appellate Board may take less time in disposal of appeals. But considering the procedure prescribed, it is doubtful to what extent it

The Patent and Designs Act of 1911, which provided product patent protection, also had elaborate provisions for compulsory licensing. But during the British rule not a single compulsory license was granted.⁴⁷ Attempts were made to improve the situation after India attained independence in 1947. The Patents Enquiry Committee (1950) found that the foreign patentees did misuse or abuse their rights, for example 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 manufacturing. But, the provisions regarding compulsory licensing were “wholly inadequate to prevent misuse or abuse of patent rights, particularly by foreigners” (p. 172). The compulsory licensing provisions (Sections 22 and 23) were amended in 1950 and in 1952, an entirely new Section (23CC) dealing specifically with drugs (and food and few other products) was added. But the procedure specified in Section 23D of the 1911 Act was very elaborate and cumbersome. The patentees could oppose grant of compulsory licenses and if granted, appeal against such decisions and indefinitely delay or prevent the actual use of compulsory licenses (see Box 2). Because of the hazards of obtaining a compulsory license which include legal battles, till 1972, i.e., when the 1970 Act came into force, only five applications were made for compulsory licenses. It was granted in only two cases and refused in one case. The applications were ultimately withdrawn in the remaining two cases (Chaudhuri 1984). It is the same procedure which the 1970 Act inherited for products other than pharmaceuticals and now the amended act has retained and made applicable for all the products including pharmaceuticals. Hence the experience under the Act of 1911 would be a rough guide to what is likely to happen in India unless some corrective actions are taken.⁴⁸

will be able to take quick decisions. As we have mentioned above, India had the option to adopt a simple administrative process. But that has not been done.

⁴⁷ The Panel on Fine Chemicals, Drugs and Pharmaceuticals (1947), appointed by the government also reported it was because of the wording of the relevant provisions that not even a single compulsory license could be obtained (p.15).

⁴⁸ For a discussion of the ineffectiveness of the compulsory licensing regime for non-pharmaceuticals under the Act of 1970, see Bagchi *et al* 1984.

Box 2

Despite elaborate provisions relating to compulsory licensing in the Patent and Designs Act, 1911, MNCs could take advantage of the cumbersome procedure prescribed and frustrate the efforts of indigenous enterprises to get compulsory licenses. Let us give some examples: A government research institute (Haffkine Institute) applied for a compulsory license. In response to the notice served on the patentee, the firm suggested that they were willing to give the license voluntarily on the basis of royalties to be fixed through negotiations. They demanded an absurdly high rate of 25%. As in the amended Act, there was no limit on the time that can be taken. It took more than 4 years to reduce it to 10%, which was however still higher than the limit of 5% stipulated by the Reserve Bank of India at that time. By that time, the Institute decided to abandon the project (Joint Committee on the Patents Bill, 1969, p. 452).

An indigenous firm (Neo-Pharma Industries Ltd) sought a license from Parke Davis to manufacture a drug. But whereas the subsidiary company in India pointed out that the matter was beyond its jurisdiction, the parent company in the USA insisted that the indigenous firm should first discuss the matter with the local subsidiary. 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 the license but simply sat over the proposal. Finally when a compulsory license was sought and granted, Parke Davis went to the court and obtained a stay order (Joint Committee on the Patents Bill, 1966, p. 493).

Government use

Article 31 of TRIPS dealing with compulsory licensing provides for special provisions “in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.”

Public use of patents or “government use” is a standard feature of patent laws in many countries. Under 28 USC Sec 1498 of the US patent law, the US government can use a patent or authorize third parties to use patents for virtually any public purpose and

the government has actually made good use of it as we have mentioned above. For any such use, the government is not required to negotiate with the patent owner. Nor is the latter provided any injunctive relief. All that it can expect is payment of compensation for the use (Love 2001).

Following the British patent law, the Indian patent law also provided for government use of patents and much of these have been retained in the recent patent amendments. The central government or anyone authorised by it may use (i.e., “make, use, exercise or vend”) an invention or acquire an invention for the purpose of the central government, state Governments or a government undertaking on payment of adequate remuneration or compensation (Sections 99 to 103).⁴⁹ Except in circumstances of national emergencies, extreme urgency or public non-commercial use, the government need not even inform the patentee about such use. The patent owner, however can challenge such a use or the terms of such use. Any such disputes are required to be judicially settled at the level of the High Court. Under the Act of 1970, the right to use included “the right to sell the goods.” In the amended Act, the right of the government is restricted to the “right to sell, on non-commercial basis.” This is an important difference. But still, in the amended Act, the government has wide ranging powers to make drugs more affordable. If the patented drugs are too expensive, then the government can produce or authorize others to produce and distribute these through public clinics. As the World Bank (2003, p. 39) has pointed out, even if the government recovers the cost of such drugs fully or partially, such an arrangement will be consistent with TRIPS so long as the government does not seek to make a profit out of it.

