Effect of Product Patents on the Indian Pharmaceutical Industry

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Introduction

The focus of the intellectual property regime that India has had to adopt since it took commitments under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) has remained on the ability of the country to provide mechanisms which can ensure that the country is able to provide access to medicines to its citizens at affordable prices. India has had a unique position among the countries in the developing world for it has a strong generic pharmaceutical industry, which has been able to provide medicines at prices that were among the lowest in the world. Much of the credit for this development goes to the Patents Act that India enacted in 1970. Two key provisions facilitated this process. The first was introduction of a process patent regime for chemicals and the second, shortening of the life of patents granted for pharmaceuticals.

However, the obligations to implement the Agreement on TRIPS changed the conditions that had seen the Indian pharmaceutical industry take roots. The critical issue was the re-introduction of the product patent regime[1] and the limitations that this change has imposed on its ability to produce technologies through reverse engineering. It was widely held that the future prospects of the industry hinged critically on the ability of the policy markers to exploit the flexibilities that existed in the framework provided by the Agreement on TRIPS.

India's commitment to fully implement the Agreement on TRIPS required three sets of amendments to the country's Patents Act. While developing countries, in general, were allowed to make their patent laws TRIPS compliant through an amendment that was to be introduced by January 1, 2000, countries like India which had process patent regime covering pharmaceuticals and agricultural chemicals, would enjoy a longer transition period before they were required to introduce product patents from January 1, 2005.

Although it is commonly held that the immediate impact of India's commitments under the TRIPS Agreement on access to medicines would be felt through the amendment of the Patents Act, 1970, a more recent development has changed this perception somewhat. The requirement under Article 39.3 of the TRIPS Agreement to introduce protection to test and other data submitted by pharmaceutical firms to the regulators for obtaining

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The views expressed here are personal

[1] The 1970 Patents Act had amended the Patents and Designs Act of 1911, which provided a product patent regime.

marketing approval for pharmaceuticals and agro-chemicals has brought yet another dimension of uncertainty for the generic industry. This has arisen as the US and EU have demanded that when firm seeks marketing approval for a product that uses new chemical entity, the data submitted by "pioneer" firm" must be granted fixed period protection during which the generic producers should not be granted marketing approval for the same or a similar product. In other words, fixed period market exclusivity for the "pioneer" firm has been demanded by the US and the EU.

The objectives of this study are two-fold. In the first instance, the study analyses the implications of the obligations that India had taken under the Agreement on TRIPS when it acceded to the World Trade Organization (WTO) in 1995, keeping in view the interests of pharmaceutical industry. As indicated above, the TRIPS Agreement has brought two substantive issues to the fore as far as the pharmaceutical industry is concerned. In the first place, India was required to effect changes Patents Act to make it compatible with the Agreement on TRIPS. The Indian Patents Act was amended three times between 1999 and 2005 in keeping with the requirements under the TRIPS Agreement. The impact of the TRIPS Agreement on the health services has not been dealt with in this study since the impact, if any, is only of an indirect nature.

As mentioned above, besides patents, the TRIPS Agreement includes a second directly relevant issue for the pharmaceutical industry concerning protection of test and other data that are submitted for obtaining marketing approval. This issue has figured prominently in the discussions in India over the past few years and our endeavour would be to focus on the issues that are involved.

The study has two substantial sections. In the first, we would try to discuss the structure of the patent regime that India has introduced in keeping with its obligations under the TRIPS Agreement. This section would also bring out the discussions centring on the implementation of the data protection regime that is required under Article 39.3 of the TRIPS Agreement. The analysis of the amendments in Patents Act, 1970 relies on inputs from a few respondents from the industry. The response of the industry was based on a set of questions that was out to them[2].

The second section of the study provides three sets of analysis to indicate the performance of the firms in the Indian pharmaceutical industry following the changes in the patent regime necessitated by the Agreement on TRIPS. In the first instance, the study would use data from the annual reports of 18 leading firms of the industry to comment on their performance since the Agreement on TRIPS became operational in India, i.e. 1995. As would be indicated in the following section, India was required to accept product patent applications for pharmaceutical products from January 1, 1995.

The second set of analysis is based on data from the regulatory agencies from in the United States and the UK, which are used for indicating the extent of market penetration of the Indian generic firms. The participation of the Indian generic firms in the Global Fund to Fight AIDS, Tuberculosis and Malaria has been used to indicate the status of these in the global market for the focus diseases. This analysis has limited itself to HIV/AIDS since 90 per cent of the Global Fund has been used for responding to this disease, with tuberculosis and malaria having shares of 6 and 4 per cent respectively.

[2] Annexure II contains the set of questions that were posed to the industry.

Chapter 1 : Key Features of the Agreement on TRIPS

The Agreement on TRIPS includes seven sets of provisions[3] that the WTO Members must adhere to while adopting domestic laws that are in conformity with the provisions of the Agreement. A set of eight substantive Articles of the Agreement on TRIPS, in addition to the preamble, underline the basic principles of the new intellectual property regime. While the preamble provides the broad set of intents, the major elements are covered by the substantive articles. The second set of provisions relates to each of the specific forms of intellectual property rights that are included in the Agreement[4]. The norms and standards of protection that are to be followed in respect of each form of intellectual property rights are spelt out in varied degrees of detail[5]. And, finally,

Article 1 of the Agreement on TRIPS provides the nature and scope of obligations that the WTO member countries are expected to meet towards protecting the rights of the owners of the forms of intellectual property that the Agreement recognises. This Article is significant for it is only here that the Agreement on TRIPS alludes to "obligations" in explicit terms. Thus, while the Member States have been subjected a set of obligations that they must fulfil while granting rights to the owners of intellectual property, the latter would not have to meet any reciprocal obligations in return for the rights that they would enjoy. The absence of any obligations on the right holders has particular significance for the developing countries in the area of patents. Developing countries, who own few patentable technologies, have historically seen foreign patentees take an overwhelmingly large number of patents. This implies that in case of the most important form of intellectual property, owners of technology would be able to exercise their dominance arising out of this imbalance that the TRIPS Agreement has introduced. The specific implications of lack of obligations on the patentee would be discussed in a later section.

Two sets of obligations have been introduced in Article 1. The first pertains to the standards of protection, wherein it is provided that the Agreement on TRIPS provides only the minimum standards of protection. In other words, WTO Members can adopt higher standards of protection if they deem fit. The second set of obligations stipulates that the Members are "free to determine the "appropriate method" for implementing the Agreement within 'their own legal system and practice'.

Although not set in terms of obligations, Article 2 of the Agreement makes it mandatory for the WTO members to accept the principal provisions of the Paris Convention on Industrial Property of 1883 (as amended through the Stockholm Act of 1967). Article 2

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[3] These are: (i) General Provisions and Basic Principles; (ii) Standards Concerning the Availability, Scope and use of Intellectual Property Rights; (iii) Enforcement of Intellectual Property Rights; (iv) Acquisition and Maintenance of Intellectual Property Rights and Related *Inter Partes* Procedures; (v) Dispute Prevention and Settlement; (vi) Transitional Arrangements; (vii) Institutional Arrangements

[4] The following forms of intellectual property rights are covered by the Agreement on TRIPS: (i) Copyright and Related Rights; (ii) Trademarks; (iii) Geographical Indications; (iv) Industrial Designs; (v) Patents (also included plant varieties protection); (vi) Layout-Designs (Topographies) of Integrated Circuits; and (vii) Protection of Undisclosed Information (includes trade secrets).

[5] In case of patents, the TRIPS Agreement provides a detailed structure of the law that the WTO Members must implement. However, in all other forms of intellectual property rights covered by the Agreement, the main elements of the law that WTO Members need to put in place are provided.

of the Agreement, in laying down this stipulation, states: "In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967)". The articles referred to form the substantive parts of Paris Convention. The inclusion of this provision is a pointer to the move towards harmonization of standards of IPP that was alluded to earlier.

In so establishing the Stockholm Act of the Paris Convention as the basic framework, the TRIPS Agreement has brought within the purview of the new patent regime not only the non-members of the Convention, but also those countries which were signatories to the earlier versions of the Convention and not to the Stockholm Act. The Paris Convention allowed members the option of not accepting later modifications, and this option, among others, was exercised by Brazil which was a signatory to the 1925 Hague Act.

National Treatment and the Most-Favoured-Nation (MFN) provisions, the cornerstones of the GATT framework, have been put down as the guiding principles of the Agreement in Articles 3 and 4. However, by so doing, the TRIPS Agreement also marked a significant departure from the manner in which the GATT applied these two provisions. While the GATT, had applied these principles to goods which was consistent with its mandate of dealing with trade in goods, the Agreement on TRIPS became instrumental in applying these principles to nationals.

An important dimension of the new regime relating to the exhaustion of rights of the rights holder has been provided in Article 6. It has been interpreted that this Article provides for the international exhaustion of rights and, therefore allows parallel imports to take place. International exhaustion of rights has been indicated to mean that a right holder cannot prevent importation of a product, for which he has secured protection, on the grounds that its importation has not been agreed to by him or his licensee. Thus, imports from any other source, where this product is being marketed in a legal manner, would be legal.

It should, however, be pointed out that the issue of exhaustion of rights has been made subject to the provisions that define the scope of protection that the rights holder can enjoy. Accordingly, "protection" has been defined to include "matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as the use of intellectual property rights...". This proviso included in Article 6 considerably dilutes its scope than would have been the case otherwise.

Two key Articles of the Agreement on TRIPS are Articles 7 and 8. While Article 7 lays down the objectives of the Agreement, Article 8 presents the principles underlying the Agreement.

In laying down the objectives of the Agreement, Article 7 states the following: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, and to the mutual advantage of the producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to the balance of rights and obligations". It is interesting to note that Article 7 provides in an all inclusive manner the range of issues that the developing countries would like to be addressed in any regime of intellectual property protection.

Another equally important issue for the developing countries, one which has implications for the technology systems in their countries, pertains to the balancing of rights and obligations of the right holders. As has been pointed to earlier, the Agreement on TRIPS

appears to provide a framework where the owners of intellectual property would be able to enjoy their rights, while the Member States undertake a host of obligations to ensure greater freedom to the rights holders.

Article 8 complements the provisions of Article 7 quite well. This Article provides that while formulating their intellectual property laws, the Member States can adopt "measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development ...". Further it is provided that "[a]ppropriate measures ... may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology".

Although it appears that Article 8 gives adequate flexibility to the Member States to evolve national legislations that suit their needs of development, an added proviso in the Article may limit this apparent flexibility. In both the provisions, stated above, it has been stated that the measures that the Members may like to adopt have to be "consistent with the provisions of the Agreement". This may be taken to imply that the general principles as laid down in Article 8, would have to be tempered with the specific provisions relating to the various forms of intellectual property before they can be applied in a substantive manner in the national legislations. And, the specific provisions of the Agreement on TRIPS, as shall be considered in case of patents in the following section, can be seen as being completely contradictory to the provisions of Articles 7 and 8.

Of the forms of intellectual property rights covered by the TRIPS Agreement, two forms, viz. patents and protection of undisclosed information, which covers trade secrets, are directly relevant for the pharmaceutical sector. The structure of the patent regime that the Agreement requires WTO Members to put in place includes the following elements: (i) re-statement of patentable subject matter; (ii) extending of the fields of activity under patent cover; (iii) nature of disclosure of the invention in the patent document, (iv) nature of exceptions that can be provided (v) duration of patent grant; and (vi) conditions governing working of patents. As regards the protection of undisclosed information, the TRIPS Agreement requires WTO Members to protect test or other data that are submitted for obtaining marketing approvals on the products. The following sections would discuss these issues at length in the context of India’s implementation of the TRIPS Agreement.

Chapter 2 : Amendments of the Indian Patents Act under the TRIPS Regime

India's commitment to fully implement the Agreement on TRIPS required three sets of amendments to the country's Patents Act. While developing countries, in general, were allowed to make their patent laws TRIPS compliant through an amendment that was to be introduced by January 1, 2000, countries like India which had process patent regime covering pharmaceuticals and agricultural chemicals, would enjoy a longer transition period before they were required to introduce product patents from January 1, 2005[6]. The longer transition period, however, came with a set of conditions elaborated in Articles 70.8 and 70.9 of the TRIPS Agreement.

The above-mentioned Articles are included in the "Transitional Arrangements", which required India to introduce two provisions in its Patents Act. Article 70.8 of the TRIPS Agreement required India to provide "a means" by which product patent applications can be filed from January 1, 1995 ("mailbox", see below). If the products figuring in these applications were granted a patent in any of the WTO member countries and the products had obtained marketing approval in any of the WTO Member countries, then, according to Article 70.9, five years exclusive marketing rights (EMRs) had to be granted by India before the patent on the product was either granted or rejected in India. The first amendment of the Patents Act, 1970 introduced the requirements under the "transitional arrangements through Section 5(2), which allowed product patent applications to be filed, while Chapter IVA provided for the grant of EMRs[7].

On January 1, 2000, a Second Amendment had to be introduced for bringing the Patents Act in conformity with all the substantive provisions the TRIPS Agreement, barring those related to the introduction of product patents. The key issues included in the Second Amendment were, re-defining patentable subject matter, extension of the term of patent protection to 20 years and amending the compulsory licensing system[8].

A third amendment had to be introduced by January 1, 2005 to introduce product patent regime in areas, including pharmaceuticals that were hitherto covered by process patents. Although the Third Amendment had a narrow remit, the Government used the opportunity to undertake yet another review of the Patents Act. Among the major issues included in the Third Amendment were provisions relating to opposition to the grant of patents[9].

A Perspective for India's TRIPS-Compliant Patent Law

It may be noted that two of the three amendments of its Patents Act that India had undertaken were adopted in the backdrop of significant global developments. Growing

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[6] Articles 65.2 and 65.4 of the TRIPS Agreement.

[7] This amendment was notified in the Gazette of India on 26 March 1999 as the Patents (Amendment) Act, 1999.

[8] This amendment was notified in the Gazette of India on 25 June 2002 as the Patents (Amendment) Act, 2002. See Govt of India (2002)

[9] The third amendment was notified in the Gazette of India on 5 April 2005 as the Patents (Amendment) Act, 2005. See Govt of India (2005a)

concerns in developing countries regarding access to medicines at prices that their citizens could afford led to considerable confabulations amongst the WTO members. The outcome of this process was the Ministerial Declaration adopted at the conclusion of the Doha Ministerial Conference held in 2001 on TRIPS Agreement and Public Health (henceforth, Doha Declaration).

The Doha Declaration unequivocally stated at the outset "that TRIPS Agreement *does not and should not prevent Members from taking measures to protect public health"* (emphasis added). The Ministers further stated "that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all". It was emphasised that the WTO Members have the right to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

Two critical issues were particularly emphasised in the Doha Declaration. The first was that the provisions of the TRIPS Agreement should "be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles". The objectives of the Agreement on TRIPS provided in Article 7 states that the protection and enforcement of intellectual property rights should among other things be "conducive to social and economic welfare, and to a balance of rights and obligations". Furthermore, Article 8 of the Agreement directs WTO Members to adopt measures necessary to protect public health and nutrition while formulating or amending their laws and regulations relating to intellectual property. Thus, Articles 7 and 8 of the TRIPS Agreement require that WTO Members must ensure that the laws relating to all forms of intellectual property rights covered by the Agreement give due consideration to issues like protection of public health and nutrition and do not merely serve the interests of the owners of intellectual property.

The second area of focus of the Doha Declaration was compulsory licences, the instrument that could have a vital role to play in determining the future prospects of the Indian pharmaceutical industry. It was mentioned in an earlier discussion that over the past few decades, India witnessed the development of a strong pharmaceutical industry largely because of the absence of the product patent regime. However, with the product patent regime establishing itself following the adoption of a TRIPS-consistent patent regime by India, the future of the pharmaceutical industry in India would critically hinge on the ability of the producers to obtain licences from the owners of proprietary technologies. For obtaining the licences, these producers would have to depend on compulsory licences, an instrument that has been embedded in the patent system for preventing abuse of patent monopoly. The grounds for the grant of compulsory licences include the refusal of the patent holder to exploit the patent commercially in the country granting the rights[10]. At the same time, however, the prospective beneficiaries of the compulsory licensing system would have to demonstrate that they have "made efforts to

[10] The Paris Convention, which has set the global standards for patenting since it was adopted in 1883, provides in Article 5A that the signatories to the Convention have the "right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work". It may also be mentioned that Article 2 of the TRIPS Agreement requires that WTO Members are required to comply with the substantive provisions of the Paris Convention.

obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time"[11].

In some ways, the Doha Declaration goes well beyond the provisions of the Paris Convention. The Declaration states that every WTO Member has "the right to grant compulsory licences and *the freedom to determine the grounds upon which such licences are granted*" (emphasis added). This, in other words, implies that the Doha Declaration allows WTO Member countries to use compulsory licensing system for realising public interest objectives like access to medicines.

The developments centring on the Agreement on TRIPS that have taken place during the past few years, a clear articulation of which was the Doha Declaration, bring home the point that the TRIPS-consistent patent laws have to take into consideration the interests of the public at large, besides of course granting patent rights on inventions that unambiguously represent advances in technology. This later point is particularly important given that the patent offices in some of the more advanced countries like the US, have been granting patents on the so-called incrementally modified drugs (IMDs), which could include new formulations, new combinations of active ingredients or new salts or esters of approved compounds[12]. Recent studies have found that in the United States brand manufacturers have flooded the market with IMDs, which "in 85% of the cases, do not provide significant improvement over currently marketed therapies"[13]. Firms have been more attracted towards IMDs because of the strong economic incentives that they bring with them. According to one of the major pharmaceutical firms, development of an IMD is "safer, faster, and more cost effective for the developer as an incremental improvement rather than an original product"[14]. What is an advantage for the firms is usually a disadvantage for the consumers since these IMDs have contributed substantially to the rising prices of medicines[15].

These developments taking place in countries like the United States, which provide the most extensive patent rights, should be seen as useful guideposts for the policy makers in India while they are in the process of adoption of a TRIPS-consistent patent regime. In a country where access to medicines at affordable prices is a major area of concern, one hardly needs to labour on the point that adequate safeguards need to be provided to ensure that the country does not witness the spectre of high prices medicines caused by the grant of IMD patents. What this implies is that strengthening of the rights of the patent holders, which is the cornerstone of the TRIPS Agreement, must be tempered by the inclusion of provisions that effectively address public interest concerns. The following discussion provides a perspective on India's patent law amendments that were undertaken to introduce a TRIPS-consistent patent regime.

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[11] Article 31(b) of the TRIPS Agreement.

[12] National Institute for Health Care Management (2002), p. 5.

[13] National Institute for Health Care Management (2002), p. 19.

[14] Submission by Dr. Nahed Ahmed, Vice President, Productivity, Portfolio & Project Management Drug Innovation & Approval, Aventis Pharmaceuticals Inc. to the United States Federal Trade Commission/Department of Justice Hearings on "Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy". See United States Federal Trade Commission/Department of Justice (2002).

[15] National Institute for Health Care Management (2002), p. 19.

Analysing the amendments

The above discussion suggests that several issues would need careful consideration as India implements a TRIPS-compliant patent regime. The following is a non-exhaustive list: (i) defining the scope of patentability to address among other issues, patents on IMDs, (ii) provisions for the grant of compulsory licences, (iii) opposition proceedings, (iv) specific exceptions as for example "parallel imports", and (iv) provisions relating to providing immunity to generic producers that are already in the market.

Scope of Patentability

It may be argued that it is critically important to define scope of patentability since in many jurisdictions, and in particular, those existing in developed countries, the definitions adopted are often so open-ended that they have undesirable consequences, as for instance, the grant on patents on IMDs. And as a later discussion would indicate, the process of examination of the product applications that are currently in the "mailbox" has revealed that patents on IMDs could be a real threat, which would have to be addressed by all relevant stakeholders in a concerted manner. The "mailbox" provisions, introduced through the amendment of the Patents Act in 1999, required India to accept applications for product patents in the area of pharmaceuticals and agro-chemicals even before the product patent regime was put in place. The purpose of the "mailbox", as based on Article 70.8, TRIPS Agreement, was to provide inventors with a means of filing applications for pharmaceutical product patents during the transition period (i.e. until 1 January 2005). Upon termination of the transition period, all applications in the mailbox then have to be examined. The effect of the "mailbox" is a legal fiction: according to Article 70.8 (b), TRIPS Agreement, the patentability criteria of novelty, inventive step and industrial applicability shall be applied after the transition period as if they were being applied on the date of filing/date of priority. In other words, the novelty of an invention is preserved, although the respective product might have been available to the public for some time.

The "mailbox" provision has attracted more than 9,000 product patent applications, a significant proportion of which is in the area of pharmaceuticals that would have to be examined according to the provisions of the recently amended Act[16]. It has been pointed out that between 1995 and 2003, only 274 new chemical entities have been granted marketing approval by the United States Federal Drug Administration (FDA), and this implies that an overwhelming majority of the applications in the "mailbox" cover IMDs.

Narrowing down the scope of patentability, particularly in respect of pharmaceuticals should be seen as the first step for ensuring that the IMDs do not get patent rights in India. This required that the amended law provide appropriate definitions/clarifications in respect of the three criteria used for assessing whether or not a claimed invention is patentable, viz. novelty, inventive step and industrial application. It needs to be noted here that the TRIPS Agreement is does not define any of these three criteria, implying thereby that the WTO Member countries are free to adopt their own definitions.

Two issues are important in this context. These are the elaboration of the criteria for patentability and the issue of patentable subject matter. Four amendments were introduced in the Patents Act, and some of these require close examination.

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[16] This figure has been quoted by Access to Medicine and Treatment Campaign (AMTC). See Narrain (2005).

The first is the elaboration of the definition of "inventive step", which was accepted as being coterminous with non-obviousness in the earlier version of the Patents Act 1970[17]. According to Section 2(ja), "inventive step" means a feature of the invention that involves technical advance as compared to the existing knowledge or having economic significance or both …" How the Patent Office interprets this definition would be seen with interest on two counts. First, the extent of "technical advance" that would be considered sufficient for the grant of the rights could depend largely on the subjective judgement of a patent examiner. In other words, a patent examiner would require a clear set of guidelines further to ensure that incremental innovations of the kind that the IMDs represent are not granted patent rights. Secondly, assessment of the inventive step based on the "economic significance" of an invention could lead to erroneous outcomes. This problem could arise from the exaggerated claims regarding the economic value of the invention that the patent applicant would be tempted to make to take advantage of this provision.

The second amendment of this genre that requires a re-look is the introduction of a new definition for "pharmaceutical substance". Section 2(ta) of the Patents Act, as amended, defines a pharmaceutical substance as "any new entity involving one or more inventive steps". If the real objective of the definition was to narrow the scope of patenting of pharmaceutical products, it falls far short of meeting this objective. In fact, the existing definition opens the door for frivolous claims aplenty in this area. It has been argued for instance that the term 'chemical' should have been inserted so that the definition would be 'any new chemical entity'[18]. That this suggestion has considerable merit can be seen from the manner in which the FDA deals with this issue. According to the FDA, new chemical entity (NCE) or a new molecular entity (NME) means a drug that contains no active moiety that has been approved by FDA in any other application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act. An active moiety means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance[19].

A third amendment tries to exclude discoveries or new use of a known substance from the ambit of patenting. Here again, the language used leaves far too much of an ambiguity. A good example of this is the exclusion of "the mere discovery of a new form of a known substance *which does not result in the enhancement of the known efficacy of that substance*" (emphasis added) from patentable inventions that is provided in Section 3 (d). The industry too has expressed its unease with the language contained in Section 3 (d). One of the respondents argued that the term 'efficacy' is being construed in a drug regulatory sense and admittedly patent examiners are ill equipped to appreciate efficacy standards.

While answers to several of these issues may eventually be settled through the disputes including those that would be in the nature of opposition to the grant of patents, there is

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[17] An invention is considered as having an "inventive step" if it is non-obvious to anyone skilled in the art.

[18] Gopakumar and Amin (2005)..

[19] Wikipedia, the free encyclopaedia (http://en.wikipedia.org/wiki/New_chemical_entity)

obviously a need to get legal certainty on this contentious issue.[20] Reflecting this need, the Government of India had set up a five-member "Technical Expert Group on Patent Law Issues" in April 2005 under the Chairmanship of Dr. R.A. Mashelkar, Director General, Council of Scientific and Industrial Research (CSIR). The Group was given the following terms of reference[21]:

(a) whether it would be TRIPS (Trade-Related Intellectual Property Rights) compatible to limit the grant of patents for pharmaceutical substance to new chemical entity or to new medical entity involving one or more inventive steps; and,

(b) whether it would be TRIPS compatible to exclude micro-organisms from patenting[22].

The Expert Group became a non-starter for the report it had submitted in December 2006 was mired in controversies. Finally, in February 2007, the Chairman of the Group withdrew the report and asked for more time for re-submitting the report[23]. These developments have caused considerable uncertainties for the patent examiners have little guidance on issues that are critical for the effective functioning of the country's patent regime.