In the absence of product patent protection in pharmaceuticals in the previous patent regime, government was not required to and in fact did not use such special provisions. As a result unlike in USA, there is no history of such use. The ability of the government to use such provisions to enhance affordability of drugs will crucially depend on whether proper administrative and judicial systems are put in place. If as in the case of compulsory licenses discussed above, any patent holder can oppose such a use by

⁴⁹ The government also has the power to revoke patents if the patentee has “without reasonable cause failed to comply with the request of the central government” to use the patent (Section 64(4)) or if the patent and the way it is exercised is “mischievous to the State or generally prejudicial to the public” (Section 66).

government and can indefinitely delay or prevent the use, then obviously such provisions will remain ineffective. Moreover, as Abbott 2002 (pp. 54-55) has pointed out, the US government did not face any internal or external pressure when it tried to invoke “government use” to tackle the anthrax crisis. But if a government of a poor country tries to do anything close to it, they would put to intense diplomatic and economic pressures from developed countries, even if the public health crisis is more severe and extensive. Government use will ultimately depend on how such pressures are tackled.

Compulsory licensing applicable in cases of national emergency or other circumstances of extreme urgency.

Any time after the sealing of the patent, an application for a compulsory license can also be made under Section 92 for a patent notified by the Central Government in the official gazette. Such a notification can be made when the Central Government is satisfied that in circumstances of national emergency, extreme urgency, or public non-commercial use, it is necessary to grant a compulsory license for such a patent. The procedure mentioned above for the grant of compulsory licenses will have to be followed for these applications too, except that the applicant will not be required to first approach the patentee and try to get a voluntary license. The procedure, however, may not be followed in certain circumstances of emergency, or extreme urgency or public non-commercial use “including public health crises relating to Acquired Immune Deficiency Syndrome, human immunodeficiency virus, tuberculosis, malaria or other epidemics.” (Section 92 (c)). This special provision for exempting the usual procedure in public health crises was not there in the Bill recommended by the Joint Committee (2001).⁵⁰ It was incorporated in the last minute.⁵¹ This is a positive provision. But the benefit of this provision will very much depend on how this is implemented. The “Rules” for administering the amended Act could have elaborated on a simple and easy to use procedure. This has not been

⁵⁰ For a critique of the Bill recommended by the Joint Committee, see Zaveri 2002.

⁵¹ The inclusion of Section 92(3) was agreed upon in the previous evening when a delegation from the Indian pharmaceutical industry met the Minister in charge (interview, Mumbai, 9 October, 2003 with N B Zaveri, a member of the delegation).

done.⁵² It is important to note that though the usual procedure is not applicable, any decision by the Controller here too can be challenged and referred to the Appellate Board. As we have mentioned above, the patent holders will obviously oppose any such compulsory licenses. If it takes a long time for such disputes to be settled, and in particular, if the patent holders can get injunction against any such use till such cases are finally disposed off, then such special provisions will effectively be of limited use. As listed below, some simple administrative steps can be taken to avoid such delays and hurdles (Chaudhuri 2002 (a)):

- Under Section 92, rather than adopting a case by case approach, the Central Government may notify the list of medicines eligible for compulsory licenses in public health crises. The list should be prepared in consultation with health experts and may be revised from time to time. Any relevant new drug should be added to the list. Both Para 5 (c) of the Doha Declaration and Section 92 (3) of the amended Act have only given examples of public health crises, for example AIDS, tuberculosis, malaria. Public health crises should be interpreted in broad terms. The list may be prepared bearing in mind the specific situation in the country, such as the disease pattern, the need for drugs and the present availability. It is well known that majority of the Indian people living in rural areas and in urban slums have no or little access to modern drugs. Medicines necessary to take care of the health needs of these people may be included in the list. As Para 5 (c) of the Doha Declaration has clarified, individual countries have “the right to determine what constitutes a national emergency or other circumstances of extreme urgency.”
- The inclusion of any drug in the list cannot be a ground for opposition and appeal. There is nothing in TRIPS or the amended Act to suggest that it should be so.
- Following the examples of Germany and Canada, guidelines may be issued for the royalty to be paid to the patent holders in case of compulsory licenses. Germany has used rates varying between 2% and 10%. In Canada, the rate used to be 4%. Both UNDP (2001, p. 108) and the patent experts who appeared before the Peoples’ Commission on Patent Laws for India 2003, p. 71), have recommended that royalty

⁵² After the Second Amendment in 2002, Patent Rules were revised on 2 May, 2003 (text accessed from www.patentoffice.nic.in).

rates may vary depending on the therapeutic value of the product and whether public funds have been used in R&D for developing the drugs. The patent experts suggested that 5% royalty may be paid for drugs with significant therapeutic benefit or less if the benefits are not significant. Where the drug is particularly innovative with higher than average R&D investment incurred, an additional royalty of up to 3% may be awarded (Peoples' Commission for Patent Laws for India 2003, pp. 71-72).