Recent developments in the US could however provide a way forward on some of the contentious aspects of the Patents Act, 1970, as amended. In a seminal judgement pronounced in April 2007, the US Supreme Court altered the standard for determining when an invention is obvious and thus cannot be patented. The ruling of the US Supreme Court came in response to a suit filed by Teleflex, a Pennsylvania-based auto parts manufacturer, which has argued that its rival KSR, a Canada-based firm, was selling gas pedals in the US in violation of its patent on the product. KSR, on the other hand, sought to dismiss the suit alleging that Teleflex's invention was too obvious to be patented[24].

Following this judgement, a slew of decisions have emerged from the Courts in the US, which would re-define the parameters on which non-obviousness would be judged while examining patent claims. Analysts have pointed out that "practitioners can expect that improvement or "optimization" claims for pharmaceuticals with different salt forms, different excipients, adjusted dosages, release rates or formulations of known active ingredients, or optimized variables for known combinations, are very vulnerable to invalidation or rejection for obviousness, even when supported by unexpected results"[25]. It has further been argued that "new compound/active pharmaceutical ingredient claims are more likely to withstand an obviousness challenge". It has also been pointed out that

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[20] See a later discussion for some of the law suits that have been filed opposing patents on drugs on some critical diseases.

[21] Govt of India (2005b).

[22] There is a view that micro-organisms should not be patented given that the review of Article 27.3(b) has been pending since 1999. Several public interest groups have supported the view that has been held by the African Group that patenting of life forms should not be allowed in the TRIPS-consistent patent regime. For the views of the African Group see WTO (1999) and WTO (2003).

[23] Sharma, Ravi and Sara Hiddleston (2007).

[24] See Box 1 for details

[25] Steinhauer, Esther H. (2007)

there exists a grey area involving “claims for new administration forms of a known active ingredient, or new combinations showing unexpected synergy, superior therapeutic efficacy or other improved properties, which are heavily dependent on the teachings of the prior art and its understanding by the person of ordinary skill in the art”.

Box 1: The KSR v Teleflex case

The patent at issue covers a gas pedal that is adjustable and that controls the engine by means of an electronic sensor. However, long before the invention date for this patent, companies had been making and selling adjustable gas pedals, as well as pedals that had electronic sensors. According to KSR, the Teleflex patent was an obvious combination of these two well-known designs, and it was thus unpatentable.

The decision of the US Supreme Court came essentially in response to the ruling that the Federal Circuit had passed on the issue. The Federal Circuit had maintained that a combination of existing elements can be considered obvious only if one can prove that, prior to the date of the invention, there was an explicit "teaching, suggestion, or motivation" to combine the existing elements (for instance, a technical manual or scientific journal that discussed the advantages of putting a sensor on an adjustable pedal).

The US Supreme Court ruled that "obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents". The Court argued that "diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way". It pointed out that in "many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends". Based on the above arguments US Supreme Court surmised that "granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility".

Source: Supreme Court of the United States (2007)

The discontinuation of the "process-patent-alone" regime in case of chemicals has been a crucial change as regards patentable subject matter. This involved removal of Section 5(1) of Patents Act, 1970 which provides for process patents in this field. This has meant that from January 1, 2005 product patent applications are being accepted and examined. Included in these product patent applications would be those applications that were made since 1995 using the "mailbox" provisions. The "mailbox" provisions were introduced in the Patents Act through the first amendment undertaken in 1999 in order to fulfil the condition imposed in Article 70 of the TRIPS Agreement (the so-called "Transitional Arrangements"). As was mentioned earlier, the "Transitional Arrangements" were in the nature of a trade-off for the longer period that India could enjoy for making its Patents Law compatible with the TRIPS Agreement[26].

It is vitally important that the scope of patentability, definition of pharmaceutical entity, is laid down in clear and unambiguous manner. This step would go a long way in

[26]Article 65 of the TRIPS Agreement gave developing countries a period of five years from the establishment of the WTO to amend their patent laws. However, developing countries having a process patent regime were given a further period of five years to introduce product patents in the areas that were covered by process patents in the pre-TRIPS phase.

reducing the number of patent litigations, which are threatening to increase. The obvious targets are patents that are being sought for drugs can be used for treating diseases like HIV/AIDS, cancer and TB. In recent months, two significant developments have taken place. The first involved the Novartis patent on a drug used for the treatment of cancer, Gleevec. Product patent application for Gleevec was made using the "mailbox" provisions, which meant that Novartis could enjoy five-years of EMRs on the basis of this application. The EMRs were granted in November 2004, but the grant of the patent was opposed and the opposition was upheld by the Patent Office in January 2006. Subsequently, however, Novartis challenged the decision of the Patent Office in the courts, but the High Court of Madras[27] gave a ruling against the petitioners (see Annexure for details).

The second case involves GlaxoSmithKline's Combivir, a fixed-dose combination of two AIDS drugs (zidovudine/lamivudine, or AZT/3TC). Opposition to the grant of this patent was submitted on March 31, 2006 by a two civil society groups, the Indian Network of People Living with HIV/AIDS and the Manipur Network of Positive People. The opposition was based both on technical and health grounds[28]. The Indian groups opposing the patent are arguing that Glaxo's Combivir (AZT/3TC) is not a new invention but simply the combination of two existing drugs.

Future of the Generic Producers

One of the more contentious issues that the third amendment of the Patents Act had to address was the future of the generic producers in India who are currently producing the products and whose product patent applications are in the "mailbox". These producers would have to cease operations in India should patent rights be granted to such products under the new dispensation[29].

Section 11A of the Patents Act, 1970, as amended, protects the interests of such generic producers whose business interests may be affected in the product patent regime. This section states that "the patent holder shall only be entitled to receive *reasonable royalty* from such enterprises *which have made significant investment* and were producing and marketing the concerned product" before January 1, 2005, and "which continue to manufacture the product covered by the patent on the date of grant of the patent …" (emphasis added). In addition to this, it is provided that "no infringement proceedings shall be instituted against these enterprises".

Although this provision is expected to provide succour to the generic producers, it would have to face a number of imponderables. First, the threshold for assessing whether or not a given level of investment can be considered "significant" is not clear. This lacuna regarding the definition of "significant" poses threat of infringement suits as the patent holder may challenge any definition of "significant investment" that may be proposed to extract high royalty payments.

A further problem may be encountered while defining the term "reasonable royalty". This issue would be discussed in greater detail in the following section.

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[27] High Court of Madras (2007).

[28] See MSF (2006a).

[29] This stems from the fact that the patent rights can be used to prevent anyone from making, using, offering for sale, selling or importing the product covered by the patent.

As is to be expected, associates of foreign firms operating in India have argued that Section 11A is one of the most damaging provisions as the legitimate patent rights of applicants filing through mail box system would be nullified in case of generic product already in market. These firms point out that this Section goes against the doctrine of reasonable expectation, wherein the patent applicants would have filed in India with a legitimate expectation of their inventions being protected by patent laws.

Compulsory Licensing

In the context of the on-going debate on the patent law reforms, a key issue, which is often glossed over, is that the compulsory licensing system is one of the essential pillars of the patent system. It has been well recognised that compulsory licences are expected to play an important role in preventing abuse of patent rights that may arise when the patent holder tries to pre-empt entry of competitors using his statutory rights.

The context for this issue has been provided by the Paris Convention. Article 5A of the Stockholm Act of the Paris Convention clarifies that "failure to work[30]" or "insufficient working" of a patent constitutes an "abuse" of patent rights. In the event of an abuse of the patent rights arising from non-working or insufficient working, the patent granting authority was given the powers to issue a licence to anyone who was willing to "work" the patent.

Viewing from it a more functional perspective, the instrument of compulsory licence provides an opportunity to the prospective users of technology, in particular the developing countries, to gain access to proprietary technologies. The compulsory licensing system could be immensely useful for the generic firms in the Indian pharmaceutical industry for they can no longer meet their technology-requirements by taking recourse to reverse engineering.

Attempts to implement the compulsory licensing system may end up in widely differing outcomes, primarily because patent owners and potential users of patented technologies, the developing countries, have given widely contradicting interpretations of how a TRIPS-consistent compulsory licensing system should function. The patent-community has given a narrow interpretation of the provisions, arguing that compulsory licences should be used only under exceptional circumstances[31]. On the other hand, Governments of several developing countries have tried to use the compulsory licensing system in a manner that would allow their domestic enterprises to engage in production, since this has been seen as a critical aspect of promoting access to medicines[32].

Developments over the past few years indicate that the point of view of developing countries has been getting better support from the global community. In 2001, legal uncertainties in respect of the use of compulsory licensing provisions for public health concerns were effectively removed by the Doha Declaration on TRIPS Agreement and

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[30] Read "Commercial exploitation".

[31] According to the Pharmaceutical Research and Manufacturers of America (PhRMA), the association of the global pharmaceutical majors, "Compulsory licenses, are an exceptional remedy for use only in the case of market failure or significant abuse of a patent (e.g. a demonstrated antitrust violation linked to use of a specific patent, or a state of national emergency under which normal rules of commerce are suspended)". For details see Coalition for Intellectual Property Rights (2002),

[32] South Africa and Brazil are among the more prominent countries that have included compulsory licensing provisions in their patent laws.

Public Health. The Declaration stated unequivocally that "[E]ach Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted".

The Commission on Intellectual Property Rights (CIPR), which was instituted by UK Department for International Development, was equally supportive of the compulsory licensing system. In its report, "Integrating Intellectual Property Rights and Development Policy", the Commission emphasised that "developing countries should establish workable laws and procedures to give effect to compulsory licensing and provide appropriate provisions for government use"[33]. The CIPR recommended that developing countries should adopt effective compulsory licensing mechanisms which include straightforward, transparent and fast procedures that do not suspend the execution of the licence. Moreover, the CIPR emphasised that developing countries should fully exploit the flexibilities within TRIPS for determining compulsory licensing, as well as for non-commercial use by the government, including production for export.

Despite the above-mentioned developments, the compulsory licence system provided by India in its amended Patents Act may not fully meet the requirements of the domestic pharmaceutical industry. We maintain this view for the reasons explained below.

The Indian Patents Act provides that an application for the grant of compulsory licence can be made only after three years from the date of grant of the patent unless exceptional circumstances like national emergency or extreme emergency can be used to justify the grant of a licence on an earlier date. Three broad grounds for the grant of the compulsory licences have been spelt out thus: (a) reasonable requirements of the public with respect to the patented invention have not been satisfied, (b) the patented invention is not available to the public at a reasonably affordable price, and (c) the patented invention is not worked in the territory of India. The Patents Act sets out the circumstances under which "reasonable requirements of the public" would not have been met. Such circumstances would arise if the patent holder refuses to grant a licence on reasonable terms, and which, in turn, affects: (i) development of new trade or industry in the country, and (ii) establishment or development of commercial activities in India, and (iii) development of the export market for a patented article manufactured in India. The last mentioned provision is aimed at ensuring that India has the option to export the products that have been produced using the licences from the patent holders. The major impact of this provision could be felt in the pharmaceutical sector, where India could well emerge as a major supplier of generic pharmaceuticals to the developing countries that do not have sufficient domestic manufacturing facilities.

But while the above-mentioned conditions for the grant of compulsory licences can be seen to be facilitating the grant of the licences, the Act also stipulates that the relevant authority have to take into consideration four additional factors before the licences can be granted. These include: (a) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensees to make full use of the invention; (b) the ability of the applicant to work the invention to the public advantage; (c) the capacity of the applicant to undertake the risk in providing capital and working the invention, and (d) the efforts made by the applicant to obtain a

[33] Commission on Intellectual Property Rights (2002), , p. 44.

licence from patentee on reasonable terms and conditions and that such efforts were not successful within a reasonable period[34].

Consideration of these factors for granting compulsory licences gives rise to several problems. First, the procedural requirements are too onerous and could consequently result in delays. Secondly, it is not clear whether the grant of a compulsory licence would automatically follow the refusal of a patentee to issue a voluntary licence on reasonable commercial terms. Thirdly, the grounds for the determination of anti-competitive practices have not been spelt out either the Patents Act or Competition Act[35]. And, finally, there is no ceiling on the remuneration payable to the patent holder, which will inevitably lead to demand for excessive royalty and unnecessary litigations. As would be discussed below, the last mentioned problem has the potential of blocking the way for the use of compulsory licensing system.

Associates of foreign firms operating in India also have serious reservations about the compulsory licensing provisions included in Patents Act, 1970, as amended. Some of these firms have pointed out that the existing triggers for issuing a compulsory licensing are far too many in number, which, according to the respondents, goes well beyond the realm of Public Health exigencies and extends sweeping CL provisions across the board and not just to "national emergency" situation, as envisaged in TRIPS and as clarified by the Doha Declaration.

The remuneration that a patent holder could demand following the decision to grant compulsory licence for the "working" of patents in the country of grant act may become a serious constraint for the smooth functioning of the compulsory licensing system. This situation arises because the Agreement on TRIPS provides the rights holder a distinctly superior bargaining position. Article 31(h) of the TRIPS Agreement, which provides the guideposts in this regard, states that "the right holder shall be paid adequate remuneration … taking into account the economic value of the authorization" (emphasis added). This Article has the potential of rendering the cost of the licence prohibitive for the drug majors have claimed that the average cost of bringing one new medicine to market is at least a billion US dollars[36].

Presenting a contra view on the issue of remuneration, associates of foreign firms have argued that the interpretation of "economic value of licenses" is not clear in the law, leaving it to the subjective judgment of the Controllers to decide the terms and conditions of the license. These firms point out that since the compulsory licensing provisions in the Indian law are such that the interests of applicant for a compulsory licence have been put

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[34] The third amendment provided some crucial clarifications pertaining to this condition. The designated authority has been allowed to interpret the term "reasonable period" to mean a period not ordinarily exceeding six months (Section 84(6)).

[35] In fact, India's Competition Act (enacted in 2002) does not address abuses of patent rights. Section 3(5) of the Competition Act, states: "Nothing contained in this section shall restrict … the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his rights which have been or may be conferred upon him under … the Patents Act, 1970. See Govt of India (2003)

[36] The Pharmaceutical Research and Manufacturers of America (PhRMA) states that it takes as long as 15 years and cost nearly 1 billion dollars to bring a new medicine from the laboratory to a pharmacy shelf. This figure has, however, been challenged by several public interest groups. See PhRMA (2006).

before that of the patentee, the patent holders could find it difficult to protect their interests.

Royalty payments would be a critical issue in the implementation of the compulsory licensing system as is provided in the Indian Patents Act. Besides the problems alluded to above, there are evidences galore of developing countries being unable to afford proprietary technologies because the high cost of acquiring such technologies. This situation has occurred primarily because the owners of technology have been able to use their superior bargaining position to seek terms that have suited their interests[37]. In an age when a web of patents covering a single product (better known as patent thickets[38]) have become commonplace, multiple licences are often required to be negotiated before any enterprise can commence production. Patent thickets have also given rise to another problem, viz. royalty stacking. According to an OECD study, firms have reported that in some cases royalty payments can exceed 20% of their net sales[39]. And, in South Africa, GlaxoSmithKline demanded a royalty of 25% before the courts intervened. A higher royalty will increase the price of generic drugs and this, in the ultimate analysis would militate against the existence of the generic producers whose *raison d'etre* is to supply medicines at affordable prices.

India's own experience with technology licensing agreements makes interesting reading. Past trends show that the licensors were able to secure payments for their technologies even when they were not transferring proprietary technologies. Surveys of foreign collaboration agreements conducted over a three decade period by the Reserve Bank of India revealed that proprietary technologies were transferred in only about 50% of the cases[40].

The provisions in the Indian Patents Act relating to the payment of royalty and other remuneration for obtaining a licence do not address the above-mentioned problems. In fact, Section 90 provides that the remuneration would take into consideration the perspective of the patentee, which includes the expenditure incurred by the patentee for making and developing the invention and for obtaining and keeping the patent in force. It may be argued that these considerations for determining the royalty and other remuneration would enhance the already superior bargaining position of the patentee and that these would need to be tempered with public interest considerations as well[41].

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[37] A well-documented Indian case from the pre-1970 phase, when the country had a product patent regime cogently illustrates this issue. In response to an application for compulsory licence by a government – owned research institute, Haffkine Institute, the patentee indicated that it was willing to grant a voluntary licence. At the end of the negotiations, however, the patentee demanded a royalty of 25%. Further negotiations followed, and after more than four years, the patentee agreed to reduce the royalty to 10 per cent, which was still higher than 5% limit fixed by the government. This protracted process of negotiations for obtaining a licence was found too costly by the prospective licensee and it was forced to abandon the project. For details see, Lok Sabha (1969).

[38] A more formal definition of patent thicket is the following: it is a "dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology", see Shapiro (2001) quoted in Federal Trade Commission (2003).

[39] OECD (2002), p. 15.

[40] Reserve Bank of India (1974); Reserve Bank of India (1985), p. 36.

[41] Dhar and Rao (2004).

These were some of the considerations that were highlighted by the Doha Declaration on TRIPS Agreement and Public Health, which, as stated earlier, provides the flexibilities to the Member countries to adopt an effective compulsory licensing system. However, in light of the above-discussion it can be concluded that India has not ensured that its compulsory licensing system can function in a manner that public interest concerns can be addressed. While the procedural complexities would delay the grant of licences, ambiguities on the methodology for determining remuneration to the patentee, can be a serious roadblock. The latter issue, in our view, requires focused attention.

It may be suggested in this context that two alternative frameworks for calculating the value of licences granted by invoking the provisions relating to compulsory licences may be considered. These formed parts of two bills that were part of bills that were presented to the 107th Congress of the United States in 2001. The Affordable Prescription Drugs and Medical Inventions Act (HR 1708) seeks to amend the US Patent Law (Title 35, United States Code) to provide for compulsory licensing of certain patented inventions relating to health. The Public Health Emergency Medicines Act (HR 3235) aims at providing for compulsory licensing of certain patented inventions relating to health care emergencies, through an amendment of the US Patent Law.

Boxes 2 and 3 provide the details of methodologies that have been suggested in the proposed Acts for determining the remuneration that the patentee should be paid in case compulsory licences are issued for "working" patented medicines.

Box 2: Considerations for Determining Remuneration for use of a Patent

In determining the reasonableness of licensing terms and the remuneration for the use of a patent under subsection (c), the Secretary of Health and Human Services or the Federal Trade Commission (as the case may be) shall consider—

1. the risks and costs associated with the invention claimed in the patent and the commercial development of products that use the invention;
2. the efficacy and innovative nature and importance to the public health of the invention or products using the invention;
3. the degree to which the invention benefited from publicly funded research;
4. the need for adequate incentives for the creation and commercialization of new inventions;
5. the interests of the public as patients and payers for health care services; and
6. the public health benefits of expanded access to the invention.

Source: House of Representatives, Affordable Prescription Drugs and Medical Inventions Act (H. R. 1708): To amend Title 35, United States Code, to provide for Compulsory Licensing of certain patented inventions relating to health, 107th Congress, 1st Session, May 3, 2001.

Box 3: Compensation for Use of a Patent

In exercising the right under subsection (a) to authorize other use of the subject matter of a patent, the right holder shall be paid reasonable remuneration for the use of the patent. In determining the reasonableness of remuneration for the use of a patent, the Secretary of Health and Human Services may consider—

1. evidence of the risks and costs associated with the invention claimed in the patent and the commercial development of products that use the invention;
2. evidence of the efficacy and innovative nature and importance to the public health of the invention or products using the invention;
3. the degree to which the invention benefited from publicly funded research;
4. the need for adequate incentives for the creation and commercialisation of new inventions;
5. the interests of the public as patients and payers for health care services;
6. the public health benefits of expanded access to the invention;
7. the benefits of making the invention available to working families and retired persons;
8. the need to correct anti-competitive practices; or
9. other public interest considerations.

Source: House of Representatives, Public Health Emergency Medicines Act (H. R. 3235): To amend title 35, United States Code, to provide for compulsory licensing of certain patented inventions relating to health care emergencies, 107th Congress, 1st Session, November 6, 2001

The limitations of the compulsory licensing system that we have alluded to above would necessitate, in our view, a review in light of the experience gained from the implementation of the newly amended Patents Act. This experience would be of crucial

value since India does not have much to show in terms of a viable compulsory licensing system[42]. In the product patent regime, i.e. in the pre-1970 phase, only five applications were made for the grant of compulsory licenses. Of these, licences were granted in only two cases and refused in one case. In the two remaining cases, the applications were eventually withdrawn[43].

The post-1970 phase saw India introduce a process patent regime covering all forms of chemicals, including pharmaceuticals. Furthermore, the term of process patent protection covering pharmaceuticals was set at five to seven years[44]. While the process patent regime allowed the Indian pharmaceutical firms to generate alternative processes for manufacturing products that were under product patent in other jurisdictions, the shortening of the term of pharmaceutical (process) patent proved to be a damper for foreign firms to seek patents in India.

Opposition Proceedings

Another issue of considerable significance to India that the third amendment of the Patents Act has dealt with is the issue of opposition to the grant of patents. While the Ordinance that was brought in December 2004 watered-down the provisions relating to pre-grant opposition while introducing post-grant opposition, the amended legislation restores the ground on which pre-grant opposition can be made. Although the grounds for opposition available in the pre-grant stage have been restored, the right of appeal is available only for post-grant opposition. India has thus become the only country among the major patent granting ones, which provides for both pre- and post-grant opposition in its patent legislation. It may well be argued that by so doing India has put the patent applicant in a disadvantageous position, an argument that can bring the entire procedure for opposition to the grant of patents before the courts[45].

An issue of immediate relevance in this context is the manner in which the opposition proceedings are conducted in case of applications that are in the "mailbox". Following "Gleevec" case, discussed earlier, pre-grant opposition proceedings have been initiated in more than 100 cases. Besides, the domestic industry, public interest groups have also initiated opposition proceedings[46]. However, effectiveness of the opposition proceedings depends upon the access to information on the mailbox applications. The Patent Office in 2005 has issued a notification in its official journal that inventions either filed or claiming priority on July 30, 2003 have been deemed to be published. However, no physical publications have been available to date. This lack of publication takes away the possibility of accessing information relating to the patent application and the ability to oppose the same. Lastly the Act refers to the publication of an application, but fails make

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[42] Although India had introduced the Patents and Designs Act in 1911, provisions specifically dealing with compulsory licenses for pharmaceutical patents were introduced only in 1953. See, Rao (2002)

[43] Chaudhuri (1984).

[44] The term was five years from the date of grant of a patent, or seven years from the date of its application, whichever was shorter.

[45] Associates of foreign firms operating in India have opposed the open-ended time time for pre-grant opposition.

[46] In May 2006, the Indian Network for People Living with HIV/AIDS (INP+) and the Delhi Network of Positive People filed an opposition to the grant of patent on tenofovir disoproxil fumarate (TDF), a key AIDS drug that is marketed under the brand name Gilead, see MSF (2006b)

the publication of the complete specification available to the public. This will greatly hamper opposition proceedings.

Associates of foreign firms operating in India have alluded to the delays in the grant of patents that the provisions allowing for pre-grant opposition had resulted in. These firms have further argued that frequent and extended delays under this system of pre-grant opposition demonstrate that India does not comply with the requirement of Article 62.2[47] and 62.4[48] of TRIPS.

Regulation of Licenses

Licensing is the most common mode of transferring a patented technology. Generally, speaking license of patents happens in three ways viz. commercial license, voluntary license and compulsory license. Within the framework of the TRIPS Agreement, licensing agreements are important because the Agreement promotes commercial and voluntary licensing by making compulsory that effort to obtain license as a pre- condition before applying for compulsory license in the normal course. Therefore, regulation of licensing agreements is critical to promote access to medicines and the transfer of technology, which is explicitly mentioned as one of the principles of the Agreement on TRIPS. The Agreement does not prevent members from regulating licensing practices or conditions that may particularly constitute an abuse of intellectual property rights and have an adverse effect on competition in the relevant market. Further, it obligates members to engage in consultation if the intellectual property owner belongs to one country and indulges in practices that violate the regulations on licensing agreements and vice versa. Certain conditions in the licensing agreement can eliminate the purpose of technology transfer. Often licensing agreements comes with various conditions to prevent the competition in the market.

The Patents Act has addressed this issue in Section 140. According to the provisions of this section, the following conditions in a licensing agreement are unlawful:

(a) to require the purchaser, lessee, or licensee to acquire from the vendor, lessor, or licensor, or his nominees, or to prohibit from acquiring or to restrict in any manner or to any extent his right to acquire from any person or to prohibit him from acquiring except from the vendor, lessor, or licensor or his nominees, any article other than the patented article or an article other than that made by the patented process; or

(b) to prohibit the purchaser, lessee or licensee from using, or to restrict in any manner or to any extent the right of the purchaser, lessee or licensee, to use an article other than the patented article or an article other than that made by the

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[47] Article 62.2 provides that "… Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection."

[48] Article 62.4 provides that "… inter partes procedures such as opposition, revocation and cancellation, shall be governed by the general principles" would have to "… be fair and equitable", and that they would "… not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays". The Article further provides that the decisions in respect of the above-mentioned procedures should preferably "be in writing and reasoned", and that they should "be made available at least to the parties to the proceeding without undue delay".

patented process, which is not supplied by the vendor, lessor or licensor or his nominee; or

(c) to prohibit the purchaser, lessee or licensee from using or to restrict in any manner or to any extent the right of the purchaser, lessee or licensee to use any process other than the patented process, exclusive dealing on non-patented article; use of a non-patented article other than that supplied by the licensor; use of any process other than the non-patented process; and exclusive grant back.

However the main lacuna of this Section is that it does not link this clause with compulsory license or anticompetitive remedies. The only remedy provided in the Act is that such conditions in a license can be used as a ground against infringement proceedings. Therefore there is a need to link these provisions to compulsory license provisos f the Patents Act.

The Two Exemptions

Section 107A of the Patents Act, 1970, as amended contains two notable exemptions. The first relates to what is better known as the "Bolar Exemptions" and the second exemption seeks to define the contours of parallel imports.

"Bolar Exemption"

One of the less focused areas of the Indian Patents Act, as amended, is the provision providing for the so-called "Bolar exemption"[49]. The basic idea behind the "Bolar exemption" is to create conditions so that the generic drug manufacturers can introduce their products immediately after the patent on a drug lapses[50]. With the leading firms in the Indian pharmaceutical showing considerable degree of dynamism in recent years, which we shall discuss in the following section, the "Bolar exemption" assumes considerable importance for the future of the generic producers in India.

The "Bolar exemption" became a feature of the US patent statute in 1984, following the ruling of the Court of Appeals for the Federal Circuit in Roche Products Inc. v. Bolar Pharmaceuticals Co. Inc. This case involved a generic manufacturer (Bolar Pharmaceuticals) who had used a patented invention to test and apply for marketing authorisation of its version of a patented medicine. The Court had determined that the common law "experimental use" defence only covered experimentation for scientific, not commercial, purposes, and that the generic manufacturer's activities therefore amounted to an infringement of the relevant patents[51].

Section 271(e)(1) of the US patent law (35 USC), which provided the "Bolar" or "experimental use exception" allowed the generic firms to conduct research on patented drugs prior to the expiration of the patent, so long as the experiments were "reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products". The effectiveness of the "experimental use exception" was however dependent on the

[49] Also called "Experimental Use Exception".

[50] Associates of foreign firms operating in India have argued that the objective of the Bolar provision is not to further scientific work in general, but more to ensure availability of products as soon as the term of a patent is over.

[51] WTO (2000), p 37.

interpretation of the term ""reasonably related", and not unexpectedly, this term was the subject matter of a litigation between Merck KGaA and Integra Lifesciences, which was adjudicated upon by the US Supreme Court[52].

In a significant ruling, the US Supreme Court clarified that "Section 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA[53]," (emphasis in original) and that "[t]his necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process." The Court held that Section 271(e)(1) applies to preclinical in vitro and in vivo studies intended to obtain information on the "pharmacological, toxicological, pharmacokinetic, and biological qualities of the drug in animals".

Following from the precedence set in the US, Canada took two significant steps to make carve outs in its Patent Act. Section 55.2(1), or the "regulatory review exception", of the Canadian Patent Act allowed all activities related to the development and submission of information required to obtain marketing approval for pharmaceutical products carried out by a third party without the consent of the patent holder at any time during the patent term. Further, Sections 55.2(2) and (3), or the "stockpiling" exception, of the Patent Act together with the Manufacturing and Storage of Patented Medicines Regulations allowed manufacturing and stockpiling of pharmaceutical products during the six months immediately prior to the expiration of the 20-year patent term.

The Members of the EC brought a dispute to the WTO maintaining that the above mentioned sections of the Canadian Patent Act violated the rights of the patent holder as provided in Article 28 of the TRIPS Agreement. According to the EC, the "Bolar exemptions" provided by Canada using Section 55.2(1) of its Patents Act took away all the rights a patent granted its owner, i.e. making, constructing, using (this included importing) and selling, and did not stipulate any quantitative limits for these activities. The only limitation set out by the law consisted in the objective of these activities, i.e. they must be "… reasonably related to the development and submission of information" required for obtaining marketing approval anywhere in the world. In addition, the permissible activities under Section 55.2(1) of the Canadian Patent Act were not limited in time. The EC argued that this in other words implies that the activities might be performed without the consent of the right holder at any point in time during the 20-year patent term.

Section 55.2(2) and (3) of the Canadian Patents Act allowed anybody in Canada to perform the acts of making, constructing and using of the invention during the last six months of the patent term without the authorization of the patent holder. EU argued that in order to perform the above-mentioned acts, no particular authorization was needed from the Canadian authorities. Besides, the provisions did not qualify the terms of the extent and volume of the use, and no royalty fees were to be paid to the patent holder. In fact, EU's view was that the patent holder did not have any right to be informed of such "unauthorized" use of his invention.

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[52]Supreme Court of the United States (2005)

[53]Supreme Court of the United States (2005).

The findings of the panel adjudicating this dispute was that while the "regulatory review exception" i.e., Section 55.2(1) of the Canadian Patent Act, was consistent with Canada's obligations under the TRIPS Agreement, Sections 55.2(2) and (3), the stockpiling exception, violated the provisions of the Agreement.

The "Bolar exemption" was included in the Second Amendment of the Indian Patents Act, 1970. Section 107A(a) of the amended law contains the relevant provisions:

> "Any act of making, constructing, using, selling or importing[54] a patented invention solely for uses reasonably related to the development and submission of information required for the time being in force, in India or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product".

Although in its essentials, Section 107A(a) mirrors the provisions of the Canadian Patent Act, it has one significant difference. Included in the exception to the rights is the act of importation, which the Canadian Patent Act does not provide. The implications of including the act of importation as a part of the "Bolar exemptions" are not immediately obvious. Nor is it clear as to how this exemption may in any way affect the applicability of Section 107A(b) that provides for parallel imports.

Parallel imports

The Agreement on TRIPS allows for the parallel imports, although the specific circumstances under which such imports can take place have not been defined. The Indian Patents Act, 1970 has taken the initiative to include the provision of parallel imports. The relevant provision, provided under Section 107A(b) reads as follows:

> "Importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product"

As has been explained by the Government, this provision of parallel import of patented product was introduced for "ensuring availability of patented products at cheaper price to the consumers"[55]. In particular, reference to a person "duly authorised under the law" to produce and sell or distribute the product seems to indicate that parallel imports may include products produced under compulsory license. OECD countries have traditionally excluded such possibility, limiting parallel imports to products marketed abroad with the consent of the patent holder. The TRIPS Agreement is silent on this issue.

The three amendments to the Indian Patents Act, which have introduced a TRIPS-consistent patent regime in the country, were brought about in the backdrop of intense debates that were focused on the need to establish a balance between the rights of the patent holders and the interests of the public at large. These debates have emphasised the point that with the rights of the patent holders getting strengthened through Agreement on TRIPS there is an urgent need to ensure a balance through the introduction of more effective instruments so that the public interest concerns, as for example, access to medicines at affordable prices are addressed. Holding the key to the realisation of the objective of access to medicines was the existence of a viable pharmaceutical industry in the country. It was therefore imperative that all available flexibilities in the framework

[54] As amended by the Patents (Amendment) Act, 2005.

[55] Lok Sabha Secretariat (2005).

provided by the Agreement on TRIPS were exploited fully so as to provide the space for the Indian pharmaceutical industry to expand.

Although the TRIPS-consistent Patents Act has been in operation for about a year now, there is growing evidence that its implementation would be "litigation-ridden". This portends to the uncertain times that await pharmaceutical firms.

It may be argued however, while the flexibilities are in the nature of necessary conditions for the future prospects of the pharmaceutical industry in the post-TRIPS patent regime, they are not sufficient conditions. The determining factor, in our view, would be the manner in which domestic firms would be able to evolve strategies for meeting the challenges posed by the introduction of the TRIPS-consistent patent regime. The following Section analyses the performance of the Indian pharmaceutical industry for making an assessment of how the domestic firms are meet the post-TRIPS challenges.

Chapter 3 : Data Exclusivity and Access to Medicines

The most recent affronts on the rights of the developing countries like India to provide access to medicines at affordable prices to its citizens, has come through pressures brought by the US and the EU for the introduction of data exclusivity. This demand is linked to the implementation of Article 39.3 of the TRIPS Agreement, which requires WTO Members to protect undisclosed test or other data, developed with "considerable effort", against "unfair commercial use" when such data are submitted for seeking marketing approval for products using "new chemical entities". In addition, Members are required to protect such data against "disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use."

While Article 39.3 is clearly intended to ensure that "undisclosed test data" was not misappropriated, the pharmaceutical industry associations in the United States and the European Union, representing the larger firms, have argued that Article 39.3 should be interpreted in a manner that provides statutory protection spanning a period of time to data submitted for obtaining marketing approval, among others.

In a submission made in 1999, the Pharmaceutical Research and Manufacturers of America (PhRMA) had argued for the implementation of effective data protection standards that provide the intended level and form of protection as provided for in Article 39.3. An effective implementation of data protection standards in view of PhRMA would require that the following steps should be taken: (i) ensure at least ten years of exclusive marketing rights for the pioneer applicant measured from the date of approval of the pharmaceutical in the WTO member; (ii) not make data protection contingent upon concurrent patent rights covering the pharmaceutical product; and (iii) preclude reliance by third parties on marketing approvals granted to the pioneer applicant by a health regulatory agency in another WTO member. These steps suggested by PhRMA are clearly intended to extend the period of protection that a product would enjoy under the patent laws, thus rendering ineffective the process of dissemination of technology, which is one of the intended objectives of the patent system. In fact, the period of data exclusivity demanded by PhRMA is twice that is currently available in the United States.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) in their position have stated that it is protection against "unfair commercial use" of data relating to pharmaceutical and agricultural chemical products that is the primary objective of Article 39.3[56]. It is this rationale for using Article 39.3, as indicated by EFPIA, which is more significant in the present context. The EFPIA have held the view that the relevance of the Article arises primarily because "more and more compounds are being developed which are not patent protected". The development of these compounds, according to EFPIA, "does not require less extensive or complex tests and clinical trial data" and hence the need to introduce data protection.

These views held by the pharmaceutical associations were also articulated in unambiguous terms by the officialdom. The USTR General Counsel stated in 1995 that "negotiators understood it [the term "unfair commercial use"] to mean that data will not be used to support, clear or otherwise review other applications for marketing approval

[56]EFPIA (2000).

for a set amount of time unless authorized by the original submitter of the data. Any other definition of this term would be inconsistent with logic and the negotiating history of the provision"[57]. More recently, the European Commission submitted thus: "Both the logic and the negotiating history of Article 39.3 of TRIPS leave no doubt that providing data exclusivity for a certain period of time was the envisaged way to protect data against unfair use as prescribed by Article 39.3… Whether any system other than data exclusivity over a reasonable period of time would meet the requirements of Article 39.3 of the TRIPS Agreement is to be assessed on a case-by-case basis, but examples of actual application by WTO Members of alternative – and TRIPS compliant – system to non-reliance over a reasonable period do not appear to exist."[58]

The European Generics Association (EGA), the representative body for the European generic pharmaceutical industry representing over 400 firms either directly or through national associations from throughout the European Union, has a contrary view. According to the EGA, the interpretation that Article 39.3 requires data exclusivity is clearly beyond the agreed terms of TRIPS. It also undermines the basic objective of the Agreement as outlined in Article 7, i.e. to seek the enforcement of intellectual property "in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

EGA has argued that Article 39.3 cannot be viewed in isolation from the whole of TRIPS. Article 39, which is devoted to effective protection against unfair competition as provided in Article 10^{bis} of the Paris Convention. The association has further added that in order to understand the nature of TRIPS Article 39.3, the difference between the "repression of unfair competition" and other forms of intellectual property protection should be understood. This difference is made clear by WIPO when it stated:

> "Industrial property deals principally with the protection of inventions, marks (trademarks and service marks) and industrial designs, and the repression of unfair competition. The three subjects first mentioned have certain features in common inasmuch as protection is granted for inventions, marks and industrial designs in the form of exclusive rights of exploitation. The repression of unfair competition is not concerned with exclusive rights, but is directed against acts of competition contrary to honest practices in industrial or commercial matters, for example, in relation to undisclosed information (trade secrets)."

EGA further pointed out that a clear definition of unfair competition, and the examples of unfair competition, is provided by WIPO:

> "The repression of unfair competition is directed against acts or practices, in the course of trade or business, that are contrary to honest practices, including, in particular:
>
> 1. Acts which may cause confusion with the products or services, or the industrial or commercial activities, of an enterprise;
> 2. False allegations which may discredit the products or services, or the industrial or commercial activities, of an enterprise;

[57] Quoted by PhRMA (2003).

[58] Quoted by PhRMA (2003).

3. Indications or allegations which may mislead the public, in particular as to the manufacturing process of a product or as to the quality, quantity or other characteristics of products or services;
4. Acts in respect of unlawful acquisition, disclosure or use of trade secrets;
5. Acts causing a dilution or other damage to the distinctive power of another's mark or taking undue advantage of the goodwill or reputation of another's enterprise."

Associations of generic manufacturers in India, in particular the Indian Pharmaceutical Alliance (IPA), have argued that the global pharmaceutical firms want to extend market exclusivity of patented products beyond the period of 20 years of patent protection by using Article 39.3. Grant of data exclusivity, in view of the IPA, would seriously jeopardise the one of the major objectives of the Indian pharmaceutical industry, which is capturing larger share of the international generic market.

Article 39.3 is likely to have an impact on the prospects of domestic pharmaceutical industries in countries like India on at least two counts. In the first place, the provisions of this Article would allow market exclusivity to be granted on products that have been in public domain even before the Agreement on TRIPS came into existence, but have not been commercialised. And, secondly, monopoly over the market in respect of a product can be exercised even after the patent term of the product would have expired (see chart 1 for details).

Article 39.3 in Perspective

The requirements under Article 39.3 can be best understood by dwelling on two aspects – one through an understanding of the essentials of the negotiating history of the provision, and two, through its textual interpretation. The following discussion dwells on these issues.

Negotiating History of the Article

The United States was among the first movers for the inclusion of protection of undisclosed information as a part of TRIPS. In one of its early submissions to the Negotiating Group made in 1987, the United States introduced the concept of trade secrets, which was defined to include undisclosed valuable business, commercial, technical or other proprietary data as well as technical information. According to the United States, misappropriation, including unauthorised use or disclosure of a trade secret had to be prevented. Furthermore, it was argued that trade secrets submitted to governments, as a requirement to do business should not be disclosed except in extreme circumstances involving national emergencies, or in case of public health and safety, if such disclosure did not impair actual or potential markets of the submitter or the value of the submitted trade secrets[59].

At least three features of the United States' submission to the TRIPS Negotiating Group are immediately evident. The first is that it introduced some of the key elements of Article 39.3, which included the concept of trade secrets or undisclosed information. Secondly, the submission went quite beyond the applicability of Article 10^{bis} of the Paris

[59] GATT (1987)

Convention, which was intended to check unfair competition as a result of the implementation of the regimes of intellectual property rights that were covered under this Convention. It may be argued that Article 10^{bis} was intended to prevent misuse of any information consequent upon the right holders disclosing their inventions, which may be to the detriment of the commercial interests of the rights holders, and this was indeed the basis of its inclusion in TRIPS. And, last but not the least important, particularly in the context of the present debate, the United States proposed a misappropriation regime as opposed to one that conferred rights, for protecting information. This initial position was later to change as has been indicated below.

A similar approach was also adopted by the business communities of Europe, United States and Japan, who made a joint statement proposing a framework for the regime of intellectual property protection that, in their view, should be adopted at the end of the TRIPS negotiations. In their submission, the business communities proposed the following in respect of protection of test data:[60]

> *Information required by a government to be disclosed by any party shall not be used commercially or further disclosed without the consent of the owner.*
>
> *Information disclosed to a government, as a condition for registration of a product shall be reserved for the exclusive use of the registrant for a reasonable period from the day when the government approval based on the information was given. The reasonable period shall be adequate to protect the commercial interests of the registrant.*

The business communities were thus clearly aiming for the realisation of a regime, which provided exclusive rights over the data that was submitted to the government for the registration of the product. European Union (EU), US and Switzerland made separate proposals to the Negotiating Group on the protection of data. According to the EU *data shall protect against unfair exploitation by competitors.*[61] US proposed the contracting parties *"shall not use the trade secrets for the commercial or competitive benefit of government or of any person other than the right holder except with the right holder's consent, on payment of the reasonable value of the use or if a reasonable period of exclusive use is given the right holder".*[62] Switzerland proposed, *"the government agencies shall not be entitled to use the information for commercial purposes".*[63]

In a later submission before the TRIPS Negotiating Group, the United States put forth the view that issue underlying the protection of trade secrets was the same as that underlying the protection of intellectual property rights generally, namely that of not benefiting from the fruits and labours of others improperly. It was suggested that a two-pronged approach should be taken to the protection of trade secrets. First, in regard to the transfer of know-how between private parties, the confidentiality of information given to employees and restrictions on its divulgation should be protectable through the courts; protection against use in a competing enterprise should also be available when such information had been improperly obtained by a third party. Secondly, there should be restrictions on the use

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[60] Quoted by Correa (2002), p. 53

[61] GATT (1990a)

[62] GATT (1990b)

[63] GATT (1990b)

and disclosure of information made available to governments. The need for exceptions in this respect was acknowledged in the United States' proposal. It was argued that such an exception could be provided in the case of a national emergency or for environmental reasons, but in no event should the recipient of the information be allowed to use such information to compete with the person who had generated it.

As regards the question of the definition of trade secrets, he referred to the definition contained in the relevant United States law. The definition contained in the Uniform Trade Secrets Act of the United States was that a trade secret is any information, including a formula, pattern, compilation, program, device, method, technique or process that (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. In essence, a trade secret was considered identifiable information, which (i) was protected from disclosure by reasonable efforts by its owner and (ii) had value because it was not known and could not be ascertained easily by others.

The Chairman of the TRIPS Negotiating Group provided the initial formulation for including undisclosed information in the proposed Agreement, which read thus:[64]

> "*Parties which require that trade secrets be submitted to carry out governmental functions, shall not use the trade secrets for the commercialisation or competitive benefit of the government or of any person other than the right holder except with the right holder's consent. Proprietary information submitted to a government agency for the purposes of regulatory approval procedures such as clinical or safety tests, shall not be disclosed …".*

The draft submitted in 1990 to the Brussels Ministerial Conference, which was supposed to conclude the Uruguay Round negotiations according to the time-table agreed to in Punta del Este where the eighth round of GATT negotiations was launched, presented the following text to the Contracting Parties in respect of undisclosed information:[65]

"Parties, when requiring as a condition of approving the marketing of pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed tests or other data, the origination of which involves a considerable effort shall [protect such data against unfair commercial use. Unless the person submitting this information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature and the expenditure involved in their preparation. In addition parties shall protect such data against disclosure, except where necessary to protect the public]" (emphasis added).

The final text of the Agreement on TRIPS adopted in 1994 made no mention about the reliance upon for the approval of competing products. Further, it also omitted reference to the period for which undisclosed information was to be granted protection. According to the European Union, "the US negotiators had decided to drop the more explicit language of the earlier drafts since they did not view such wording as essential" because the

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[64] GATT (1990a)

[65] GATT (1990b)

common understanding of protection against unfair commercial use included granting of protection for a fixed period of time.

The veracity of this claim made by the EU can be questioned in using the explanation given by the Vienna Convention on the Law of Treaties on the interpretation of treaty language. According to the Vienna Convention, "a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose". Hence, one cannot argue that the term unfair commercial use obligates members to provide data exclusivity beca use such reference to the concerned article has been removed in the final text.

A Textual Interpretation of the Article

According to Article 39.3 of TRIPS "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use."

Thus there are two obligations under Article 39.3 viz. (i) to protect data submitted for marketing approval against unfair commercial use and (ii) to protect the submitted data against disclosure by the authorities and the disclosure is permitted only under two circumstances i.e. to protect the public and to disclose data after taking steps against unfair commercial use. Therefore, the moot question is whether the reliance of originator's data for the subsequent marketing approval constitutes an unfair commercial use under Article 39.3 of TRIPS. In other words, India can define the parameters of unfair commercial use to exclude data exclusivity (non-reliance). The following paragraph examines this question.

Our view is that the obligations under Article 39.3 should be understood in the light of Article 39.1 of TRIPS. According to Article 39.1 "in the course of ensuring effective protection against unfair competition as provided in Article 10^{bis} of the Paris Convention (1967), Members shall protect … data submitted to governments or governmental agencies in accordance with paragraph 3." Thus the obligation of the members is to protect data submitted to the government or government agencies in the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention. Even though, Article 39.3 uses the term unfair commercial use instead of unfair competition the purpose and the meaning of the word unfair commercial use conveys the same meaning. Article 10 bis of the Paris Convention defines unfair competition as "any act of competition contrary to honest practices in industrial or commercial matters". The examples given in the same Article do not talk about any exclusive rights on the undisclosed information. Further, the World Intellectual Property Organization (WIPO) developed Model Provisions on Protection Against Unfair Competition" (Model Law) in 1996, essentially to give effect to Article 10bis does not give any exclusive rights on undisclosed information. According to WIPO, "repression of unfair competition is not concerned with exclusive rights, but is directed against acts of competition contrary to honest practices in industrial or commercial matters, for example, in relation to undisclosed information (trade secrets)". This Model Law spells out the requisites, which in view of the WIPO would be essential for implementing Article 10bis.

The Model Law does not indicate that a fixed term of protection of undisclosed information is what is necessary for effectively implementing the above-mentioned Article of the Paris Convention. More importantly, under the discipline of unfair competition, protection is not based on the existence of "property" rights . According to Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) appointed by the World Health Organisation, Article 39.3 "does not create property rights, nor a right to prevent others from relying on the data for the marketing approval of the same product by a third party, or from using the data except where unfair (dishonest) commercial practices are involved"[66]. Hence, there is no obligation under Article 39.3 to create exclusive rights on the data submitted for market approval.

It needs to be emphasised here that protection of data against unfair commercial use does not prevent government or its agencies from relying on the originator's data to provide the subsequent marketing approval. Such reliance on the data by government or its agencies cannot be termed as commercial use, let alone it being unfair commercial use because the purpose of such reliance is in the public interest to ensure access to safe and quality medicines. Further, the obligation is to protect the data against unfair commercial use and therefore it necessarily implies that the data can be used/relied for fair commercial use. Reliance of data by the DRA for the subsequent marketing approval is a fair commercial use for the competitor and also termed as a fair use by the government.. Hence, there is no obligation to provide data exclusivity under Article 39.3.

Article 39.3 also prescribes certain criteria for the protection against unfair commercial use. Firstly, the obligation against unfair commercial use is limited to undisclosed test data and does not cover the whole range of data submitted for marketing approval. This means the data, which is already published or available in the public domain, is not eligible for protection. Hence, a large chunk of data, which is published through research journals and other publications, need not be protected against unfair commercial use or by the regulatory authority. Further, there are two more criteria are to be satisfied to qualify for protection under Article 39.3. These criteria are: the data should be related to new chemical entities (NCE) and the origination of data should involve considerable effort. TRIPS Agreement does not provide any clarifications/definitions on the meaning of these terms. Therefore it is up to each member to define these terms.

From an operational perspective, Article 39.3 hinges on these two key terms. The first is that the scope of protection is limited only to NCEs. The second issue is that protection can only be justified when considerable effort has been expended for the development of the pharmaceutical (or agricultural chemicals). These elements need clarification since the TRIPS Agreement does not provide any guidance on their possible definitions.

According to USFDA a new chemical entity means "a new molecular entity (NME) or new chemical entity (NCE) means a drug that contains no active moiety that has been approved by FDA in any other application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act. An active moiety means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance ". However, the advocates of data

[66] Commission on Intellectual Property Rights, Innovation and Public Health (2006), p. 143

exclusivity would like to increase the scope of the definition hence the data exclusivity protection is available to change in dosage, route of administration and even salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance. This would result in the number of monopoly in the pharmaceutical market. Hence, developing countries like India need not protect any data related known substance.

The last requirement to eligible for the protection is *Considerable Effort*: The data, which is entitled to protection, should involve considerable effort in the origination of data. In the normal sense of the term, considerable effort is required only to develop a new chemical entity and not to change the dosage or route of administration of a known substance. Therefore, the data created through truncated trails need not be protected against unfair commercial use under Article 39.3.

Recent Developments

Currently, many developing countries including Argentina, Brazil, India and South Africa do not provide data exclusivity. The USA had requested the constitution of a panel under the WTO Dispute Settlement Understanding against Argentina on the question of data exclusivity. However, the USA withdrew its request for panel. It is with the same understanding on Article 39.3 that USA is insisting on explicit data exclusivity provisions in the Regional Trade Agreements (RTA) and Free Trade Agreements (FTA) with developing countries.