- For any drug in the public health list, the Controller may immediately after receiving an application, grant the compulsory license, fixing a royalty rate using the royalty guidelines. Any opposition or appeal against the grant of a compulsory license in this case can only relate to the royalty rate fixed. (As we have argued above, the patentees should not have the right to object to the inclusion of any drug in the list). The opposition to the rate fixed should not hold up the use of compulsory license. While this is being adjudicated, the non-patentee could begin to use the patent on the basis of an undertaking that the royalty rate finally decided will be paid in full.

Such a simple administrative structure does not contravene TRIPS, but speeds up the use of compulsory licenses. Two important TRIPS conditions which are often considered to stand in the way of fast use of compulsory licenses are that any grant of compulsory licenses must be (i) considered on individual merits (Article 31 (a)) and (ii) subject to review by higher authorities (Article 31(h and j)). As Watal 2001(a) (p. 322) has clarified, consideration of individual merits does not mean patent-by-patent consideration. In fact while TRIPS was being negotiated, USA did not want the phrase, "each case" to be mentioned because that would have gone against her own law and practice. In the procedure suggested here, the merits of each case would be the consideration of the royalty rates payable. Again the requirement that any compulsory licensing decision would be subject to review, does not mean that the actual use should be held up till all disputes are settled. TRIPS does not require governments to grant injunctive relief to patent holders (Article 44 (2) (Love 2001, p. 1). The consideration of any opposition to the royalty rate proposed would satisfy the requirement of review of the compulsory licensing decision.

Compulsory licenses for export to countries with no manufacturing capacities

A country can issue a compulsory license not only for manufacturing drugs in the country but also for importing drugs. Before 1 January, 2005, patented drugs could be imported by countries with insufficient or no manufacturing capacities⁵³ from countries such as India which had manufacturing capacities but did not grant product patent protection in pharmaceuticals. Now with the introduction of product patent protection under TRIPS, such supplies will dry up. Generic manufacturers from India will no longer be permitted to produce new patented drugs unless they are specifically authorized to do, for example by getting a compulsory license. But a major limitation of any compulsory license that a drug manufacturer in India may get is that under Article 31(f) of TRIPS, production will have to be “predominantly for the supply of the domestic market of the member authorizing such use,” (unless the compulsory license were issued to remedy anticompetitive practices under Article 31(k)). In other words, a compulsory license cannot be granted in countries with manufacturing capacities exclusively or mainly to export to countries with no manufacturing capacities. Thus under TRIPS, a country with manufacturing capacities can resort to compulsory licensing to manufacture drugs to tackle problems such as public health needs. But the compulsory licensing provisions of TRIPS cannot be used by a country with no manufacturing capacity to import drugs to take care of her health needs. The Doha Declaration recognized this major lacuna of TRIPS and instructed TRIPS Council to find an expeditious solution to this problem and to report to the General Council before the end of 2002.⁵⁴

Even after several rounds of formal meetings and informal discussions, a consensus could not be arrived at by the deadline of December 2002. The delay was basically because of the differences between the developed countries and the developing countries over the scope of the solution, including the diseases and the medicines to be covered, the countries to be eligible to import and the procedures to be followed. Ultimately a compromise was reached on 30 August, 2003. The agreement was in the form of a decision adopted by the General Council to be implemented in the light of the

⁵³ Balance, Pogany and Forstner 1992 lists more than 60 countries (such as Bhutan, Chad, Congo, Oman, Swaziland) which have no pharmaceutical industry. The situation has not changed much since then.

⁵⁴ For a discussion on the background of the paragraph 6 problem, see Correa 2002(b), pp. 19-20.

“shared understandings of Members regarding the Decision” as contained in the Statement read out by the Chairperson in the General Council.⁵⁵ The solution takes the form of a temporary waiver (pending the amendment) of the obligation under Article 31(f) of TRIPS that compulsory license can be granted predominantly for the supply of the domestic market. The decision permits countries producing patented drugs under compulsory license to export these to countries with no manufacturing capacities.

But several conditions have been attached to the Decision which raise serious doubts about the extent to which it can be used at all. Rather than facilitating exports of drugs to countries which urgently require them, unnecessary procedural complications and limitations have been introduced.⁵⁶

India as a low cost producer of drugs, has particular significance from the point of view of supplies to countries with no manufacturing capacities. But in line with the 30 August, 2003 decision, no attempts have been made in the patent amendments to facilitate such exports. The Patent Ordinance has simply inserted a new section (92A) permitting compulsory licenses to these countries provided compulsory licenses have also been obtained there. The lack of concern is reflected in that the Ordinance does not even clarify that in the 50 odd least developed countries (LDCs),⁵⁷ as permitted by the Doha Declaration, pharmaceutical product patents are not mandatory till 2116 and hence the question of getting compulsory licenses there does not arise.

V: RECAPITULATION AND CONCLUSIONS

Under TRIPS, it is mandatory for all member countries of WTO to provide patent protection for all products including pharmaceuticals. But the protection of the rights of the patentees is not the sole concern of TRIPS. TRIPS provides flexibility for governments to strike a balance between the private rights of patentees and the socio-economic needs and objectives of its people.

⁵⁵ For the text of the Decision and the Statement, see the WTO website, www.wto.org.

⁵⁶ For a discussion on the essential features of the 30 August decision, see Matthews, 2004, pp. 95-98; Correa 2003, pp. 2-3; Velasquez 2003.

⁵⁷ The United Nations has designated 50 countries as least developed countries, for example, Afghanistan, Bangladesh, Cambodia, Ethiopia, Malawi, Uganda, Zambia. See *The Least Developed Countries Report 2004*, Geneva: UNCTAD (accessed from www.unctad.org).

The costs of high prices resulting from product patent protection can be tackled by:

- (i) resorting to parallel imports or granting compulsory licenses during the patent term and
- (ii) ensuring that the entry of generics is not delayed after the expiry of patents.

The recent amendments to India's patent law provide for parallel imports and hence the country can shop around and import cheaper alternatives, if available. But considering the status which the generic companies in India have achieved, what is of greater importance in India is a proper compulsory licensing system. In a product patent regime, a proper compulsory licensing system is of vital importance in promoting competition while ensuring that patentees get compensation through royalties. In fact compulsory licensing is one of the ways in which TRIPS attempts to strike a balance between promoting access to existing drugs and promoting R&D into new drugs. But India has not been able to take full advantage of the compulsory licensing provisions. The wording of the general grounds for compulsory licenses is not amenable to easy interpretation and is not operationally useful. The procedure is cumbersome and time consuming. The process is much more legalistic than what TRIPS requires. It provides opportunities to the powerful patentees to manipulate the process by litigation to prevent others from getting such licenses. Even in cases of special provisions relating to national emergency, extreme urgency or public non-commercial use, adequate care has not been taken to put in place a proper structure to prevent delay due to litigation.

India as a low cost producer of drugs, has particular significance from the point of view of supplies to countries with no manufacturing capacities. Care has not been taken in the patent amendments to facilitate such exports

In the absence of compulsory licensing, generic companies can enter the market only after the expiry of the patents. But the entry of generics depends on patent and other legislation. India has incorporated the Bolar provision. This will permit the generic producers to use the patents even before the expiry to get regulatory permission and hence to enter the market as soon as the patent expires. India has also not yet provided data

exclusivity. Hence lack of access to test data may not prevent generic entry after the expiry of patents.

But multiple patents can be taken to effectively extend the patent term. While deciding on the inventions eligible for patents, the terms, “new”, “inventive” can be defined to grant patents only for new drugs which represent significant therapeutic advances. Modifications of existing chemical entities, which do not involve clinical improvements, can be excluded. This would restrict the number of patents and prevent the delay of generic entry. Such qualifications have not been provided in the patent amendments carried out in India.

If the bias in the Patents Act, 1970, which did not provide product patent protection in pharmaceuticals, was in favour of the non-patentees, the bias in the amended Act is clearly in favour of the patentees. No time limit has been specified for processing of compulsory licensing applications and a compulsory license can be used only after the appeals against the grant of such a license by the Controller of Patents are turned down following a detailed procedure. But in the case of applications for product patents, time limit has been specified and patents can be granted even before it is convincingly settled that it can be granted. Unlike in the case of compulsory licenses, full scale opposition proceedings can start only after the grant of patents.

The aim appears to be not to deprive the patentees of the exclusive patent rights except under very special cases. India has effectively provided a more extensive protection to patentees than what is required under TRIPS.

The Patents Ordinance of 2004 will have to be followed up with the necessary legislation. While this is deliberated in India’s Parliament, it is still possible to incorporate the necessary public health provisions in India’s patent law.

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