India's submission to the World Trade Organisation (WTO), along with other developing countries, expressed the above position. India's submission to the TRIPS Council on 29 June 2001 states: *"Article 39.3 of the TRIPS Agreement leaves considerable room for Member countries to implement the obligation to protect test data against unfair competition practices. The Agreement provides that 'undisclosed information' is regulated under the discipline of unfair competition, as contained in Article 10 bis of the Paris Convention. With this provision, the Agreement clearly avoids the treatment of undisclosed information as a 'property' and does not require granting 'exclusive' rights to the owner of the data"*.[67] This submission also clarified that provisions of Article 39.3 should be taken to mean "*that a third party could be prevented from using the results of the test undertaken by another company as background for an independent submission for marketing approval, if the data had been acquired through dishonest commercial practices"*. More importantly, it was added, *"Article 39.3 does permit a national competent authority to rely on data in its possession to assess a second and further applications, relating to the same drug, since this would not imply any "unfair commercial use"*.[68] It is our view that there has not been any fundamental change in the circumstances during the past few years that can be used to justify a complete turnaround from the position that the country had taken in 2001.

Therefore, the obligation to protect data against unfair commercial use under Article 39.3 is in accordance with Article 10^{bis} of the Paris Convention. Thus the protection against unfair commercial use does not prevent government authorities for using the data for subsequent market approval and the prohibition is against the use of data by private parties for unfair commercial advantages as mentioned in Article 39.3 of TRIPS.

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[67] WTO (2001b).

[68] WTO (2001b).

Even two independent international commissions share the same view on data exclusivity. The Commission on Intellectual Property Rights (CIPR) recommends that *"Countries may allow health authorities to approve equivalent generic substitutes by "relying on" the original data. Developing countries should implement data protection legislation that facilitates the entry of generic competitors, whilst providing appropriate protection for confidential data, which may be done in a variety of TRIPS-compatible ways. Developing countries need not enact legislation the effect of which is to create exclusive rights where no patent protection exists or to extend the effective period of the patent monopoly beyond its proper term".*[69] The same concern is squarely reflected in the report of CIPIH, which states, "*A public health justification should be required for data protection rules going beyond what is required by the TRIPS Agreement. There is unlikely to such a justification in markets with a limited ability to pay and little innovative capacity. Thus developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built in TRIPS".*[70] Therefore, India should emphasise on the public health aspects of data exclusivity rather than looking at corporate gains of a few pharmaceutical firms.

[69] Commission on Intellectual Property Rights (2002), p. 51

[70] Commission on Intellectual Property Rights (2006), p. 144

Chapter 4 Implementation of Article 39.3 of the TRIPS Agreement in India

Implementation of its commitments under Article 39.3 by India has been under the scanner by its larger trading partners, particularly the US and the EU, for a number of years. The US, for instance, has, for years on end, identified India as a country that has denied effective protection to intellectual property rights, consequent upon annual investigations undertaken by the United States Trade Representative (USTR) in pursuant with the powers given to it by the Special 301 provisions of the Trade Act. Introduced as an amendment of Section 301 of Trade Act, 1974 in the Omnibus Trade and Competitiveness Act of 1988, the provisions of Special 301 were intended to prepare the ground for possible unilateral trade retaliatory action[71] by the USTR against countries, which, in its view, were undermining US commercial interests in the area of intellectual property rights. Although the threat of unilateral trade retaliatory action has receded since the clarifications given by the US in the dispute initiated by the EU challenging the WTO-legality of these Sections, the annual investigation nonetheless provide a handle to the US trade administration to force countries to comply with the changes that it desires.

In its Special 301 investigations, the USTR has been commenting about the lack of protection against unfair commercial use for data generated to obtain marketing approval[72]. Faced with this pressure, the Government of India decided to set up an Inter-ministerial Committee (henceforth "Data Protection Committee", which also included independent experts to "consider the steps to be taken by the Government in the context of the provisions of Article 39.3 of the TRIPS Agreement for the protection of undisclosed information"[73].

In May 2007, the Chairperson of the Data Protection Committee submitted the report which considered two substantive sets of issues: (i) steps to be taken in the context of Article 39.3 of TRIPS Agreement, (ii) whether data protection can be offered under the existing legal provisions or an appropriate new dispensation is required.

The report of the Data Protection Committee[74] gave a broad set of directions that India could adopt while implementing its commitments under Article 39.3 of the TRIPS Agreement. The report covered two sets of issues. The first was the definition of a "new chemical entity" covering pharmaceutical and agro-chemical products, in respect of which Article 39.3 requires WTO Members to protect test and other data submitted for obtaining marketing approval. And, the second was the mechanism that India could adopt for providing protection to test and other data for a "new chemical entity". These recommendations of the Committee were formulated based on inputs from various stakeholders, which included representatives of both domestic and foreign pharmaceutical firms, representatives of agro-chemical industry, public interest groups and other independent experts.

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[71] Sanctioned by Sections 305 and 305 of the Trade Act.

[72]Office of the United States Trade Representative (2007), p. 26

[73] Government of India (2004).

[74] Government of India (2007).

The Committee proposed three different regimes for agro-chemicals, herbal/traditional Indian medicines and modern pharmaceutical products. In each case the Committee favoured the introduction of a regime providing fixed period protection to test and other data submitted by the so-called "pioneer" firms, which the Regulators could not rely on while approving subsequent applications on same/similar products.

In case of herbal/traditional Indian medicines, the Committee recommended that fixed period data protection should be provided for *at least five years* (emphasis added) The Committee further clarified that this mechanism should be adopted irrespective of the nature or the period of data protection granted to pharmaceuticals sector in general. During this period the Drug Regulator would have to seek full data from each of the applicants The Regulator would be able to rely on the data of the first applicant only for the purposes of comparison with the data submitted by the subsequent applicants, but would not be allowed to rely on the data of the first applicant while granting marketing approval to the second and the subsequent applicants. It was argued that providing data protection to these products would act as an incentive and encourage greater research in the field.

According to the Committee, data protection in respect of herbal/traditional Indian medicines would cover the following:

(i) Data in support of new use or new dosage forms for traditionally used medication;

(ii) Data protection for a new biologically active marker for standardisation;

(iii) Data protection for safety/efficacy data of an existing or a new product.

The recommendations in case of herbal/traditional Indian medicine are clearly beyond the remit of Article 39.3. As was indicated earlier, Article 39.3 requires data protection to be granted to pharmaceuticals and agro-chemicals when the products seeking marketing approval use "new chemical entities". But by recommending that data for "new use or new dosage forms for traditionally used medication", the Committee tabled a contentious interpretation of the coverage under Article 39.3.

The Committee adopted a cautious approach while recommending data protection for pharmaceutical products. While it recommended that the current practice of approving pharmaceutical products based on the bio-equivalence of the products in question may be followed for the present, the Committee was of the view that "in the long run it may be in India's interest to move towards higher standards of data protection". Accordingly, the Committee suggested introduction of the data protection regime as applicable to pharmaceutical products in two phases, with the second phase providing a fixed term protection for test data, with adequate safeguards for protecting public health concerns. The Committee submitted that various stakeholders favoured introduction of a fixed term protection for it was perceived that this model will help in early introduction of new drugs in India as also provide an impetus for R&D. It was however felt that further analysis of the implications of this model was required.

The Committee opined that as long as the current practice of approving pharmaceutical products as persisted with, i.e. during the "transitional period" before the fixed term data protection was introduced, there is need to introduce the *minimum requirements of Article*

39.3[75], i.e. non-disclosure of test data and non-acceptance of fraudulently obtained data, for better data management and to ensure its confidentiality (emphasis added). Several measures were suggested to ensure that the above-mentioned objective was realised. These include:

(i) Government should take adequate steps to ensure that specified undisclosed data submitted for seeking marketing approval for pharmaceutical products was not disclosed to any third party;

(ii) Officials in the Office of Drug Controller General of India should be under an obligation to keep secret the undisclosed information submitted to Drug Regulator for approval of new drug;

(iii) In case data was obtained fraudulently by the second or subsequent applicants it should be considered an unfair commercial use and should not be accepted by the Drug Regulator

(iv) Necessary improvements in data management may be adopted and best practices prevalent in other countries may be examined for adopting these in India.

(v) Physical infrastructure for safe storage of data should be considerably strengthened

(vi) Liability of third parties in case of use without consent of the trade secret information, to be enforced through courts, should be clearly spelt out

The Committee recommended that in the second phase, the Drug regulator would provide five-year data protection to *proprietary test data*[76] submitted by the originator for obtaining marketing approval for a new drug which is a new chemical entity and actually relied upon by the Drug Regulator for that approval (emphasis added). While the data is protected, the Drug Regulator would not accord final approval to any subsequent applicant by relying on the data submitted by the originator.

As regards the critical issue concerning the definition of a "new chemical entity", the Committee offered two sets of alternative definitions. The first drew upon the existing definition of a new drug, as provided in Rule 122E of the Drugs and Cosmetics Act, 1940 (as amended), according to which a new drug includes "bulk drug substance which has not been used in the country to any significant extent under the conditions prescribed, recommended or suggested in the labelling thereof and has not been recognized as effective and safe by the licensing authority ..". The second definition draws upon the Indian Patents Act, 1970 (as amended)

A drug based on a new chemical entity which had no prior application for approval of the same drug in India or where the same drug or chemical entity was not previously known to commerce'. However following would be excluded from the definition of NCE

(i) new indications;

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[75] It is interesting to note that the Committee describes the non-disclosure of test data etc. as the minimum requirements of Article 39.3 even when a large body of independent opinion has held that implementation of this Article requires WTO Members to ensure that the data are not disclosed.

[76] "Proprietary test data" was defined by the Committee as the data that have not been published or are known to the public at the time of or after its submission for marketing approval anywhere in the world.

(ii) new dosage forms;

(iii) New combinations of two or more drugs;

(iv) polymorphs/hydrates/solvates/isomers, salts, esters, metabolites, particle sizes, mixtures of isomers, complexes, chelates, mere admixtures or compositions etc of known substances unless they result in the significant enhancement of the known efficacy of that substance.

The Committee recommended that in order to avoid any adverse effects arising from the model of fixed period data protection for pharmaceutical products suitable safeguards would have to be adopted in the interest of public health imperatives. The safeguards could include:

(i) New chemical entities discovered after 1st January, 1995 would be eligible for protection of test data for 5 years and this would be applied with prospective effect.

(ii) Protection should be provided to only new chemical entities not granted market approval by the Drug Regulator.

(iii) Protection would be for only undisclosed proprietary data and not to data already published or publicly available, through publication in journals, symposiums, promotional literatures, and information available on web-sites of various drug approving authorities and other related web sites

(iv) In the case of data protection for patented drugs, the period of protection should not go beyond the 20-year period of patent protection in India

(v) The period of data protection may be counted from the date of the first marketing approval anywhere in the world and the originator of the data must apply for marketing approval in India within 24 months of that date.

(vi) The generic applicant in India can apply for marketing approval of the same drug in the following circumstances:

a. Within 24 months of the date of first marketing approval of the drug anywhere in the world with the authorization of the "pioneer" firm

b. After the period of 24 months has elapsed from the date of first marketing approval of the drug in the world.

c. Prior to the expiry of 24 months for tentative marketing approval, which would become final only after expiry of the 24 months, in case the "pioneer" firm did not apply within this period

(vii) Marketing approval of a new drug would cease to be valid if the product was not marketed within six months of its grant and if not marketed for twelve consecutive months at any time thereafter. Drug Regulator can therefore grant marketing approval to second and subsequent applicants though the period of data protection may not have expired.

(viii) Provisions for the grant of compulsory license (akin to those provided in the Patents Act) should be introduced in the relevant laws and these should override the provisions for data protection. In case a compulsory licence was issued for a patented drug there would be automatic waiver of data protection.

(ix) Government would have the right to waive off all or any provision pertaining to data protection in case of a public health emergency. In such a situation, the Drug Regulator would be free to grant marketing approval to subsequent applicant(s) based on published data and limited test data generated in India.

(x) In cases where repeating the clinical trials for a drug was not considered essential, the Regulatory Authority may allow marketing approval to subsequent applicants of a drug similar to an earlier approved drug by placing reliance on the first applicant's undisclosed data .

(xi) Drugs for life threatening diseases like HIV/AIDS may be exempted from the provisions of fixed period data protection as mentioned above i.e. the Drug Regulator may place reliance on the data submitted by the first applicant in India/ foreign country and grant market approval to subsequent applicants for same product in India.

A number of key issues arise in the context of the recommendations made by the Data Protection Committee. The more significant of these are the following: (i) the likely impact of the recommendations on access to medicines at affordable prices, and (ii) the complementary measures that are needed to ensure that field/clinical trials are conducted in a transparent manner so as to eliminate adverse implications for human health and its genetic wealth of the country

The recommendations made by Committee in respect of pharmaceutical products need thorough examination for they could impact on the access to medicines at affordable prices in India. This could arise because the space available for the domestic firms, which can best ensure the availability of affordable medicines, can be truncated after the fixed period data protection is provided. This could adversely affect competition in the marketplace, thus resulting in upward movement in the prices of medicines. During the past few years, the domestic firms have increased their R&D activities, and as a result, several of these firms have reached the threshold of developing new products[77]. It is conceivable that some of the products developed by the domestic firms are similar to those developed by "pioneer" firms and for which they would have obtained fixed period protection for the test and other data submitted for obtaining marketing approval. The data protection regime adopted by India must ensure that the domestic firms, which have developed similar products by investing in R&D, are not denied permission to market the product in India. Failure to provide this safeguard to the domestic firms could stymie the recent spurt in R&D activity, thus affecting the dynamism that the Indian pharmaceutical industry has seen in the recent past.

A second dimension of concern arises from the manner in which field/clinical trials for agro-chemicals/pharmaceuticals are conducted in India. India has a rich genetic stock, which has prompted global agro-chemicals/pharmaceutical firms to conduct field/clinical trials in the country. In fact, one of the arguments advanced in favour of fixed period data protection is that such a measure would encourage foreign investment to flow into this sector. It must, however, be pointed out in this context that necessary safeguards to protect the genetic diversity are an absolute necessity. The regulator could play a critical role in this regard by ensuring that the firms that are seeking marketing approval have taken all the necessary precautions to prevent loss of genetic diversity.

[77] Details have been discussed in a later section.

The possibility of increased interest of global agrochemical/pharmaceutical firms to conduct field/clinical trials in India following the adoption of fixed period data protection regime in the country, also brings to the fore safety issues involved in the conduct of these trials. This aspect can assume significant proportions in the pharmaceutical sector, where serious questions have been raised about the safety aspects involved in clinical trials in a number of cases[78]. The WHO has tried to address this issue through the establishment of the International Clinical Trials Registry Platform (ICTRP). The Platform is aimed at standardising the way information on medical studies is made available to the public through a process of registering all medical studies that test treatments on human beings, including the earliest studies, whether they involve patients or healthy volunteers. There is no gain saying that India needs to develop effective mechanisms to the implement the ICTRP. This will provide the much needed safeguard against questionable clinical trials in India.

[78]Indian Journal of Medical Research (2006), pp 587-590

Chapter 5 Recent Performance of the Indian Pharmaceutical Industry

The Indian pharmaceutical industry has evolved over three phases. The first was the period prior to 1970, when the industry was dominated by a small set of foreign owned and controlled firms[79]. The second phase, spanning the second half of 1970s to the early 1990s, was a period during which the industry experienced structural transformation through the growth of the Indian generic industry. This development was a result of the adoption of the Patents Act of 1970. As mentioned in an earlier discussion, introduced two changes in the country's patent regime viz. introduction of a process patent regime and shortening the term of pharmaceutical patents, both of which had considerable impact on the shaping of the pharmaceutical industry in India. Firms belonging to Indian promoters began to take roots in the industry during the 1970s, and by the 1990s, these firms had consolidated their position in the industry[80].

The Indian pharmaceutical industry that thus developed has a three-tier structure. It consists of a large private sector[81], which can be further divided into two categories of firms, viz. firms that are affiliates of foreign firms in India[82] and those that have Indian promoters and producer generic drugs; and the small scale units.

Yet another way of looking at the Indian pharmaceutical industry is to characterise it in terms of the scale of operation of the units. From this perspective, the Indian pharmaceutical industry can be characterized as "long tailed", i.e. there are a relatively small number of large firms and a large number of small firms[83].

Various aspects of performance of the pharmaceutical industry in India can be seen by analysing data that are available only with respect to the large firms[84]. One of the limitations of this data is that firms belonging to the small scale-sector are not represented, since most of them have not are not public limited firms. It must be stated, however, that the focus of the analysis on the larger firms provides has one distinct advantage – it helps in a better understanding the broad trends in the Indian

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[79]In India, a distinction was made between "foreign owned" and "foreign controlled" firms. "Foreign owned" firms were those in which non-residents had majority in the equity (voting) shares. The "foreign controlled" firms were identified by the Reserve Bank of India as those firms in which the equity (voting) shares were 26% or more.

[80] For a discussion on the evolution of the Indian pharmaceutical industry see Dhar and Rao (2002)

[81] In the earlier decades, public sector firms, or the government promoted firms, were set up, essentially with the objective of producing the bulk drugs or the active ingredients. These firms went out of business after the market-oriented reforms were initiated in the early 1990s.

[82] The foreign owned and controlled firms were forced to "Indianise" by diluting their foreign equity holding in the beginning of the 1970s. As a result, most of these firms became "foreign-controlled", which, according to the Reserve Bank of India (India's Central Bank), were firms having more than 25% foreign equity holding.

[83] In the year 2000, the latest year for which Government of India provided data on the number of units involved in the production of pharmaceutical products in India, it was reported that "about 250 large units and about 8,000 small scale units [are] in operation…". See, Government of India (2000).

[84] Most of these firms are public limited firms and they their financial data, in particular, are in the public domain. The data that we have used have been obtained from the Prowess database of the Centre for Monitoring Indian Economy (CMIE).

pharmaceutical industry. This advantage is reinforced by the fact that the in the large firms have an overwhelming presence in the industry. Data available from the top18 firms, 8 of which operate in India as affiliates of foreign firms[85], with the remaining 10 having Indian promoters[86], provides evidence in this regard. For instance, in 2006, nearly 80 per cent of the net worth of the pharmaceutical industry was accounted for by these 18 firms. For our analysis of the Indian pharmaceutical industry in the present study, we would therefore focus on the performance of these 18 firms indicated above.

The decade of the 1990s was singularly important for it saw the Indian pharmaceutical industry perform strongly on all fronts. Total production of the industry (large firms and the small scale units taken together) expanded more than four-fold in value terms (in domestic currency). The dollar value of exports too had a similar increase. There was strong evidence that the Indian industry was getting increasingly outward oriented – the share of exports in total production almost doubled during the decade[87].

But it was in the post-1995 phase that the large firms in the industry have performed strongly on all fronts. During this phase, it was the set of leading generic producers that were relatively more active as compared to the leading firms that are affiliates of foreign firms. This is evidenced by the fact that while in 1995, five of the top ten pharmaceutical firms (in terms of sales turnover) were foreign affiliates, in 2004 GlaxoSmithKline was the only foreign affiliate in the top ten list. What appears are most striking is that this robust performance by the Indian pharmaceutical firms, and in particular the generic segment of the industry, has come during a phase when they were facing an uncertain future, with the process patent regime being dismantled following India's accession to the WTO. The following discussion provides the evidence in support of the above-mentioned point.

We shall use several performance indicators to provide evidence regarding the performance of the leading firms in the Indian pharmaceutical industry. The first indicator that we shall use, one which provides evidence of the market value of the firms, is net worth.

The first indicator for analysing the performance of the pharmaceutical industry that we shall use is the net worth of the firms, which is a reflection of their respective market values. Table 1 below provides the details.

Table 1: Growth in Net Worth of Leading Firms in Indian Pharmaceutical Industry

Firms	1995-2006	1995-2000	2000-2006
Aurobindo Pharma Ltd.	178.9	83.9	49.7
Cadila Healthcare Ltd.	166.8	247.8	7.4
Cipla Ltd.	141.4	78.0	39.7
Orchid Chemicals & Pharmaceuticals Ltd.	116.1	99.0	18.3

[85] The following are firms with foreign affiliations currently operating in India: GlaxoSmithKline Pharmaceuticals Ltd, Aventis Pharma Ltd., Pfizer Ltd, Merck Ltd, Novartis India Ltd, Abbott India Ltd, Wyeth Ltd, AstraZeneca Pharma India Ltd

[86] The ten major firms of Indian origin are: Ranbaxy Laboratories Ltd, Dr. Reddy's Laboratories Ltd, Cipla Ltd, Sun Pharmaceutical Inds. Ltd, Aurobindo Pharma Ltd, Wockhardt Ltd, Cadila Healthcare Ltd, Lupin Ltd, Nicholas Piramal India Ltd, Orchid Chemicals & Pharmaceuticals Ltd.

[87] Dhar and Rao (2002)

Lupin Ltd.	112.4	21.7	143.2
Sun Pharmaceutical Inds. Ltd.	91.3	36.9	48.0
Dr. Reddy's Laboratories Ltd.	51.5	3.2	78.9
Pfizer Ltd.	47.1	19.2	35.9
AstraZeneca Pharma India Ltd.	46.0	30.5	23.3
Merck Ltd.	41.0	18.3	31.3
Aventis Pharma Ltd.	32.6	3.5	48.5
Abbott India Ltd.	30.6	15.0	24.9
GlaxoSmithKline Pharmaceuticals Ltd.	23.6	4.6	32.1
Wyeth Ltd.	23.1	17.2	15.0
Nicholas Piramal India Ltd.	22.0	22.3	25.5
Ranbaxy Laboratories Ltd.	14.2	12.8	9.3
Wockhardt Ltd.	4.3	-11.7	42.2
Novartis India Ltd.	1.0	2.3	-0.1

Source: CMIE, Prowess database

As can be seen from the table, most of the generic manufacturers consolidated their positions in the industry. The larger among them, viz. Dr Reddy's and Cipla, experienced very high rates of growth of net worth during the 11 years for which data have been presented in the Table. In contrast, however, the largest among the Indian firms, Ranbaxy Laboratories, did not experience comparable increase in market value.

The data presented in Table 1 also indicates that barring a couple of exceptions, firms that are affiliates of foreign firms increased their stakes in the Indian industry. More importantly, these firms increased their stakes at a much faster rate during the present decade, as compared to the second half of the 1990s. This tendency was prominently displayed by Aventis, with the firm having consolidated its position to emerge as the largest firm in this group after GlaxoSmithkline Ltd.

Table 2 shows that measured in terms of its market value, Ranbaxy Laboratories was the largest Indian pharmaceutical firm during the entire period, 1995-2006. But as was evident from the increase that its net worth has seen during this period, Dr Reddy's Laboratories had grown to a size comparable to that of the industry leader. And, at the same time, Cipla was fast catching up with the leaders.

An interesting observation that can be made from the data on net worth of the leading firms in the industry is that in 2006, the industry was divided into two segments. All the generic firms were US $ 100 million-plus net worth firms, while six of the eight associates of foreign firms, had net worth below this threshold in 2006. In other words, the generic manufacturers had secured a prominent position in the Indian pharmaceutical industry.

Table 2: Net worth of leading pharmaceutical firms during select years

(figs. in US $ million)

Firms	Dec-95	Dec-97	Dec-99	Dec-01	Dec-02	Dec-03	Dec-04	Dec-05	Dec-06
Ranbaxy Laboratories Ltd.	204.8	320.8	334.6	315.6	392.8	479.3	545.5	536.9	523.8
Dr. Reddy's Laboratories Ltd.	75.7	77.0	81.0	100.4	303.3	373.4	445.5	468.5	504.4
Cipla Ltd.	26.6	74.0	107.2	156.2	184.4	219.0	272.9	348.6	440.1
Sun Pharmaceutical Inds. Ltd.	29.6	47.7	73.5	101.9	112.3	143.9	187.1	249.7	326.6
GlaxoSmithKline Pharmaceuticals Ltd.	74.0	76.0	85.7	122.7	121.5	137.9	201.1	214.3	266.4
Nicholas Piramal India Ltd.	63.2	82.2	73.4	89.8	52.5	78.3	96.7	123.3	216.2
Wockhardt Ltd.	0.0	152.5	151.8	72.4	77.4	97.8	135.1	181.9	213.3
Aurobindo Pharma Ltd.	9.8	13.4	29.6	60.6	75.6	110.2	164.6	178.1	201.9
Orchid Chemicals & Pharmaceuticals Ltd.	13.9	32.2	39.4	82.8	62.8	83.1	91.1	106.4	175.0
Cadila Healthcare Ltd.	0.0	13.2	20.2	118.9	115.6	90.7	114.2	137.1	164.2
Lupin Ltd.	10.7	13.3	15.7	79.0	71.2	79.0	97.5	180.8	143.6
Aventis Pharma Ltd.	28.8	31.2	21.6	46.5	52.4	62.5	87.9	114.5	132.0
Pfizer Ltd.	15.4	19.1	24.9	37.2	53.6	52.6	61.5	76.8	95.1
Merck Ltd.	15.9	21.1	25.0	32.2	34.0	40.6	54.0	67.3	87.6
Novartis India Ltd.	67.6	58.7	65.9	36.6	43.7	50.3	55.7	64.2	75.3
Abbott India Ltd.	12.6	28.8	28.1	28.3	35.0	30.3	41.0	48.9	54.8
Wyeth Ltd.	15.5	19.3	25.6	32.6	38.0	45.9	55.6	54.8	54.7
AstraZeneca Pharma India Ltd.	5.2	7.9	11.0	14.7	15.9	20.3	20.8	28.7	31.6

Source: CMIE, Prowess database

Further evidence of the strength of the generic manufacturers in the Indian pharmaceutical industry is available from the market penetration of these firms achieved by these firms during 1995-2006. Table 3, which provided data on the growth in sales registered by the leading firms in the industry, shows that the generic firms recorded sales growth that far outstripped those registered by the associates of foreign firms in India.

Another feature of the sales growth profiles of the firms presented in table 3 is that the associates of the foreign firms experienced a turnaround in their sales during after the year 2000. In the second half of the 1990s, seven of these firms saw a single-digit growth in sales, while Novartis suffered a decline in total sales.

Table 3: Growth in sales[@] recorded by the leading firms

Firms	1995-2006	1995-2000	2000-2006
Lupin Ltd.	176.5	-3.7	400.7
Orchid Chemicals & Pharmaceuticals Ltd.	116.4	96.4	137.3
Aurobindo Pharma Ltd.	99.8	105.3	91.2
Sun Pharmaceutical Inds. Ltd.	93.5	62.6	173.1
Dr. Reddy's Laboratories Ltd.	66.0	16.0	358.8
Cipla Ltd.	57.0	17.5	288.3
Nicholas Piramal India Ltd.	52.5	25.6	197.4
Cadila Healthcare Ltd.	32.0	13.4	170.7
Astrazeneca Pharma India Ltd.	25.2	8.8	161.5
Ranbaxy Laboratories Ltd.	24.5	16.2	104.0
Wockhardt Ltd.	21.8	16.6	85.3
Pfizer Ltd.	11.7	2.0	108.6
Aventis Pharma Ltd.	10.8	0.0	118.9
Abbott India Ltd.	7.5	6.6	37.1
Wyeth Ltd.	5.8	8.1	16.5
Merck Ltd.	4.2	5.9	12.9
GlaxoSmithkline Pharmaceuticals Ltd.	2.8	-4.9	73.2
Novartis India Ltd.	-1.7	5.7	-36.9

@ Sales in US $
Source: CMIE, Prowess database

The growth in sales registered by the leading generic producers led to a complete transformation of the composition of market leaders in the Indian pharmaceutical industry. In 1995, five of the ten top firms in terms of sales were the associates of foreign firms, with GlaxoSmithkline (then Glaxo India Ltd) as the market leader. But in 2006, nine of the top four producers were generic firms, and GlaxoSmithkline was only the fifth largest firm in terms of sales.

The largest firm in the Indian pharmaceutical industry, viz. Ranbaxy, was fast approaching a billion US dollars in terms of sales turnover in 2006, after registering a four-fold increase for the period since 1995. It should be noted is that in 1995, Ranbaxy was the only generic firm that had sales turnover exceeding US $ 100 million, but in 2006, 21 generic firms figured in this list.

Table 4: Value of sales of leading pharmaceutical firms in select years

(in US $ million)

Firms	Dec-95	Dec-97	Dec-99	Dec-01	Dec-02	Dec-03	Dec-04	Dec-05	Dec-06
Ranbaxy Laboratories Ltd.	252.7	326.3	448.6	517.1	725.6	876.7	930.4	838.9	933.9
Cipla Ltd.	95.1	127.5	148.7	233.0	293.7	325.0	447.3	542.3	692.0
Dr. Reddy's Laboratories Ltd.	63.2	70.4	101.2	217.0	358.9	352.3	400.2	392.8	522.0
Lupin Ltd.	18.8	25.8	26.2	199.0	202.0	225.6	260.6	275.2	382.9
GlaxoSmithkline Pharmaceuticals Ltd.	293.1	214.8	212.9	250.2	250.9	256.6	327.7	362.4	382.1
Nicholas Piramal India Ltd.	49.6	137.6	105.0	125.8	200.3	237.2	313.5	295.5	336.3
Aurobindo Pharma Ltd.	27.5	62.5	130.8	219.0	217.7	246.5	291.9	262.4	329.0
Sun Pharmaceutical Inds. Ltd.	26.8	49.4	85.3	134.1	156.8	177.5	206.0	236.2	301.9
Cadila Healthcare Ltd.	0.0	63.6	85.9	111.4	123.5	212.5	255.1	260.2	298.5
Wockhardt Ltd.	0.0	88.4	206.9	142.2	155.5	158.5	191.8	209.7	238.8
Aventis Pharma Ltd.	98.8	115.0	126.8	133.5	141.7	149.5	178.1	201.9	216.5
Orchid Chemicals & Pharmaceuticals Ltd.	14.3	54.6	79.5	81.3	89.2	112.2	155.2	155.7	196.9
Pfizer Ltd.	77.6	46.4	78.5	91.0	146.7	122.7	150.3	164.5	177.9
Novartis India Ltd.	149.5	172.7	180.1	97.7	99.4	100.0	113.2	110.4	121.1
Abbott India Ltd.	66.3	78.4	8.4	81.5	89.2	92.2	103.2	106.5	121.0
Merck Ltd.	56.3	62.8	66.5	74.8	80.8	83.5	91.0	99.0	82.3
Wyeth Ltd.	43.0	46.7	60.7	65.0	64.6	69.4	76.6	65.5	70.4
Astrazeneca Pharma India Ltd.	17.4	22.4	24.5	15.8	32.1	40.5	46.0	55.8	65.6

Source: CMIE, Prowess database

Table 5 captures the profitability ratios of the leading firms in the Indian pharmaceutical industry. In recent years, most of the top firms recorded double-digit profitability ratios. Importantly, the associates of foreign firms operating in India recorded better profitability ratios as compared to the generic firms. In fact, there was a considerable gap in the profitability ratios recorded by the two leading firms belonging to the two groups. While for Glaxo SmithKline the profitability ratio was on the upswing during the more recent years, Ranbaxy's profitability ratios were moving in the opposite direction after 2003.

Table 5: Profitability Ratios of Leading Indian Pharmaceutical Firms

(Figs. in %)

Firms	Dec-95	Dec-97	Dec-99	Dec-01	Dec-02	Dec-03	Dec-04	Dec-05	Dec-06
GlaxoSmithkline Pharmaceuticals Ltd.	4.9	6.7	6.3	7.9	14.5	20.3	24.8	26.1	27.7
Wyeth Ltd.	15.3	15.3	14.2	14.0	18.8	16.5	19.9	4.0	23.4
Astrazeneca Pharma India Ltd.	13.8	14.4	14.8	5.0	9.2	18.4	19.4	23.5	23.1
Aventis Pharma Ltd.	9.0	7.1	-0.7	10.9	11.8	16.9	24.3	22.1	22.0
Merck Ltd.	12.7	13.4	9.7	17.2	14.5	21.5	23.4	23.5	21.9
Cipla Ltd.	11.1	19.6	22.0	20.5	20.3	18.4	18.5	18.5	19.4
Pfizer Ltd.	6.0	10.1	13.3	18.2	12.4	6.8	9.1	11.0	16.9
Wockhardt Ltd.		16.9	15.1	16.9	16.1	17.4	22.2	15.5	15.2
Novartis India Ltd.	6.4	3.3	12.4	11.1	13.6	9.4	11.9	13.0	14.7
Lupin Ltd.	13.5	17.8	18.4	13.7	16.7	13.7	18.9	7.4	13.2
Abbott India Ltd.	11.1	11.7	10.6	13.1	16.7	17.7	17.8	15.5	12.7
Cadila Healthcare Ltd.		6.2	9.5	11.0	11.3	11.2	9.1	9.9	11.8
Orchid Chemicals & Pharmaceuticals Ltd.	12.3	18.1	13.1	13.4	7.0	8.1	8.2	9.3	10.5
Nicholas Piramal India Ltd.	12.0	6.1	9.6	11.7	10.3	13.7	13.3	7.8	10.2
Ranbaxy Laboratories Ltd.	11.4	13.1	8.2	8.3	18.7	18.9	12.5	1.7	10.2
Aurobindo Pharma Ltd.	7.0	8.1	11.4	11.4	9.9	13.8	14.5	5.3	7.4
Dr. Reddy's Laboratories Ltd.	18.0	15.2	13.3	21.3	32.6	23.5	15.4	-0.5	6.8
Sun Pharmaceutical Inds. Ltd.	16.5	17.5	16.9	21.7	23.7	27.7	18.4	7.0	-2.0

Source: CMIE, Prowess database

The trends in the profitability ratios that the leading firms in the pharmaceutical industry have displayed during the period 1995-2006 can be better understood by looking at the ratios across different periods. Table 6 provides the details.

Table 6: Profitability Ratios across periods

Firms	1995-2006	1995-2000	2000-2006
Merck Ltd.	16.6	12.8	20.3
GlaxoSmithkline Pharmaceuticals Ltd.	13.7	7.1	20.2
Cipla Ltd.	18.7	18.1	19.3
Aventis Pharma Ltd.	11.8	5.7	18.0
Wockhardt Ltd.	16.6	15.9	17.2
Dr. Reddy's Laboratories Ltd.	16.2	16.0	16.5
Astrazeneca Pharma India Ltd.	15.6	14.7	16.4
Sun Pharmaceutical Inds. Ltd.	16.3	16.5	16.1
Wyeth Ltd.	15.4	14.8	16.1
Abbott India Ltd.	13.3	11.1	15.6
Lupin Ltd.	14.4	14.9	13.9
Pfizer Ltd.	10.9	9.4	12.4
Novartis India Ltd.	10.6	8.9	12.3
Ranbaxy Laboratories Ltd.	10.9	10.2	11.7
Nicholas Piramal India Ltd.	10.4	9.7	11.2
Cadila Healthcare Ltd.	9.1	7.1	10.7
Aurobindo Pharma Ltd.	9.9	9.5	10.4
Orchid Chemicals & Pharmaceuticals Ltd.	11.7	14.1	9.4
Associates of foreign firms	**13.5**	**10.6**	**16.4**
Generic firms	**12.2**	**12.0**	**12.4**

Source: CMIE, Prowess database

Table 6 shows that the associates of foreign firms in India were recording substantial higher profitability ratios than the generic firms. Both Merck and Glaxo SmithKline, the two firms to have recorded the highest average profitability ratios during 2000-2006, had substantially improved their performance over the immediately preceding quinquennium. In contrast, the larger generic producers, viz. Ranbaxy, Cipla and Dr Reddy's, maintained their profitability ratios across the periods indicated in the table. The above observations for the leading firms in the two groups of firms hold true also for the groups as a whole. As can be seen from the above table, the associates of foreign firms recorded far higher profitability ratios than their generic counterparts during 2000-2006.

A noteworthy feature of the pharmaceutical industry is that the industry was the most profitable among all the leading sectors of the Indian industry. Interestingly, the profitability ratio of the pharmaceutical industry increased almost consistently through the period for which data are presented in Table 7. It needs to be mentioned here that the pharmaceutical industry had out-performed other sectors of the industry despite facing an additional dose of uncertainty arising from the changes in the patent regime, a point that was made in an earlier discussion.

Table 7: Profitability of some of the major sectors in Indian Industry

Sectors	Dec-95	Dec-97	Dec-99	Dec-00	Dec-01	Dec-02	Dec-03	Dec-04
Chemicals	5.8	4.8	4.8	4.2	3.5	4.4	5.8	6.3
Food & beverages	4.8	4.1	4.9	4.8	5.1	4.2	3.6	5.2
Machinery	5.5	3.7	3.5	2.6	1.5	2.7	1.7	3.1
Textiles	5.6	0.6	-1.9	-1.0	-2.4	-2.9	0.9	-0.4
Transport equipment	5.8	7.3	3.1	3.3	1.0	3.3	5.0	6.3
Drugs & pharmaceuticals	8.8	7.5	6.6	7.5	10.0	12.4	11.3	13.4

Source: CMIE, Prowess database

The global integration of the Indian economy, which many sectors of the economy considered as a threat, was a wide window of opportunities for the generic pharmaceutical industry. This was essentially because the leading firms of this segment of the industry were considerably more outward oriented as compared to those belonging to other industries. The trend towards enhancing the outward orientation of the industry had begun in the early 1990s, which went through a rapid consolidation in the subsequent years. This was particularly noticeable in case of the large generic firms in the industry. Table 8 shows that for the three largest firms of this segment, viz. Ranbaxy, Dr. Reddy's and Cipla, exports in terms of value were more than one-half of their sales turnovers. For these firms, therefore, foreign markets were relatively more important than the domestic market and this gave them the impetus to improve their operating efficiencies

Table 8: Ratio of Exports to Total Sales Turnover of the Leading Firms

(Figs. in %)

Firms	Dec-95	Dec-97	Dec-99	Dec-01	Dec-02	Dec-03	Dec-04	Dec-05	Dec-06
Orchid Chemicals & Pharmaceuticals Ltd.	95.9	94.3	87.7	85.7	83.2	83.2	74.9	75.6	75.2
Ranbaxy Laboratories Ltd.	38.4	45.3	43.1	45.9	58.2	60.3	58.8	63.5	65.8
Aurobindo Pharma Ltd.	29.2	40.8	39.2	54.5	46.9	47.4	48.1	48.4	56.4
Dr. Reddy's Laboratories Ltd.	32.1	28.0	28.0	43.5	57.0	54.3	53.6	52.9	51.7
Cipla Ltd.	10.4	13.8	19.1	25.0	35.5	36.4	42.4	45.7	50.4
Lupin Ltd.	0.0	0.2	0.0	25.5	32.2	38.0	48.1	45.8	46.0
Wockhardt Ltd.		21.5	15.9	25.7	31.1	36.9	37.1	38.6	37.9
Sun Pharmaceutical Inds. Ltd.	5.0	5.0	17.3	18.5	17.9	16.3	21.7	27.4	29.9
Aventis Pharma Ltd.	12.7	20.1	12.3	17.1	19.1	21.2	26.1	27.1	24.3
Cadila Healthcare Ltd.		8.8	8.5	11.8	14.4	10.1	15.1	12.0	16.4
Nicholas Piramal India Ltd.	5.9	8.6	1.3	0.6	1.1	3.9	7.0	17.0	14.9
Merck Ltd.	5.3	6.0	5.7	4.7	3.8	5.3	3.9	4.3	5.2
Pfizer Ltd.	1.8	4.5	5.8	4.7	8.3	4.6	3.5	3.7	3.6
Glaxosmithkline Pharmaceuticals Ltd.	6.2	6.0	8.5	6.9	5.6	3.3	2.6	2.9	3.5
Astrazeneca Pharma India Ltd.	10.0	2.5	1.0	0.0	0.9	1.1	1.7	1.5	2.1
Novartis India Ltd.	8.7	12.2	6.9	3.3	1.2	1.3	1.6	2.1	1.1
Abbott India Ltd.	0.1	6.1	1.4	1.0	1.4	0.7	0.8	0.7	0.7
Wyeth Ltd.	1.1	1.2	6.8	9.5	11.8	7.5	6.7	0.0	0.1

Source: CMIE, Prowess database

But for the associates of the foreign firms operating in India, their production capacities in the country were increasingly being used for satisfying India's internal demand. This tendency stands out particularly prominently in case of the larger firms in the global industry like Glaxo SmithKline and Pfizer. Both these firms had reduced their exports from the Indian entity since the early years of the present decade. This, in other words, implies that the global pharmaceutical majors did not show much interest in converting their production facilities in India into manufacturing hubs from which they would like to supply to the global markets.

This strong performance of the generic industry in the global markets resulted from a number of its inherent advantages. It has been argued that Indian firms have lower costs – estimated to be one-eighth in R&D activities and one-fifth in manufacturing - as compared to the Western firms[88]. The cost advantages are most pronounced in respect of lower fixed asset costs and labour costs, where the costs in India can be one-eighth of the cost in the US.

The key issue that arises in the context of the above discussion is whether the strong showing of the pharmaceutical industry in India, in particular the generic industry, which has provided the much needed depth to the industry, can be sustained over a period of

[88] Grace (2004)

time. This question, in our view, can be best answered by analysing the performance of the generic industry in the realm of technology. The following discussion provides the details in this regard.

Chapter 6 The Technology Dimension

A major factor driving the progress of the leading firms in the Indian pharmaceutical industry was their emphases on the technology. This section explores this dimension of the industry in detail.

The pharmaceutical industry can be divided into three product groupings, viz., bulk drugs, intermediates and formulations. While bulk drug production can be sustained over a long period only through sustained involvement in research and development (R&D) activities, formulations production can be carried out relatively low level technological sophistication.

A typology of the world's pharmaceutical industries was provided by Ballance et al[89]. They identified ten countries, all of which were developed, as countries having sophisticated pharmaceutical industry and a significant research base. Another group of seventeen countries were identified as countries having innovative capabilities. India was identified as once of the countries belonging to this group. The authors noted that while this group of countries were not active in discovering new chemical entities, they had the necessary technological capabilities to reverse engineer existing drugs. However, as we shall see in subsequent discussion, the Indian pharmaceutical industry has come a long way since the above-mentioned characterisation was made. The industry has taken definite strides towards development of innovative processes and discovery of new drugs.

During the past decade, however, the R&D profile of the Indian pharmaceutical industry has undergone major changes. The most obvious of these is the manifold increase in the spending on R&D that was witnessed, particularly since the beginning of the current decade. In 2004, R&D spending of the organised pharmaceutical industry as a whole was nearly US $ 340 million, which was an increase of more than 300% from the level existing in 2000 (Table 9).

Table 9: R&D Expenditures in Major Sectors Indian Industry

(Figs. in US $ million)

Sectors	Dec-95	Dec-97	Dec-99	Dec-00	Dec-01	Dec-02	Dec-03	Dec-04
Chemicals:	110.6	168.9	184.4	187.6	222.4	278.8	306.1	447.9
Of which: Drugs & pharmaceuticals	51.7	73.6	78.0	85.9	117.7	171.9	204.6	339.7
Food & beverages	9.1	9.1	11.4	8.9	11.0	12.6	15.2	22.4
Machinery	85.8	122.6	98.5	102.9	108.0	109.8	111.4	153.8
Textiles	8.1	85.0	7.8	8.1	5.8	7.6	8.0	6.9

Source: CMIE, Prowess database

Table 10 shows that the R&D spending undertaken by the pharmaceutical industry during 1995-2004, has two key features, One, the level of spending was significantly higher than

[89] Ballance et al (1992)

that recorded by other industry groups. And, two, the pharmaceutical industry was the only one among the leading industries to have consistently improved it R&D spending.

The increase in R&D intensity of the Indian pharmaceutical industry since 2000 is the other significant aspect. This is an indication that the pharmaceutical industry in India was allocating increasing amounts of its sales turnover towards R&D spending. Table 7 shows that R&D intensity of the industry went up by more than 150% since the beginning of the decade.

Table 10: Ratio of R&D to Sales of Major Sectors of Indian Industry

(Figs. in %)

Sectors	Dec-95	Dec-98	Dec-99	Dec-00	Dec-01	Dec-02	Dec-03	Dec-04
Chemicals	0.2	0.3	0.3	0.2	0.2	0.3	0.3	0.4
Drugs & pharmaceuticals	1.4	1.3	1.5	1.6	2.1	2.7	2.9	4.1
Food & beverages	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Machinery	0.6	0.7	0.6	0.6	0.6	0.6	0.7	0.8
Textiles	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1

Source: CMIE, Prowess database

The figures for R&D intensities[90] of the leading firms in the pharmaceutical industry are presented in Table 11. The table shows that the leading firms in the industry can be divided into two groups, again based on the ownership pattern. While most firms belonging to the generic segment of the industry have been displaying upswings in their R&D intensities over time, the associates of foreign firms have shown very little change in their R&D intensities.

The two largest among the Indian pharmaceutical firms, viz. Ranbaxy and Dr. Reddy's Laboratories showed the most impressive increase in their R&D intensities, with the latter spending more than 17% of their sales on R&D in 2005. In fact, R&D intensity of Dr. Reddy's Laboratories registered the sharpest increase among the leading firms in the Indian industry. Perhaps the more important dimension here is that some of the medium sized enterprises, like Glenmark Pharmaceutical and Torrent Pharmaceuticals are among the highest spenders on R&D. This indicates that the increase in R&D propensity of the generic industry is having a spread-effect.

In sharp contrast, firms like Glaxo SmithKline, Pfizer and Aventis have shown remarkable stagnancy in their R&D intensities, which have remained well below the 1% level.

[90] R&D spending as a percentage of sales

Table 11: R&D intensities of leading pharmaceutical firms

(Figs. in %)

Firms	Dec-95	Dec-97	Dec-99	Dec-01	Dec-02	Dec-03	Dec-04	Dec-05	Dec-06
Wockhardt Ltd.		8.5	4.2	6.2	6.2	7.9	7.9	8.7	11.9
Sun Pharmaceutical Inds. Ltd.	4.0	4.0	2.7	4.1	4.5	7.7	11.4	11.1	11.9
Ranbaxy Laboratories Ltd.	4.6	4.3	2.9	3.3	5.6	6.5	9.3	17.2	11.6
Dr. Reddy'S Laboratories Ltd.	2.0	3.1	2.2	4.2	5.9	9.6	12.3	17.1	10.8
Cadila Healthcare Ltd.		1.0	3.5	7.9	7.1	3.7	7.5	9.0	8.9
Orchid Chemicals & Pharmaceuticals Ltd.	3.4	2.4	1.0	3.8	4.1	5.1	5.6	7.6	6.9
Lupin Ltd.	0.0	0.2	2.5	4.9	5.6	3.3	3.8	6.9	6.3
Nicholas Piramal India Ltd.	0.2	1.1	5.6	1.8	2.1	1.6	3.9	8.3	6.0
Aurobindo Pharma Ltd.	0.0	0.0	0.0	0.9	1.2	1.8	3.7	4.7	5.2
Cipla Ltd.	0.0	3.6	3.8	3.8	3.3	0.0	2.7	4.1	5.0
Pfizer Ltd.	0.9	2.7	4.1	3.2	2.7	3.6	3.4	3.1	3.0
Astrazeneca Pharma India Ltd.	2.8	2.7	2.7	6.4	1.8	1.3	1.3	0.9	0.9
Merck Ltd.	0.1	0.1	0.2	0.2	0.1	0.0	0.1	0.4	0.4
Abbott India Ltd.	0.4	0.6	0.6	0.5	0.5	0.3	0.3	0.3	0.4
Glaxosmithkline Pharmaceuticals Ltd.	0.5	0.4	0.5	0.3	0.3	0.3	0.3	0.3	0.4
Aventis Pharma Ltd.	3.0	2.9	0.9	0.5	0.7	0.6	0.5	0.4	0.3
Novartis India Ltd.	0.3	0.8	0.8	0.4	0.1	0.2	0.2	0.1	0.3
Wyeth Ltd.	0.6	0.6	0.5	0.4	0.3	0.5	0.2	0.1	0.2

Source: CMIE, Prowess database

The R&D intensities of the major generic firms in India look considerably better when the figures are compared with those of the global pharmaceutical majors. Table 12 gives the R&D intensities of top ten pharmaceutical firms (in terms of sales) as recorded in 2004-05

Table 12: R&D Intensities of Global Pharmaceutical Majors in 2004-05

Rank (in terms of sales turnover)	**Firm**	**R&D to Sales (%)**
1	Pfizer Inc, USA	14.6
2	GlaxoSmithKline, UK	13.9
3	Sanofi-Aventis, France	15.6
4	Johnson & Johnson, USA	11.0
5	Roche, Switzerland	16.3
6	Novartis AG, Switzerland	14.9
7	Merck Inc, USA	17.5
8	AstraZeneca, UK	17.7
9	Eli Lilly and Company, USA	19.4
10	Bristol-Myers Squibb, USA	12.9

Source: UK Department of Trade and Industry, R&D Scoreboard 2005 (http://www.innovation.gov.uk/rd_scoreboard/index.asp)

Tables 11 and 12 show that in 2006, R&D intensities of the largest firms in the global industry and the largest Indian generic firms are yet very divergent - the Indian generics are considerably behind the global firms having highest R&D intensities. But with leading firms in the generic industry increasing their R&D activities in a consistent manner, the next few years could witness these firms close the existing gap in R&D intensities with the global firms.

With the R&D activities remaining confined to the generic industry, the following discussion would provide a detailed account of the various dimensions of the R&D activities of generic industry.

(i) R&D Activities of the Generic Industry

Analysis of the R&D activities of generic firms requires examination of two dimensions. These are: (i) the organisation of R&D activities, and (ii) specific areas of involvement.

It is pertinent to note in this context that in recent years, R&D efforts of the industry have received support from the Government, which has initiated measures for supporting pharmaceutical R&D. This includes exploration of collaboration between the pharmaceutical firms and the large network of public sector research institutions. This dimension would be explored in the concluding part of this section.

Organisation of R&D Activities

The leading firms in the generic industry have adopted a three-pronged strategy to strengthen its technological sinews. First, their in-house R&D activities have been beefed-up, which is evident not only from their increased R&D spending indicated above, as also the range of activities that the firms have been engaged in. Second, these firms have started entering into alliances with foreign firms. Although these alliances are focused essentially on product development, which would help the Indian firms expand their presence in the global market, there have also been R&D-based alliances, including contract research being undertaken by the firms in India.

Areas of R&D Spending

The R&D structure built by the leading firms in the generic industry has four dimensions. These are: (i) development of generics, (ii) novel drug delivery systems (iii) development of new processes and (iv) new drug discovery and research. The following discussion provides the main features of R&D activities undertaken by the domestic firms.

Development of Generics

During the past few years, the global market for generics has been expanding at a substantially higher rate than the proprietary medicines. In 2005, for instance, the global pharmaceutical industry grew by almost 7%, with the ten major markets[91], registering a growth of 5.7%, compared with 7.2% the previous year[92]. In contrast, 2005 sales of generics in the top eight markets (US, Canada, France, Germany, Italy, Spain, U.K. and

[91] Australia, Belgium, Canada, France, Germany, Italy, Japan, Spain, the UK and the US (Source: IMS Health)

[92] IMS Health Reports Global Pharmaceutical Market grew 7 percent in 2005, to $602 billion, Mar 21, 2006.

Japan, and are expected to experience double-digit growth over the next five years. The expansion registered by the generic industry in 2005 was substantially higher than the projections made in 2004, which showed that the sales of generic medicines in the seven largest markets (the US, Canada, Germany, France, Italy, Spain and the U.K.) would reach $59.9 billion by 2008.

Perhaps the most significant driver for the expansion of the generic industry was the acceptance of its low priced products by the consumers. According to estimates provided by the Congressional Budget Office, US consumers saved $ 8-10 billion on retail prescription drug purchases in 1994 by purchasing generic equivalents. It was further noted that "with patents set to expire within the next four years on brand-name drugs that have combined retail sales of almost $20 billion, the already substantial savings are likely to increase dramatically"[93]. And, it is in this lucrative market for generic medicines that the leading Indian firms have established their presence.

The trigger for the development of the generics market in the US came in the form of legislative action initiated in the first half of the 1980s. The Drug Price Competition and Patent Restoration Act of 1984 (better known as "the Hatch-Waxman Act") created opportunities for marketing of generics or the so-called abbreviated new drug applications (ANDAs)[94]. The Hatch-Waxman Act established the ANDA approval process, which allows lower-priced generic versions of previously approved innovator drugs to be brought into the market. The details of the approval processes provided under the "Hatch-Waxman Act" are provided in the Appendix.

Data obtained from the FDA show that the leading Indian firms have taken measured steps towards establishing themselves as important players in the ever-expanding market for generics in the US. It appears that these moves taken in the world's largest market for drugs have enabled the Indian firms to extend their presence in markets in Europe, most notably in the UK.

Two sets of data indicate the extent to which generic firms have been seeking opportunities to market their products in the US. The first set of data pertains to the market approvals that the leading generic firms have received for their products in the US. The second set of data relates to the "Drug Master Files". A Drug Master File (DMF) is a package of proprietary information that is voluntarily filed by a firm with the FDA. The information contained in a DMF is kept confidential until such time as an FDA reviewer requests a review of the DMF. This is done only by FDA reviewers in conjunction with their review of a specific Investigational New Drug Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Biologics License Application (BLA) or for an Active Pharmaceutical Ingredient (API). The DMFs

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[93] Federal Trade Commission (2002).

[94] Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug). One way scientists demonstrate bioequivalence is to measure the time it takes the generic drug to reach the bloodstream in 24 to 36 healthy, volunteers. This gives them the rate of absorption, or bioavailability, of the generic drug, which they can then compare to that of the innovator drug. The generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug.

can therefore be seen as an expression of interest that firms that have filed them have in obtaining marketing approval in the US.

Data on market approvals in the US provided by the FDA show that seven Indian firms have obtained approvals for their product thus far. Year-wise approvals obtained by the top 5 firms are provided in Table 13[95].

Table 13: Market Approvals obtained by the Leading Indian Firms in the US

Firms	Before 2000	2000	2001	2002	2003	2004	2005	Total
Ranbaxy Laboratories Ltd*	24	17	7	27	39	34	26	174
Dr Reddy's Laboratories Ltd*	1	3	11	5	5	11	8	44
Lupin Ltd	0	0	0	0	9	1	14	24
Aurobindo Pharma Ltd	0	0	0	0	0	13	7	20
Wockhardt Ltd*	7	4	2	0	4	0	5	22

* Includes approvals taken by the firms that are its subsidiaries

Source: US FDA Orange Book database.

As can be seen from the Table 10 an overwhelming proportion of the approvals obtained by the Indian firms were in the post-2000 period. For instance, Ranbaxy, which has the largest number of approvals among the Indian firms, had only 24 approvals prior to 2000. But in the following six years, the firm had obtained approvals for another 150 drugs.

An interesting aspect of the FDA approvals obtained by Ranbaxy and Dr. Reddy's Laboratories, the two largest firms in terms of number of approvals, is that most of their approved drugs are prescription drugs[96]. In case of Ranbaxy, only 6 of the 174 approved drugs are OTC (over-the-counter) drugs, while for Dr. Reddy's, 4 of their 44 FDA approved drugs belong to the OTC category.

Since 2002, both Ranbaxy and Dr. Reddy's have taken steps towards registering themselves as the first movers in the generics' for a number of drugs. Data obtained from the FDA shows that while Ranbaxy has been able to obtain approvals for 22 drugs as the "first-time generics" between 2002 and 2005, Dr. Reddy's has been able to obtain similar approvals for 8 drugs.

A significant recent development for the Indian firms is their entry in the market for anti-retroviral (ARV) drugs in the US. Two firms, viz. Ranbaxy and Aurobindo Pharma, have been able to obtain tentative or full approval from the US Department of Health and Human Services (HHS) and the FDA for five ARV drugs during 2004-05. These drugs were approved as a part of the Emergency Plan for AIDS Relief[97] that President George Bush had announced in 2003 for bringing low-cost, high-quality anti-retroviral therapy (ART) to the patients. The Indian firms had also marked their significant presence in the

[95] The two remaining firms are Sun Pharmaceuticals and Glenmark Pharmaceuticals.

[96] Approvals granted by the FDA are for either prescription or the OTC (over-the-counter) drugs.

[97] Better known as "President's Emergency Plan for AIDS Relief", or PEPFAR.

implementation of the Global Fund to Fight AIDS, Tuberculosis and Malaria that was established in 2002. The details in this regard are given in the following section

The second indicator of the increased interest of the generic industry in the US market was sharp increase in the filings of Drug Master Files (DMFs) in recent years. The database maintained by the FDA provides an "active list" of "Type II DMFs" by pharmaceutical firms that supply drug substances, drug products, intermediates, and material used in their manufacture[98]. While in the overall list of "active Type II DMFs", Indian generic firms have a share of almost 13%, during a more recent period viz., 2000-05, their share had increased to 22%. Table 14 provides a list of firms from the generic industry that were most active in "active Type II DMFs" filings.

Table 14: DMF Filings by the top 10 firms in the Indian generic industry

Firms	No of DMF Filings
Dr Reddy's Laboratories Ltd	63
Cipla Ltd	59
Matrix Laboratories Ltd.	53
Aurobindo Pharma Ltd	48
Ranbaxy Laboratories Ltd	41
Cadila Healthcare Limited	37
Sun Pharmaceuticals Inds Ltd	34
Lupin Ltd	25
Orchid Chemicals and Pharmaceuticals Ltd	22
Wockhardt Ltd	18

Source: US FDA database (http://www.fda.gov/cder/dmf/)

The above discussion indicates quite cogently that the firms from the Indian generic industry have been improving their presence in the market for generics in the US. The number of approvals, including approvals as "first time generics", that some of the leading firms in the industry have obtained particularly since the beginning of the current decade is a testimony of this fact. There has, however, been yet another dimension of the dynamism that the Indian firms have shown in the US markets lately and this relates to the challenges they have mounted on the patent holders while seeking approval for their generic products.

In an earlier discussion, we had indicated the market for generics in the US was given the initial boost by the Hatch-Waxman Act of 1984. The Act requires that an abbreviated new drug application (ANDA) must include a patent certification (better known as paragraph I-IV certification)[99]. While paragraphs I-III applications can be made only after the patent has expired or with the consent of the patent holder, Paragraph IV allows the generic manufacturer to either challenge the validity of applicable patents or certify that the generic equivalent product will not infringe any patent held by the pioneer drug firm. If the generic producer is able to obtain approval from the FDA on a "paragraph IV"

[98] DMFs can be of four types: Type pertains to manufacturing site, facilities, operating procedures, and personnel (this was discontinued in the year 2000); Type II relate to drug substances, drug substance intermediates, and material used in their preparation, or drug product; Type III concern packaging material; Type IV relate to excipient, colorant, flavour, essence, or material used in their preparation; and Type V relate to FDA accepted reference information.

[99] For details see Appendix

application, it can get 180-day market exclusivity for its product. The implication of this "market exclusivity" is that during the "exclusivity" period, other generic manufacturers are denied entry into the market. However, if the producer of the patented drug files an objection against the move by the generic manufacturer to obtain a "paragraph IV" approval, the former can obtain a 30-month stay on the decision allowing the latter to operate in the market. In a study conducted by the Federal Trade Commission (FTC), it was pointed out that the "paragraph IV" provisions are biased against the interests of the generic producers and that changes need to be brought about. Based on the recommendations of the FTC, some amendments to the "paragraph IV" provisions have been introduced.

The is no doubt that "paragraph IV" route for obtaining market approvals for their products is quite attractive for the generic manufacturers because the 180-day market exclusivity provides them an opportunity to leap-frog over the competing firms in what is an extremely competitive market. But then, there is a risk of losing out on the entry into the market altogether since the owner of the patent which has been challenged, can obtain a 30-month stay. From the available evidence, it seems that the two leading Indian firms, viz. Ranbaxy and Dr. Reddy's have decided to take the risks of using the "paragraph IV" option.

The impetus for Ranbaxy's paragraph IV challenges was provided by the success that it had registered while contesting the patent infringement suit brought by GlaxoSmithKline against Ranbaxy's Cefuroxime Axetil, a generic version of GlaxoSmithKline's antibiotic Ceftin. GlaxoSmithKline filed the suit in the US District Court of New Jersey in October 2000, and the court issued a preliminary injunction which prevented Ranbaxy from marketing its generic version. In 2001, however, Ranbaxy commercially launched its product after the United States Court of Appeals for the Federal Circuit vacated the preliminary injunction. After a full trial, the district court ruled that Ranbaxy's product did not infringe GlaxoSmithKline's patent and that Ranbaxy was not required to pay any damages.

More recently, Ranbaxy has had yet another success as it could enter into an agreement with Cephalon, Inc. to settle their pending patent infringement dispute in the US related to Provigil (Modafinil) Tablets. According to the terms of the agreement, Cephalon granted Ranbaxy a non-exclusive royalty-bearing licence to market and sell a generic version of Provigil in the US, which would become effective in October 2011 but no later than 2012. An earlier entry by Ranbaxy could occur based upon the entry of another generic version of Provigil. In addition, the two firms also agreed to a series of business arrangements related to Modafinil. Cephalon also agreed to enter into certain arrangements with Ranbaxy related to the supply of active pharmaceutical ingredient of Modafinil.

Alongside the above-mentioned successes, Ranbaxy has had to face a number of failures. The most recent case was the one involving Pfizer's blockbuster blood pressure drug, Accupril. In response to the suit brought by the patent owner viz. Pfizer and Warner Lambert Co., the Court of Appeals for the Federal Circuit ruled that Ranbaxy's generic

version of the drug violated the patent. What implications this case would have on the pending paragraph IV challenges of Ranbaxy would be seen with interest[100].

Although the paragraph IV challenges made by Dr Reddy's make up for a longer list as compared to that of Ranbaxy's, the former has not yet been successful in defending its generics against suits brought by the patent owners. Some of the major firms against which Dr. Reddy's had made paragraph IV challenges include Pfizer, Novartis, GlaxoSmithKline and Eli Lilly.

The generic drug manufactures from India have also started establishing their presence in Europe, and in particular the UK. Data obtained from the Medicines and Healthcare Products Regulatory Agency (MHRA) for the period 2001-2005 confirms this fact. Here again, the two leading firms, Ranbaxy and Dr Reddy's, have led the way and they have been joined by three other firms, viz. Aurobindo Pharma, Nicholas Primal and Orchid Healthcare. Ranbaxy obtained the largest number of approvals (204), followed by Dr. Reddy's Laboratories (57). Table 15 gives the year-wise approvals obtained by the top three Indian firms to have obtained approvals from MHRA.

Table 15: Year-wise Approvals Obtained from MHRA by the top-3 Firms (2001-2005)

Firms	2001	2002	2003	2004	2005	Total
Ranbaxy Laboratories Ltd	62	24	32	65	21	204
Dr Reddy's Laboratories Ltd	…	7	13	20	17	57
Aurobindo Pharma Ltd	…	…	…	2	17	19

Source: UK, Department of Health, Medicine and Healthcare Products Regulatory Agency (http://www.mhra.gov.uk/home)

The above discussion points to the increasing presence of the leading firms from the generic industry in some of the larger markets for drugs in the world. Interestingly, the increase in the market penetration by these firms has taken place since the beginning of the current decade. This implies that the consolidation of the operations of the leading pharmaceutical firms seen during the past decade had a key role to play in increasing their presence in the global markets.

It would appear that seeking global markets is only one aspect of the strategy adopted by the leading Indian firms. The other aspect of the strategy is to deepen the R&D activities in order that the firms can benefit from dynamic efficiencies. The R&D activities were focused on two areas. The first is the area of Novel Drug Delivery Systems, an activity in which the leading generic firm, viz., Ranbaxy, has experienced landmark successes. The second area is the production of innovative drugs, i.e., drugs on which the firms have sought patent protection, especially in some of the developed countries.

[100] The pending paragraph IV challenges of Ranbaxy include: (i) AstraZeneca patents on the ulcer treatment drug Nixium (Esomeprazole Magnesium), (ii) GlaxoSmithKline patents on the antiviral drug Valtrex (Valacyclovir HCl), (iii) Takeda Chemical Industry patents on anti-diabetic drug, Actos (Pioglitazone HCl) and (iv) Wyeth and Scherer and Cardinal Health patents on cold and sinus drug Advil (Ibuprofen and pseudo-ephedrine).

Novel Drug Delivery Systems

Novel drug delivery systems (NDDS) have been the focus of activities of most leading firms in the generic industry. Developing a new drug delivery system is far simpler in terms of the costs incurred and the time expended, besides, of course the degree of expertise required. NDDS of an existing drug could be developed in 3-4 years with an investment of $20-50 million[101].

Regulatory requirements in case of a drug with NDDS would involve establishing its bioequivalence with the 'normal' brand. This, in simple terms, means that the drug in its new mode of delivery should provide similar concentrations in the blood, as would the conventional drug. Several Indian firms are working towards this end – JB Chemicals, Cadila Healthcare, Zydus Cadila, Morepen Laboratories, Neuland Laboratories and Aurobindo.

In the area of NDDS, Ranbaxy recorded the most noteworthy success. The firm was able to develop an improved version of one the new generation antibiotics, viz. ciprofloxacin, which was developed by Bayer AG and was under patent protection until 2003. Ranbaxy Laboratories was able to produce a once-a-day formulation instead of the multiple-dose a day therapy promised by the Bayer formulation. The Ranbaxy formulation assured better patient-compliance and was hence, considered to be a major step forward. Bayer recognised the improvement and entered into a licensing agreement with Ranbaxy for its version of ciprofloxacin. Under the agreement, Ranbaxy Laboratories received US$ 65 million from Bayer over a four-year period, with an initial payment of US $ 10 million. The agreement allowed Bayer AG to have the worldwide marketing rights over ciprofloxacin, except in India and the CIS countries where Ranbaxy Laboratories had the marketing rights.

In 2001, significant progress was made by the firm towards developing platform technologies and products in the area of Oral-Controlled Release system. Ranbaxy initiated the process of clinical development of its once-a-day formulations of Ofloxacin by filing an IND application with the US FDA in late 2001.

The current global market for products with NDDS is estimated to be about $ 20-22 billion. Some estimates have indicated that by 2009, the market for NDDS in the US will be worth $91 billion. The US drug delivery industry is transforming ordinary drugs into better drugs optimised for a broad range of applications. Drug delivery is helping to expand other pharmaceutical industry sub-sectors such as biotechnology drugs, generic drugs, specialty pharmaceuticals and more. Major pharmaceutical firms are using the technology to extend their drug product life cycles. That the Indian firms have shown considerable promise in this rapidly expanding segment of the industry augurs well for their future prospects.

Development of Innovative Drugs

The propensity of the leading firms in the generic industry to increase their R&D intensity is possibly best reflected in their drive to obtain patents not only in India, but in several developed countries as well. As with other activities described in the foregoing, patenting activities of top 10 spenders on R&D have improved consistently since 1999-

[101] Quoted by industry sources.

2000. The best among the performers is the top spender on R&D, viz. Ranbaxy. Global patent filings of the firm increased from a mere 14 during 1999 to more than 250 during 2005. Besides Ranbaxy, Cipla and Dr. Reddy's have also contributed to the increase in the patent applications filed by the leading Indian firms, which in 2005 had increased to nearly 500. Table 16 gives the details

Table 16: Worldwide Patent Filings of leading Indian generic firms

(Number of applications)

Firms	1999	2000	2001	2002	2003	2004	2005
Ranbaxy Laboratories Ltd.	14	31	53	69	127	208	259
Cipla Ltd.	0	5	15	12	21	38	56
Dr. Reddy's Laboratories Ltd.	3	5	5	25	69	77	49
Lupin Ltd.	12	9	8	8	12	25	32
Cadila Healthcare Ltd.	1	2	3	9	14	19	29
Wockhardt Ltd.	2	0	3	14	14	18	25
Orchid Chemicals & Pharmaceuticals Ltd.	0	1	1	7	31	48	25
Nicholas Piramal India Ltd.	0	0	1	7	4	8	11
Sun Pharmaceutical Inds. Ltd.	1	0	2	0	2	8	4
Aurobindo Pharma Ltd.	0	0	0	5	6	9	2
Total	**33**	**53**	**91**	**156**	**300**	**458**	**492**

Source: EPO database (http://www.epo.org/patents/patent-information.html)

The top three firms in terms of the patent applications made have increasing tendency to seek international patents. This is evidenced by the fact that almost 50% of the applications made by both Ranbaxy and Cipla have been made through the PCT route[102]. Dr Reddy's, however, shows a different tendency, with the share of PCT applications in the total patent applications falling during 2004 and 2005 (Table 17).

Table 17: PCT applications made by the top three firms in terms of patent applications

(Number of applications)

Firms	1999	2000	2001	2002	2003	2004	2005
Ranbaxy Laboratories Ltd.	2	15	21	27	47	105	129
Cipla Ltd.	0	3	6	4	8	22	25
Dr. Reddy's Laboratories Ltd.	6	8	4	20	38	15	17

Source: EPO database (http://www.epo.org/patents/patent-information.html)

[102] The PCT, or Patent Cooperation Treaty, which operates under the aegis of the World Intellectual Property Organization (WIPO), allows patent applicants to use a single application to seek patents in a number of countries. In her/his application for a patent submitted in a designated PCT Office, which exists in every PCT Member State, the applicant can indicate the countries in which she/he is seeking patent rights. Within a period of 18 months, the PCT process informs the applicant if the invention she/he is seeking protection for, is patentable in the countries listed in the application.

As regards their preferred destinations for seeking patent rights the three top firms have shown a marked variation. For Ranbaxy, member states of the EPO[103] seem to be the preferred destination with the firm having applied for 73 patents during 2005. For Dr. Reddy's on the other hand, the US has been the major area of interest with the firm having made patent 31 applications during 2005, which is far in excess of the applications it has made using the PCT route. In contrast, Cipla has applied for patents in countries other than in the US or EPO member states.

It may however be argued that the penchant for obtaining patent rights that the leading Indian firms have shown during the past few years could have longer term implications for access to medicines at affordable prices in India. Many observers are of the view that these firms have benefited from the lax patenting standards that been used by the patent offices in several developed countries, most notably the US Patent and Trademark Office (USPTO). It is a well-documented fact that the patenting standards adopted by the USPTO have their basis the severe constraint it faces in terms of resources to examine the increasing number of patent applications that it receives annually in a proper manner. Consequently, "questionable patents" or patents of "poor quality" have been granted by the USPTO[104]. Examples of patents of "questionable quality" granted in the area of pharmaceuticals would be those that are granted for formulations or for new use of a known substance, which may be treated as incrementally modified drugs (IMDs)[105]. The quality of patent on IMDs can be best judged from the comment made by FDA that in a vast majority of cases IMDs "do not provide significant improvement over currently marketed therapies"[106].

The increasing evidence relating to the grant of patents in the US, which are in the nature of incremental innovation, have arisen because the strong economic incentives that they bring with them have driven the firms towards IMDs. The lawmakers in the country, mindful of the above-mentioned adverse implications of the functioning of the patent system in the area of pharmaceuticals, tried to provide an alternative route for accessing drugs at affordable prices by promoting the generic industry. In an earlier discussion, we had indicated that the Hatch-Waxman Act was adopted in 1984, which allowed the space to the generic drug manufacturers to challenge the patent holders by seeking market approval using the paragraph IV route, which would have given them 180-day market

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[103] The EPO has membership of 31 states, which includes all EU Member States except Malta. Other members of the EPO are Bulgaria, Iceland, Liechtenstein, Romania, Switzerland and Turkey.

[104] It has been argued that if the USPTO had more examiners, made a greater effort to keep experienced examiners, and gave patent examiners more time to spend on their initial examination, the PTO would issue fewer questionable patents. This comment on the working of the USPTO has been made by the Federal Trade Commission in its Report. See Federal Trade Commission (2003). See also Blumenthal (2006).

[105] This characterisation of formulations and new-use patents are patents of "questionable quality" has been made in the amendment to India's Patents Act, 1970. The Indian policy makers have accepted the argument that patents are granted for inventions and that patents on formulations and new-use of known substances do not merit a 20-year patent protection since these products do not represent substantial effort on the part of the innovator. But while mere formulations or new-use of known substances have been excluded from the ambit of patenting, there remains a grey area in respect of patenting of pharmaceuticals in India that could be influenced by the patenting standards set by the patent offices in the developed countries in general and the USPTO in particular.

[106] This point was made in detail an earlier discussion.

exclusivity. In other words, no other generic drug manufacturer would be allowed to operate in the market once approval under paragraph IV was obtained.

But the experience of the generic firms has shown that the paragraph IV option has not proved very profitable since the patent holders have been able to block the entry of the generic producers by obtaining a 30-month stay that they are allowed under the Hatch-Waxman Act[107]. For the generic drug manufacturers seeking market exclusivity for their product, which may well be an IMD, the option could then be to obtain a patent. That generic manufacturers are inclined to take patents for their NDDS and this evidenced by the fact that Ranbaxy has obtained two patents on its most successful NDDS involving ciprofloxacin[108]. As stated earlier, Ranbaxy had licensed the ciprofloxacin NDDS to Bayer AG, the owner of the patent on the product, even before the expiry of the patent.

With several of the leading Indian firms having acquired significant expertise in developing the generics, which are essentially in the nature of IMDs, it is not surprising that alliance building efforts involving some of the major pharmaceutical firms in the global market are being witnessed in India. Two forms of alliances are being witnessed in India. The first involves collaboration between the foreign and the domestic firm in India. The second, and a more recent, but perhaps strategically more significant in the longer term, is the increasing evidence of Indian firms making acquisitions in the foreign markets. The following section elaborates this phenomenon.

Alliance Building Efforts

The first significant of these alliances between Indian and foreign firms in the area of pharmaceuticals was the one involving Ranbaxy. This was an interest case for it involved the first commercially viable process that came out of the Ranbaxy R&D stable involving Cefaclor, a cephalosporin antibiotic.

Although the initial forays of Ranbaxy Laboratories into research and development (R&D) activities began in the late 1970s, it was not until the late 1980s that the firm had made some progress in this area through the development of a novel process for Cefaclor. Patent for Cefaclor, was owned by Eli Lilly obtained in 1979. This antibiotic was one of the best selling drugs in 1980s. Ranbaxy started work on developing a new seven-stage process for the production of Cefaclor in 1989. After spending nearly Rs. 20 million on a three-year project, Ranbaxy had emerged as the only other manufacturer of Cefaclor besides the patent holder, Eli Lilly. Not only did Ranbaxy produce the product successfully; it also managed to obtain high yields from its process. In 1993, Eli Lilly and Ranbaxy Laboratories agreed to set up two joint ventures in India. One was to conduct research in India and the other was to market Eli Lilly's products in the South Asian market.

What started as exceptional collaborative venture more than a decade and a half back has now become the most happening event in the generic industry. Not only are the leading firms in the Indian industry involved in R&D collaborations with some of the global pharmaceutical majors, their exertions have prompted smaller enterprises to enter into a

[107] Some amendments have been introduced in the provisions governing paragraph IV, which essentially limits the application of the 30-mont stay. For details see Annex.

[108] The first of these patents (Pat No. 6261601) was obtained in 2001 and the second (Pat No. 6960356) in 2005.

variety of collaborative ventures with foreign enterprises. These collaborations have taken two principal forms. The first involves contract research arrangements, the second, contract manufacturing and outsourcing arrangements.

Contract research arrangements have included activities related to product development as well. One of the critical components in this regard is clinical trials. Clinical trials in India are considered to be cheaper and faster than those in developed markets. Available estimates indicate that in India, contract research organisations can hire the required personnel at less than a third of the wages prevailing in most developed countries. Besides, the Indian population provides a vast diversity in terms of ethnicity as well as the disease profile. Because of these advantages, overall clinical development costs in India are estimated to be 40–60% lower than those in most developed countries[109].

Among the successful cases of product development through contract research that has been recorded thus far, two cases involving Ranbaxy and Dr Reddy's are the most interesting. In March 2003, Ranbaxy successfully challenged GlaxoSmithKline's patent on Ceftin, but, soon afterwards, GlaxoSmithKline hired Ranbaxy to research on molecules that could become the building blocks for drugs. According to the agreement, GlaxoSmithKline assumed exclusive commercialisation responsibilities worldwide, while Ranbaxy would have the rights over Indian markets (although Ranbaxy could co-promote in the US and the EU, with permission from its collaborator). Similarly, Novartis is working with Dr Reddy's in various R&D areas, despite an ongoing lawsuit over a generic version of Novartis' antifungal cream Lamisil. Some of the more recent contract research arrangements are included in Box 4.

Contract manufacturing has emerged as a major growth area in the pharmaceuticals sector. The Boston Consulting Group has estimated that the contract manufacturing market for global firms in India would touch $900 million by 2010. Industry estimates suggest that the Indian firms bagged manufacturing contracts worth $75 million in 2004. Although most of the firms active in this area belong to the group of the smaller and emerging firms, there have been several large firms that have also entered into the fray. Thus, the mid-sized firms in the industry, including Dishman Pharma, Divis Laboratories and Matrix Laboratories, have been undertaking contract jobs for global pharmaceutical majors along with their larger counterparts firms like Orchid Pharmaceuticals. Top global firms like Pfizer, Merck, GSK, Sanofi-Aventis, Novartis and Teva etc. are largely depending on Indian firms for many of their Active Pharmaceutical Ingredient (APIs) and intermediates[110].

The trends observed in the collaborations between the foreign and the India firms in the generic industry do portend to a strengthening of the industry in the ensuing years. While the larger firms would be able to effectively compete with the global players, now that they have are establishing partnerships in the area of product development, the smaller firms would be able to improve their bottom lines by becoming dedicated suppliers to the

[109] Grace (2004). The objective of preclinical studies is to come up with a molecule that is effective against the disease vector and safe in animal testing. This is the Investigational New Drug (IND) stage. This stage of investigation may take anywhere between 3 to 5 years and cost between $100-150 million overseas or about Rs.40-60 crore in India.

[110] FICCI (2005).

global pharmaceutical majors. This could indeed provide sustenance to the generic industry in the long term.

During the past couple of years, yet another dimension has been added to the activities of the Indian pharmaceutical firms. Several of the firms have been involved in the acquisition of firms based in the developed and some of the more advanced among the developing countries. Annex Table 2 provides a non-exhaustive list of acquisitions that have taken place since 2004. It may be noted from Annex 2 foreign acquisitions by the Indian firms have not been restricted to only the top firms. Several of the mid-sized firms like Glenmark Pharma, have been among the firms that have been more active in the acquiring firms.

Coming on back some impressive performance on the export front, this development may be termed as "trade-led investment", which has until now been conceptualised only in the context of the FTAs[111]. And while India is actively engaged in FTA negotiations with a number of its trading partners, including the EU, the ASEAN and the MERCOSUR members, the lead taken by the generic firms to enhance trade and investment possibilities in the industry could provide useful guidance for the negotiating process.

[111] UNCTAD (2003), Annexes.

Box 4: Collaborative Ventures Involving Foreign and Indian Pharmaceutical Firms

1. Matrix Laboratories Ltd. signed a collaborative agreement for drug discovery with Japan's aRigen Inc. The agreement outlines a multi-year joint drug development program whereby the firm would prepare compounds to determine the lead compound and supply samples to aRigen.
2. Themis Medicare Ltd signed a long-term agreement with Schering-Plough Animal Health Corp. (SPAH), for a new drug delivery system. Themis would transfer all ownership rights, title and interests, patent rights and formulations to the worldwide animal health business of Schering-Plough Corp.
3. Panacea Biotec Ltd entered into a tie-up with U.K.-based Cambridge Biostability Ltd for manufacturing of vaccines using the "stable liquid technology".
4. Orchid Chemicals and Pharmaceuticals entered into a seven–year Master Research and Development agreement with Pfizer International LLC. Under this agreement, Orchid will provide research and development services to Pfizer's Animal Health business
5. Dr Reddy's teamed up with the UK's Argenta Discovery to jointly develop a novel approach to the treatment of chronic obstructive pulmonary disease
6. Dr Reddy's Laboratories entered into a co-development and commercialisation agreement with the Denmark-based Rheoscience A/S for joint development and commercialisation of Balaglitazone, a molecule for the treatment of type-2 diabetes.
7. Dr Reddy's licensed two anti-diabetic compounds to Novo Nordisk and one to Novartis between 1997 and 2001.
8. Ranbaxy licensed uroselective α-blocker to Shwarz Pharma AG
9. Torrent sold first right of refusal for an advanced glycosylation end (AGE) breaker compound being developed primarily for hypertension to Novartis
10. Glenmark licensed a PDE-4 compound for asthma and COPD to Forest Labs.

(ii) Governmental measures for Promoting Pharmaceutical R&D

Government's role in promoting pharmaceutical R&D has been two-fold. One, providing incentives to the pharmaceutical industry for increasing R&D spending, and, two, facilitating collaboration between the private sector and the large network of publicly funded research institutions, in particular, those functioning under the Council for Scientific and Industrial Research (CSIR).

Incentives for Increasing R&D Spending

The Government has provided incentives to the pharmaceutical firms to increase spending on R&D principally in two forms. In the first place, products of the firms that have been more actively involved in R&D activities were exempted from the price control mechanism. Secondly, fiscal instruments have been used to provide incentives for R&D spending.

The pharmaceutical industry in India had been subjected to rigorous price controls since 1970 through the adoption of the Drugs Price Control Order or DPCO. The DPCO was aimed at fulfilling two objectives. The first and more obvious objective was to ensure that drugs were available at reasonable prices in India. The second was to create an incentive structure for domestic producers to produce new formulations and to use, as active ingredients, new drugs that were products of original research in India[112]. However, since the late 1980s, the focus of the Drug Policy adopted by the Government was more on providing market-based incentives to the Indian generic industry.

Accordingly, the number of drugs under price control was reduced. Some of the criteria that were used to exclude drugs from being covered by the DPCO were as under:

(i) A manufacturer producing a new drug patented under the Indian Patents Act, 1970, if developed through indigenous R&D, would be eligible for exemption from price control for a period of 15 years from the date of the commencement of its commercial production in the country.

(ii) A manufacturer producing a drug in the country by a process developed through indigenous R&D and patented under the Indian Patents Act, 1970 would be eligible for exemption from price control until the expiry of the patent from the date of the commencement of its commercial production in the country.

(iii) A formulation involving a new delivery system developed through indigenous R&D and patented under the Indian Patents Act, 1970, for process patent, would be eligible for exemption from price control in favour of the patent holder formulator from the date of the commencement of its commercial production in the country until the expiry of the patent.

The second dimension of Government's incentive for firms engaging in R&D activities was the tax breaks that firms could enjoy. Under the existing laws, pharmaceutical (and biotechnology) firms having in-house R&D facilities can benefit from a weighted deduction of 150% on any expenditure on scientific research (excluding cost of land or building) until March 31, 2007. And, R&D units can enjoy exemption from income tax

[112] Dhar Rao (2002).

for the same period. Furthermore, any firm carrying on scientific R&D is allowed 100% deduction on profits for a period of 10 years if it is approved by the Ministry of Science and Technology before April 1, 2007.

For several years, the industry has been arguing for extending the fiscal benefits that the Government has been providing. The main argument of the industry has been that results of R&D efforts can be realised only after a considerable lag and therefore it would be appropriate to extend the tax exemptions and other concessions that the Government provides at present by another 10-years[113].

Public-Private Partnership in Promoting R&D

During the past six decades, India's R&D infrastructure has been built around the network of institutions created under the CSIR[114]. In addition, the Indian Council of Medical Research (ICMR), around 25 universities and a few pharmacy colleges, funded largely by the Government, provided the additional sinews to the R&D efforts. With the maturing of private enterprise in the country, there was recognition of the need to build effective synergies between R&D efforts undertaken by the state-funded organisations and those that the private sector had put in place.

However, the concrete manifestation of this need came relatively recently. In 1999, the Government set up a Committee, the Pharmaceutical Research and Development Committee (PRDC) under the Chairmanship of Dr. R.A. Mashelkar, Director General, CSIR, which, among other things was expected to "suggest mechanisms for establishing organic linkages between private sector and government organisations/laboratories/universities with a view to synchronising and synergising national R&D efforts in pharmaceuticals"[115].

The PRDC made two major contributions. First, it tried to set India's priorities for pharmaceutical R&D. Secondly, and perhaps more importantly, the Committee tried to identify the institutional mechanism that was needed to undertake R&D activities. A key element of the latter exercise was the identification of the publicly funded research facilities that were in existence.

The most prominent among the recommendations made by the PRDC was the setting up of an autonomous Drug Development Promotion Foundation (DDPF). It was suggested that the Foundation be managed jointly by the industry and the Government-supported institutions, would have several key responsibilities. The more important of these were: (i) enhancing the basic research component with special emphasis on risk-taking in discovery and development of new drug delivery systems, plant based preparations, etc., and (ii) providing international co-operation in discovery and development of new drug delivery systems and plant, mineral, animal and herbal based preparations to reduce risks, costs, and development duration.

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[113] FICCI (2005).

[114] The CSIR has 40 laboratories spread all over the country.

[115] The terms of reference of the PDRC also included the following: (i) to appraise the current status of R&D in the Indian pharmaceutical sector and to suggest measures to boost it in the context of drug price control regime and changes in laws on Intellectual Property Rights, and (ii) to suggest new and innovative fiscal and non-fiscal measures for boosting R&D in pharmaceutical sector. See Government of India (2001).

The PRDC also recommended that the Foundation should be financed through the Pharmaceutical R&D Support Fund (PRDSF), which should have an initial corpus of Rs 5 million to be funded by the Government. PRDSF was eventually operationalised in 2004-05 with an initial corpus of Rs 15 million. The management of the PRDSF was entrusted to Drug Development Promotion Board (DDPB)[116] that comprised of all the relevant Ministries/Departments of the Government and had, as industry representatives, only the three associations representing largely the "Indian" pharmaceutical industry[117].

The idea of participatory research involving both the public and the private sector that the PRDC was intending to promote, and which was critically dependent on the autonomous DDPF and PRDSF, has undergone significant dilution on two counts. One, the DDPB was established with an overwhelming majority of institutions representing the Government, which raised questions about its "autonomous" character. And, two, the PRDSF, which was to provide the "corpus" for supporting R&D activities, was discontinued in 2006. It and was replaced by an annual government grant "for furthering R&D activities in the country and for defining areas of relevance and value to the Indian populace and intensifying the work in such areas by synergizing the core competence of the constituents for developing the synergies between the various actors involved in the area of pharmaceutical research"[118]. The moot point here is whether these changes have resulted in another state-funded and managed structure that has failed, in the past, to ensure effective participation of the pharmaceutical industry.

The eventual outcome of the initiatives taken by the PRDC to encourage public-private partnerships in the area of pharmaceutical R&D notwithstanding, there are growing evidence of collaboration Government institutions and pharmaceutical firms in recent years. The three laboratories, which are most active in area of pharmaceuticals viz., Central Drug Research Institute (CDRI), Indian Institute of Chemical Technology (IICT), and Centre for Cellular and Molecular Biology (CCMB)[119], have established several collaborative ventures with the pharmaceutical firms (Annex Table 2 gives the details). These ventures are a pointer to the fact that the public-private partnerships in the generic industry have overcome the limitations of the policy-induced initiatives for promoting pharmaceutical R&D in the country. The real issue is whether this partnership can deliver s efficiently as has been provided in its blueprint.

The discussion in the foregoing indicates that the future holds much promise for the Indian generic firms. At the same time, however, several issues of concern remain, particularly when the perspective is one of access to medicines at affordable prices. We had mentioned at the outset that the major concerns in India about the future of its domestic pharmaceutical industry in the new TRIPS-consistent patent regime arose from this above-mentioned perspective. Hence, policy makers were intensely lobbied by the

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[116] Rajya Sabha (2005).

[117] The industry associations included in the DDPB were: (i) Indian Drug Manufacturers Association (ii) Bulk Drug Manufacturers Association and (iii) Indian Pharmaceutical Alliance. These associations essentially represent the interests of the pharmaceutical firms that are owned and controlled by Indians. In other words, they do not include firms that are affiliates/associated of foreign firms.

[118] Government of India (2006).

[119] Apart from these institutions, National Chemical Laboratory (NCL), Pune has also been involved in this area.

public interest groups to evolve a patents regime that fully took cognisance of the flexibilities in the TRIPS Agreement, which could be used to address critical issues like access to medicines. While a number of flexibilities were included in the amendments introduced to usher in a TRIPS-consistent patent regime, there are others, which have remained unimplemented.

It may be argued that the developments in the generic industry enumerated in this study may not entirely assuage the concerns pertaining to access to medicines at affordable prices for two significant reasons. First, the penchant for patenting displayed by some of the larger firms like Ranbaxy and Dr Reddy's, could create intrusive monopolies in a market that should have available for competition among the generic producers. These firms have already taken patents in the US on incrementally modified drugs, and if the patent examination procedures in India are not rigorous enough, these patents may find their way in this country as well. For instance, Ranbaxy had submitted a product patent application on its NDDS on ciprofloxacin and had even argued for the grant of EMRs, which was rejected[120]. This implies that although the public interest groups are arguing for the adoption of a narrow definition of "pharmaceuticals" to eliminate the possibility of patenting of older drugs like ciprofloxacin, their efforts could eventually be neutralised by the "research-oriented" Indian generic firms.

The second weakness of the Indian pharmaceutical industry, viewed from the public health perspective, is that their increased collaboration with the foreign firms would hardly help them focus on the "neglected diseases". Although in recent years, this issue has received renewed attention because of the global initiative taken, among others, by the Médecins Sans Frontiéres (MSF)[121], it seems improbable that the generic industry in India would be a meaningful partner in this global initiative.

These weaknesses notwithstanding, the Indian industry has made noteworthy contributions in the global action against HIV/AIDS. The following section provides the details in this regard.

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[120] LEX ORBIS (2006)

[121] The MSF launched the "Drugs for Neglected Diseases Initiative" or DNDi, to address the need for research and development of new field-adapted, effective, and affordable drugs for patients suffering from "neglected diseases". The initial idea was to harness accumulated knowledge and cutting-edge science and technology to develop critically needed drugs for neglected diseases, making sure they are suitable for and accessible to the poorer patients of the world. The essential element of this initiative is to collaborate predominantly with developing country organizations and governments.

Chapter 7 Access to HIV/AIDS Drugs and the Indian Generic Industry

Universal access to drugs is a well-recognised strategy to counter the spread of HIV/AIDS. It was a bold decision of the Brazilian government in 1996 that paved the way for free ARV treatment movement. Even though, Brazil started the free ARV treatment programme using drugs from the brand name firms, it later shifted to generic drugs to ensure the sustainability of the programme. The high cost of patented ARV drugs threatened the sustainability of free ARV programme. The cost of ARV drugs till 2000 was between US$10,000 to 15,000 for per person per year (ppy). As a result, free treatment programmes were beyond the reach of most of the countries. The high cost of patented ARV drugs forced the Brazilian government to start the domestic production of ARV drugs. Thus Brazil introduced first generic version of ARV drugs, which was priced at US$ 3000 ppy. This showed for the first time that ARV drugs can be produced at a lower price than the patented drugs and it accelerated the demand for cut in the ARV drug price.

It was the initiative taken by the Indian firm, Cipla, to reduce the prices of ARV drugs, which triggered the "domino effect". In February 2001, Cipla announced that it would sell the triple combination[122] for US$ 350 ppy. This shattered many myths on drug prices. Even the announcement itself forced brand name firms to cut ARV drug prices. This led to fall in the price of ARV drugs. The fall in the prices of ARV drugs encouraged many governments and non-governmental organisations to initiate free ARV treatment programmes. Generic ARV thus became the focal point of all free ARV treatment programmes including USA's PEPFAR. Presently a first line triple combination is available at US$132 ppy.

(i) Indian Generic Industry and ARV Drugs

The generic firms in India have brought three path breaking contribution to the availability and accessibility of ARV drugs. Firstly, Indian firms started the production and marketing of the generic version of first line tipple combination drugs at an affordable price. This triggered the price war in ARV drugs segment. It was Cipla which first to announce the introduction of generic ARVs in February 2001. Secondly, Indian firms introduced fixed dose combinations (FDCs) of ARV drugs. As result, the number of pills had been reduced from six pills per day to two per day. FDCs not only improved the adherence but also reduced the price of ARV drugs. Thirdly, Indian firms also introduced the paediatric formulation of ARV drugs.

Producers of ARV drugs in India benefited from the fact that the Indian Patents Act did not allow patenting of pharmaceutical products until the Act was amended in 2005.

Following the lead given by Cipla, other generic firms also entered in the ARV drugs segment. Currently there are 14 firms active in the ARV drugs production. Out of these 14 firms, 8 firms are active only in the API segment of ARV production. The following table shows the list of firms active in the ARV drugs production.

Table 18: Firms active in ARV Drugs Production

[122] Cipla's triple combination included stavudine, lamivudine and nevirapine.

Name of the Firm	API	Formulation
Cipla Ltd	X	X
Ranbaxy Laboratories Ltd	X	X
Aurobindo Pharma Ltd	X	X
Strides Arcolab Ltd	X	X
Hetero Drugs Ltd	X	X
Emcure	X	X
Zydus Cadila Healthcare Lt	X	
Sun Pharmaceutical Inds. Ltd	X	
Samarth Pharma Ltd	X	
Matrix Laboratories Ltd	X	
IPCA Laboratories Ltd	X	
Dr. Reddy's Laboratories Ltd	X	
Eastern Surgical Company	X	
Mac Leods	X	

Source: Annual Reports of Firms (various years)

Possibly the most significant dimension of the operations of the Indian firms in the market for ARV drugs is that they have emerged as a major source of supplies to the affected countries. Six firms have obtained registrations for supplying ARV drugs as of October 2005, the details of which are provided in Table 19.

Table 19: Approvals Received by Indian Firms for supplying ARV Drugs

Firms	**Total Drugs Registered**	**WHO pre-qualified Drugs**
Aurobindo Pharma Ltd	41	3
Cipla Ltd	31	10
Eastern Surgical Company	22	…
Emcure Pharmaceuticals Ltd	16	…
Hetero Drugs Ltd	23	1
Ranbaxy Laboratories Ltd	21	7
Strides Arcolab Ltd	11	4

Source: WHO, The Regulatory status of Antiretroviral Drugs Database, (last update on 25th October, 2005)

The largest number of registrations has been granted to Aurobindo Pharma, although it is Cipla, which has the largest number of WHO pre-qualified drugs. The other noteworthy feature of the registrations granted to the Indian firms is that all firms, with the exception of Eastern Surgical and Emcure, have registered their presence in most countries of Africa, which is by far the most affected region.

The Indian firms have also proved their capabilities in terms of supplying the ARV drugs to the affected countries. Since the Global Fund to Fight AIDS, Tuberculosis and Malaria (henceforth "Global Fund"), started providing funds for the free treatment programme, Indian firms emerged as the major suppliers of ARV drugs. Between June 2003 and January 2006, more than 1300 consignments of ARV drugs were supplied using the

Global Fund and of these Cipla is the largest supplier[123]. Table 20 gives the list of top 10 suppliers of ARV drugs under the Global Fund.

Table 20: Top 10 Suppliers of ARV Drugs under Global Fund in terms of Consignments (June '03 to Jan '06)

Firms	No. of consignments
Cipla Ltd.*	342
Aspen Pharmacare*	221
Bristol Myers Squibb	158
GlaxoSmithKline Ltd.	144
Abbott Laboratories	88
Merck	73
Ranbaxy Laboratories Ltd*	45
Hetero Drugs Ltd*	35
Roche	32
Boehringer Ingelheim	25

* Supplied from a single source

Source: Global Fund to Fight AIDS, Tuberculosis and Malaria (http://www.theglobalfund.org/en/about/procurement/list/)

Although three Indian firms were among the ten top suppliers of ARV drugs under the Global Fund in terms of the number of consignments, only two figured in the top 10 suppliers in terms of value of drugs supplied. Table 21 provides the details.

Table 21: Top 10 Suppliers of ARV Drugs under Global Fund in terms of Value (June '03 to Jan '06)

Name of manufacturer	Total value (in US $ million)
Bristol Myers Squibb	8.0
Cipla Ltd.	7.4
GlaxoSmithKline Ltd.	3.9
Roche	3.5
Merck	3.1
Aspen Pharmacare	3.1
Abbott Laboratories	0.8
Ranbaxy Laboratories Ltd	0.7
Boehringer Ingelheim	0.6
Abbot Laboratories Ltd	0.5

Source: Global Fund to Fight AIDS, Tuberculosis and Malaria (http://www.theglobalfund.org/en/about/procurement/list/)

During the period June 2003 and January 2006, the Global Fund provided nearly US $ 34 million for procurement of ARV drugs and the share of the Indian firms was close to 25%. This establishes the point that Indian firms have become major global suppliers of ARV drugs, particularly in the recent years. The future of the generic firms therefore becomes important not only for the fact that it has a critical role to play in the India's quest for obtaining drugs at affordable prices, but now as its pivotal position as global suppliers of ARV drugs to some of the most affected regions. The following section

[123] A part of Cipla's supplies were met by its marketing joint venture in South Africa, Cipla Medpro.

looks at the future of India's ARV drugs production capacities under the products patent regime.

(ii) Products Patents and Future of ARV Generics

Introduction of product patent regime in India has created serious doubts on the future supply of generic ARV drugs. Generic availability of ARV drugs is required to meet both the domestic and export markets. Further, many countries that are among the worst affected by HIV/AIDS, do not posses the technical expertise to produce ARV drugs. These countries have, therefore, to depend upon the countries like India, Brazil and China[124] for the supply of ARV generics, even in the absence of a product patent protection at the domestic level. In other words the access to drugs in many countries depends upon the flexibility available in the patent laws of major generic producing countries.

Our contention is that introduction of product patent in India raises several concerns. These include: (i) whether product patent regime would affect supply of generic ARVs from India; (ii) whether Indian firms can produce ARV drugs, which are currently available, but are not produced in India; (iii) whether India can export ARV drugs to countries having no or insufficient manufacturing capacity in the pharmaceutical sector[125]; and (iv) how will Indian firms produce new ARV drugs in pipeline.

Future of Existing Supply

All ARV drugs, which are currently available for the treatment were invented and patented in the USA or other developed countries before 1995. Hence, these drugs *per se* are not eligible for patent protection in India because the TRIPS Agreement requires India to consider grant of products patents on drugs which were invented after 1st January 1995. Annex Table 3 shows the patenting status of ARVs as listed in the US FDA's Orange Book. However, Annex Table 3 shows that the ARV drugs have been covered by multiple patents and that the applications for the recently granted patents were made post-1995. In other words, India would have to recognise the latter patents, should applications be made in this country. It may, however, be argued that the latter patents would be in the nature of improved formulations and are not eligible for the grant of patent in India, following the provisions of Section 3 (d) of the Indian Patents Act, 1970, as amended. According to this section, a the *mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant*[126].

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[124] It may be pointed out that China's existing strength is in production of API and not formulations.

[125] As provided in the Doha Declaration on TRIPS Agreement and Public Health. See WTO (2001) for details

[126] The explanation accompanying this Section provided further clarification as regards the scope: "For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy".

This Section, however, qualifies the exclusion with efficacy requirements. As result, if the applicant proves that the claimed invention increases the efficacy of the known substance, patent can be granted on the invention concerned. In this context, it needs to be pointed out that the Indian Patent Office is yet not well equipped to evaluate claims on efficacy, and that the patent applicants may eventually get a favourable nod from the authorities. Further, patents are filed before the marketing approval of drugs therefore, it is not possible to make claim on efficacy at the time of filing. Pharmaceutical firms could use this exception to claim patents on the known substance to extend the patent monopoly. For instance, in the dispute on the patent on Gleevec, which was discussed earlier, it was observed that the patent applicant Novartis relied on the efficacy argument to defend their claim on a beta-crystal format of a known substance invented in 1993. The Controller accepted the efficacy argument but rejected Novartis claim on lack of evidence in this regard.

In India, several firms have filed patent applications claiming that their inventions constitute improvements of known substances in India. Table 22 provides a non-exhaustive list of pending patent applications on ARV drugs in the mailbox. Indian Patents Office is currently examining these patent applications. These applications have claimed patents either in the salt form or in the form of combinations or isomers. Therefore patents on any of these claims may affect the availability of existing ARV drugs. Even though the Indian Patents Act provides immunity to the existing producers of ARV drugs, patent on such drugs would increase the cost of such drugs since payment of royalty to the patent holder is entailed. We had argued earlier that the patent holder could try to extract supernormal rents by way of royalty payments, given that the language of Article 11A of the Patents Act, which operationalises the “immunity provision”, allows such possibilities. These supernormal rents could reflect in the price of generics price. Further, in the absence of clear ceiling on royalty the patent holder may raise the higher percent of royalty. This may lead to situation where the existing patients on the ARV treatment may end up in paying an increased price.

Table 22: Pending Product Patent Applications for ARV Drugs filed in India

Substance Name	Title	Indian application No	Priority Date	Applicant
Lamivudine + Zidovudine	Pharmaceutical Compositions	2044/cAL/1997A	31/10/1996UK	Glaxo
Nevirapine / Hemihydrate	Pharmaceutical Suspension Comprising Neverapine Hemihydrate	2485/DEL/1998A	NA	Boehringer Ingelheim
Trizivir	Antiviral Combinations	1206/CAL/1997A	NA	Glaxo
Tenofovir-3 applications	Nucleotide Analog Composition	986/DEL/2002A	25/7/97/US	Gilead
	Nucleotide Analog Composition	963/DEL/2002A	25/7 /97/US	Gilead
	A method for preparing Form 2 or Form 4 Crystalline Adefovir Dipivoxil	989/DEL/2002A	25/7 /97/US	Gilead
Lamivudine	Pharmaceutical Compositions	479/CAL/1998A	24/03/1997& 26/03/1997	Glaxo
Amprenavir +AZT + Ziagen	Antiviral Combinations	1206/CAL/1997A		Glaxo
Amprenavir+AZT+3TC+FTC	Vaccine	2172/MAS1998A	26/09/1997	SmithKline Beecham
Amprenavir	Pharmaceutical Formulations	727/DEL/1997A	22/03/1996 USA	Glaxo
Abacavir	A Novel salt	872/CAL/98	17/5/97 UK	Glaxo
Lexiva Fosamprenavir Calcium	Calcium (3S)	IN/PCT/2001/00039	18/7/1998 GB	Glaxo
Lopinavir	Process and Intermediates for preparing retroviral Protease Inhibitors	259/MUMNP//2003	31/08/2000	Abbott

Source: Govt. of India, Controller General of Patents Designs and Trade Marks (http://www.patentoffice.nic.in/)

Production of Existing ARVs

As stated earlier, the introduction of generics have brought down the price of first line ARV drugs. However, patients who are already on first line ARV drugs needs to change to the second line treatment. The second line treatment is very costly. For instance, until recently, Brazil spent 63% of its ARV drug budget on only three second-line ARV drugs.

The following table shows the comparative price difference in first line and second line drugs. It shows that the price of second line drugs is exorbitant and people who develops resistance to the first line drugs many not able to easily switch over to the second line. The high cost of ARVs could also raise serious questions on the sustainability of the second line treatment by countries that have initiated the free treatment programme. It hardly needs to be emphasised that this issue should be addressed to avoid a public health catastrophe.

Table 23: Price Comparisons of the "First" and "Second Line Regimen"

Country	First line regimen	Price in US$(ppy)	Second line	Price in US$(ppy)
Cameroon	3TC/d4T/NVP	277	AZT+ddi+NFV	4763
Malawi	,,	288	,,	1875
Kenya	,,	292	,,	1594
Cambodia	,,	350	AZT+ddi+LPV/r	1215
Thailand	,,	352	AZT+ddi+SQV/r	3500
Honduras	,,	426	D4T+ddi+NFVor AZT+ddi+NFV	3,796 NFV only

Source: MSF (2005)

Table 24 shows that Indian firms are producing 13 ARV drugs out of 20 ARV drugs, which are currently available for treatment. Most of these drugs are started production prior to 2005 and therefore eligible for immunity clause under Section 11A of the Patents Act, 1970, as amended. However, immunity clause would not apply to drugs, which have not been produced prior to 2005. 7 ARV drugs are outside the scope of the immunity clause. Currently, Indian firms are producing 7 types of fixed dose combinations, which are used for the first line treatment (Table 25). But fixed dose combinations required for the second line treatment are also not eligible for immunity. Likewise, Emtricitabine, Tenofovir and Saquinavir have only one producer. Hence, Indian firms cannot start producing and marketing these drugs if patents are granted. Therefore, the future of the "mailbox" applications would determine the accessibility of these drugs. As table 19 shows, a number of patent applications on Lopinavir and Amprenavir, including those that are in the "mailbox", are awaiting examination.

Further, production of fixed dose combination also would be affected if patents on the combinations were granted. Table 22 shows that at least one such combination, which may be useful in the future, has its patent application pending in the mailbox. Hence, application of Section 3(d) of the Patents Act would determine the availability of those 7 drugs and the fixed dose combinations for second line drugs.

Table 24: Existing ARV Drugs Production Capacities of Indian Firms

Drugs	**Cipla**	**Ranbaxy**	**Aurobindo**	**Strides**	**Hetero**	**Emcure**
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)						
Abacavir	X	X			X	
Didanosine (ddl)	X	X			X	
Lamivudine	X	X	X	X	X	X
Stavudine (d4T)	X	X	X	X	X	X
Zalcitabine (ddC)						
Zidovudine (AZT)	X	X	X	X	X	X
Emtricitabine (FTC)					X	
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)						
Delavirdine						
Nevirapine	X	X	X	X	X	X
Tenofovir					X	
Efavirenz	X	X	X	X	X	X
Protease Inhibitors						
Amprenavir						
Indinavir	X	X		X		
Nelfinavir	X			X	X	
Ritonavir	X			X	X	
Saquinavir				X		
Lopinavir + Ritonavir						
Atazanavir						
Fosamprenavir Calcium						
Fusion Inhibitors						
Enfuvirtide						

Source: Annual Reports of the Firms

Table 25: Production of "Fixed Dose Combinations" by Indian Firms

Combination	**Aurobindo**	**Cipla**	**Ranbaxy**	**Strides**	**Hetro**	**Emcure**
Lamivudine + Stavudine + Nevirapine		X	X	X	X	X
Lamivudine + Zidovudine + Nevirapine		X	X		X	X
Abacavir + Lamivudine + Zidovudine			X		X	
Lamivudine + Stavudine		X		X	X	X
Lamivudine + Zidovudine	X	X		X	X	X
Lopinavir + Ritonavir					X	
Emtricitabine + Tenofovir					X	

Source: Annual Reports of the Firms

This brings the focus on the back to the compulsory license regime in India. To follow the above strategy there is a need for simple and easy to use compulsory regime. However, the present regime does not provide a useful compulsory license regime, a point that was emphasised earlier. It was pointed out that generally, a compulsory license is available only after 3 years from the date of grant of the patent. The only exception is national emergency, extreme emergency or public non-commercial use. Even though,

HIV/AIDS is in effect a national emergency for India, the Government has not officially recognised it as such.

Concluding remarks

The Indian pharmaceutical industry has witnessed considerable changes over the past few decades, particularly with the emergence a strong generic industry. The growth of the industry and its subsequent consolidation was largely contributed by the Patents Act that was enacted in 1970. Patents Act, 1970 had two key features that facilitated the growth of the generic industry in India. First, only process patents were allowed for chemical entities, including pharmaceuticals, and two, the term of patent protection was made shorter for the pharmaceutical patents. The process patent regime enabled the generic manufacturers to develop alternative processes for products that were already in the market. Although the critics, the act of reverse engineering that the generic firms were engaged in was tantamount to counterfeiting, none of the generic manufacturers could be challenged by the global firms whose products they were reverse engineering.

The patents regime that Patents Act, 1970 had introduced underwent a change following the implementation of the commitments India had taken under the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS-consistent patent regime brought with it uncertainties for the generic manufacturers for their ability to reverse engineer products would be limited to a considerable extent. Furthermore, India is under pressure to introduce data exclusivity, a move that could also affect the future prospects of the generic manufacturers.

This study analysed the performance of the Indian pharmaceutical industry in the post-TRIPS patent regime. The analysis in the study covers the post-1995 period, i.e. the period since India acceded to the WTO. In our analysis we included 18 leading manufacturers in the industry, ten of which were generic manufacturers and remaining were associates of the global majors operating in India.

Our analysis showed that the leading generic firms of the industry have been showing considerable dynamism since 1995. The consolidation of the Indian firms, which began in the first half of the 1990s, improved considerably since the beginning of the current decade. Particularly noteworthy was the increase in the R&D spending of some of the leading firms, in particular, Ranbaxy and Dr Reddy's. As a result, R&D intensities of the firms have improved significantly.

The R&D efforts of the leading generic firms have borne considerable fruits. Market approvals in both the US and the UK, in particular, have increased in the past few years. Both Ranbaxy and Dr Reddy's have developed improved generics and Novel Drug Delivery Systems (NDDS), which have opened the doors for collaboration with the pioneer producers. India is fast emerging as the hub for contract research and manufacturing with a number of pharmaceutical majors establishing joint ventures with the Indian generic producers.

Although Indian firms are yet to make a mark in the area of new drug discovery, the firms seem to be on course for major developments even on this front given the sharp increase in their patenting activity of late. This activity could be strengthened by the increased efforts made by the Government to participate in the R&D activities involving the industry.

These efforts taken with a view to strengthening the technological sinews of the Indian generic industry should stand the industry in good stead as it evolves strategies to meet the challenges posed by the post-TRIPS patent regime. Improvements in the generic versions of proprietary drugs has become the established strength of the generic industry in India and with the prospects of faster growth of the market for generics in the near future, the industry should be looking at major gains.

One area where the Indian industry has got its act in place is the market for ARV drugs. Supplying these drugs at prices that the population of the affected regions can afford has become a priority and several of the Indian firms have met considerable success. With the global community now focused on obtaining drugs at affordable prices, it does appear increasingly probable that the pharmaceutical industries in the developing world, like the one existing in India, would offer the much-needed solutions.

These successful forays of the generic firms would have to be assessed in the context of its role in accessing medicines at affordable prices. We have indicated that the penchant for patenting, involving the incrementally modified drugs at that, does focus on the bleak side of the industry. Besides, the R&D priorities are being increasingly set in tune with the global trends, and this focus has increased since the firms have enhanced their level of collaboration with the foreign firms. Particularly affected in this process would be the "neglected diseases".

The above-mentioned concerns arising from the successes of the Indian pharmaceutical industry has important policy lessons for the developing countries. In the first instance, it is necessary to provide sufficient flexibilities in the patent laws so that the domestic pharmaceutical industries can get a chance to develop. It must be recognised, however, that the advantages that the Indian policy makers could provide to their nascent pharmaceutical industry in the 1970s, by way of introducing a process patent regime cannot be replicated in a TRIPS-determined patent system. But at the same time, these countries can provide an enabling environment for the domestic industries by carefully designing provisions that relate to patentable subject matter and compulsory licences.

The study also analysed the implications of introducing a data exclusivity regime in India while implementing Article 39.3 of the TRIPS Agreement. This Article requires WTO Member countries to provide protection to test and other data when such data are submitted to the regulatory authorities for obtaining marketing approval.

The study dwelled on the possible implications of a data exclusivity regime and tried to argue that its ramifications can be quite considerable on the Indian generic industry. Introduction of a data exclusivity regime of the kind prevailing in the United States and the European Union would be a death knell for the generic firms in India. The consequences of this threat faced by these industries would be felt by most sections of the populations in not only the countries that are home to these industries but also other countries, which have been dependent on the industries.

It is particularly important to point out that the positions taken by industry associations of the pharmaceutical majors, which has been endorsed by the United States Trade Administration through its annual Special 301 Reports is a violation of the multilateral system. The discussion in this study has pointed to the fact that neither Article 39.3 of TRIPS Agreement nor Article 10^{bis} of the Paris Convention require that the WTO

Member Countries need to introduce regimes of data exclusivity of the kind that the United States and the European Union provide. The attempts to impose global standards of data exclusivity are aimed at ensuring that the pharmaceutical majors get protection for their products into perpetuity, thus maintaining their stranglehold over the markets for pharmaceutical products.

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Appendix: The Hatch-Waxman Act

An innovator drug applicant must include in its new drug application (NDA) information about any patents that claim the drug that is the subject of the NDA, or the use of such drug product (21 USC 355(b)(1) and (c)(2))[127]. The FDA publishes this patent information upon approval of the NDA or a supplemental NDA in "Approved Drug Products with Therapeutic Equivalence Evaluations", which is better known as the "Orange Book".

An applicant for a abbreviated new drug application (ANDA) must include a patent certification (better known as paragraph I-IV certification) as described in section 505(j)(2)(A)(vii) of the Hatch-Waxman Act. Paragraph I certification requires the applicant to declare that the product for which approval is sought does not have an accompanying patent. Paragraph II certification requires the applicant to declare that the product in question is based on an expired patent. Paragraph III certification is applicable when the applicant has expressed his/her desire to market the product in question after the expiry of a patent. And, finally, Paragraph IV allows the generic manufacturer to either challenge the validity of applicable patents or certify that the generic equivalent product will not infringe any patent held by the pioneer drug firm. The generic manufacturer is required under the Paragraph IV provisions to notify the innovator manufacturer that it is filing a Paragraph IV certification with its ANDA.

Paragraph IV thus established an incentive for generic manufacturers to file ANDAs and to challenge listed patents as invalid, or not infringed, by providing for a 180-day period of marketing exclusivity. The first generic firm that files an ANDA can obtain a market exclusivity period of 180 days during which it can exclude any other prospective generic market entrant from marketing a generic product based on the same pioneer drug. The 180-day exclusivity commences upon a generic manufacturer's first sale of its product after obtaining FDA's approval for its ANDA. However, under the original Hatch-Waxman provision, if the generic firm holding the exclusivity period never put the drug up for sale, all other generic manufacturers who have filed ANDAs for the same drug would be precluded from marketing another generic version of the same pioneer drug.

However, the pioneer manufacturer can obtain a 30-month stay of FDA approval of an ANDA if, upon the receipt of a notice of a generic applicant's paragraph IV certification, it files a suit for patent infringement within 45 days of that notice. Filing of the lawsuit stays FDA's approval of the ANDA until: (1) the date the patents expire; (2) a determination of non-infringement or patent invalidity by a court in the patent litigation; or (3) the expiration of 30 months from the receipt of notice of the paragraph IV certification. The earliest of the three dates is used as a reference.

In 2002, the Federal Trade Commission conducted a study to determine if the 180-day exclusivity and the 30-month stay provisions of the Hatch-Waxman Amendments have been used strategically to delay consumer access to generic drugs. The study had two major findings: (i) there was increasing evidence of ANDAs being subjected to 30-month

[127] US Department of Health and Human Services (2003)

stays, (ii) there were more multiple 30-month stays than in years past, and (iii) more patents on average are now being litigated per generic drug application than in the past[128].

The new rule will limit an innovator drug firm to only one 30-month stay of a generic drug applicant's entry into the market for resolution of a patent challenge. For the generic drug producers, this change in the rule pertaining to the 30-month stay has provided them with greater latitude to seek decisive market entry in the US.

[128] Federal Trade Commission (2002).

Annex Table 1: Select Contract Manufacturing Deals in India

Indian Firm	Manufacturing for (Name of the Firm)	Product(s)
Lupin Laboratories Ltd	Fujisawa	Cefixime
	Apotex	Cefuroxime Axetil, Lisinopril (Bulk)
Nicholas Piramal Ltd	Allergan	Bulk and formulations
	Advanced Medical Optics	Eye Products
Wockhardt Ltd	Ivax	Nizatidine (anti-ulcer)
Dishman Pharmaceuticals and Chemicals Ltd	Solvay Pharmaceuticals	Eprosartan Mesylate
IPCA Laboratories Ltd	Merck	Bulk Drugs
	Tillomed	Atenolol
Orchid Chemicals & Pharmaceuticals Ltd	Apotex	Cephalosporin and other injectables
Sun Pharmaceutical Inds. Ltd	Eli Lilly	CVS Products, anti-infective drugs and Insulin
Kopran Laboratories Pvt. Ltd	Synpac Pharmaceuticals	Penicillin –G Bulk Drug
Cadila Healthcare Ltd	Altana Pharma	Intermediates for Pantoprazole
	Boehringer Ingelheim	Gastrointestinal and CVS Products
Biocon Ltd	Bristol Myers Squibb	Bulk Drugs

Annex Table 2: Foreign Acquisitions by Indian Generic Firms (2004-2006)

Year	Acquirer	Target	Target's country
2006	Aurobindo Pharma Ltd	Milpharm Limited	UK
2005	Dishman Pharmaceuticals and Chemicals Ltd	Synprotec DCR Ltd	UK
2006	Dishman Pharmaceuticals and Chemicals Ltd	Pharma services business of Solutia Inc.	Switzerland
2004	Dr. Reddy's Laboratories Ltd	Trigenesis Therapeutics Inc	US
2005	Dr. Reddy'sLaboratories Ltd	Roche's API business	Mexico
2006	Dr. Reddy's Laboratories Ltd	Betapharm Arzneimittel GmbH	Germany
2004	Glenmark Pharmaceuticals Ltd	Clonmel Healthcare Ltd	Ireland
2005	Glenmark Pharmaceuticals Ltd	Laboratorios Klinger	Brazil
2005	Glenmark Pharmaceuticals Ltd	Napo Pharmaceuticals	US
2005	Glenmark Pharmaceuticals Ltd	Servycal S.A.	Argentina
2004	Hikal Ltd	Marsing & Co	Denmark
2004	Jubilant Organosys Ltd.	PSI group	Belgium
2005	Jubilant Organosys Ltd.	Target Research Associate	US
2005	Jubilant OrganosysLtd.	Trinity Laboratories Inc	US
2006	Kemwell Private Ltd	Pfizer Health AB	Sweden
2005	Malladi Drugs Pharmaceuticals Ltd	Novus Fine Chem	US
2006	Marksans Pharma Ltd.	Nova Nova Pharmaceuticals	Australia
2005	Matrix Laboratories Ltd	MCHEM Pharma (Group) Ltd	China
2005	Matrix Laboratories Ltd	Docpharma N.V.	Belgium
2005	Matrix Laboratories Ltd	Explora Laboratories S.A.	Switzerland
2006	Natco Pharma Ltd	NICK's Drugs Store	US
2004	Nicholas Piramal Ltd	Rhodia's anaesthetics business	UK
2005	Nicholas Piramal Ltd	BioSyntech Inc	Canada
2005	Nicholas Piramal Ltd	Avecia Pharmaceuticals	UK
2004	Ranbaxy Laboratories Ltd	RPG Aventis	France
2006	Ranbaxy Laboratories Ltd	Terapia S.A.	Romania
2006	Ranbaxy Laboratories Ltd	Unbranded generic business of Allen SpA	Italy
2006	Ranbaxy Laboratories Ltd	Ethimed N.V.	Belgium
2006	Shasun Chemicals and Drugs Ltd.	Customs synthesis business of Rhodia	UK
2004	Shreya Life Sciences	SciGen Ltd	Singapore
2005	Strides Arcolabs Ltd.	Beltapharm SpA	Italy
2005	Strides Arcolabs Ltd	Biopharma	Venezuela
2004	Sun Pharmaceutical Inds. Ltd	Three niche brands from US based Women's First Healthcare	US
2005	Sun Pharmaceutical Inds. Ltd	Able Laboratories Inc	US
2005	Sun Pharmaceutical Inds. Ltd	ICN Hungary Co.	Hungary

2005	Torrent Pharmaceuticals Ltd.	Heumann Pharma GmbH & Co	Germany
2004	Wockhardt Ltd	Esparma Gmbh	Germany
2004	Zydus Cadila Group	Alpharma France	France
2005	Zydus Cadila Group	Bouwer Bartlett Pty Ltd	South Africa

Annex Table 3: Collaboration between Government Research Organizations and the Pharmaceutical Industry

CDRI (Lucknow)	IICT (Hyderabad)	CCMB (Hyderabad)
Novo Nordisk, Denmark	Dr. Reddy's Laboratories, Hyderabad	Shantha Biotechnics Pvt. Ltd., Hyderabad
Krebs Biochemicals Ltd., Hyderabad	Lupin Laboratories Ltd., Mumbai	Dr. Reddy's Research Foundation, Hyderabad
Avon Organics Ltd., Hyderabad	Cadila Laboratories Ltd., Ahmedabad	Bangalore Genei Pvt. Ltd., Bangalore
Cipla Ltd., Mumbai	SOL Pharmaceuticals Ltd., Hyderabad	Dabur Research Foundation, Sahibabad
Dabur India Ltd., Ghaziabad	Neuland Laboratories, Hyderabad	Biological Evans Ltd., Hyderabad
Duphar Interferan Ltd., Mumbai	Cipla Ltd., Mumbai	Sun Pharmaceuticals Ltd., Mumbai
Hindustan Latex Ltd., Thiruvananthapuram	Nectar Laboratories Ltd., Hyderabad	
IPCA Laboratories Ltd., Mumbai	Orchid Chemicals, Chennai	
Lupin Laboratories Ltd., Mumbai	Trident Laboratories Pvt. Ltd.,Hyderabad	
Malladi Drugs and Pharmaceuticals, Chennai	Unichem Laboratories Ltd., Mumbai	
Nicholas Piramal India Ltd., Mumbai	Armour Chemicals Ltd., Mumbai	
Lumen Marketing Co., Chennai	Bombay Drug House, Mumbai	
Ranbaxy Laboratories Ltd., New Delhi	Cheminor Drugs Pvt. Ltd., Hyderabad	
Themis Medicare Ltd., Mumbai	Torrent Pharmaceuticals Ltd., Ahmedabad	
Torrent Pharmaceuticals Ltd., Ahmedabad	Coromandal Pharma, Hyderabad	
Unichem Laboratories Ltd., Mumbai		
Wockhardt Ltd., Aurangabad		

Annex Table 4: ARV Drugs & Patent Status : Orange Book Listing

I: Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

Generic Name	Brand Name	Firm	US patent Nos.	Patent Expiry
Abacavir	Trizivir (Abacavir + Zidovudine+ Lamivudine) & Ziagen (Plain Abacavir)	GSK	4818538 4833130 5034394 5089500 6417191 5905082 6180639 6294540	Sep. 2005 Sep 2005 June 2009 June 2009 May 2016 May 2016 Jan 2018 May 2018
Didanosine (ddl)	Videx	BMS	5616566 5254539 5880106	Aug 2006 Aug 2006 Jul 2011
Lamivudine	Combivir (Zidovudine + 3TC) & Epivir (3TC alone)	GSK	4724232 4818538 4828838 5047407 5859021 5905082 6113920 6180639 6004968	Sep 2005 Sep 2005 Sep 2005 Nov 2009 May 2016 May 2016 Oct 2017 Jan 2018 Mar 2018
Stavudine (d4T)	Zerit	BMS	4978655	June 2008
Zalcitabine(ddC)	Hivid	Hoffman La-Roche	4879277 502659	Nov 2006 July 2008
Zidovudine (AZT)	Retrovir	GSK	4818538 4833130 4828838 4837208	Sep 20 Sep 2017
Emtricitabine (FTC)	Emtriva	Gilead Sciences	5210085 5814639 5914331 6642245	May 2010 Sep. 2015 Sep. 2015 Nov.2020

II: Non-nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

Generic Name	Brand Name	Firm	US patent Nos.	Patent Expiry
Delavirdine	Rescriptor	Pfizer	5563142 6177101	Oct 2013 June 2018
Nevirapine	Viramune	Boehringer Ingelheim	5366972	Nov 2011
Tenofovir	Viread	Gilead	4808716 5977089 6043230 5935946 6057305 5922695	Apr 2006 July 2017 July 2017 July 2017 May 2017 July 2017
Efavirenz	Sustiva	Merck	5519021 5663169 6238695 6555133 6639071	May 2013 Sep 2014 Apr 2019 Apr 2019 Feb 2018

III: Protease Inhibitors

Generic Name	Brand Name	Firm	US patent Nos.	Patent Expiry
Amprenavir	Agenerase	GSK	5585397 5646180 5723490	Dec 2013 July 2014 May 2015
Indinavir	Crixivan	Merck	5413999 6645961	May 2012 May 2018
Nelfinavir	Viracept	Agouron Pharmaceuticals	5484926 5952343 6162812	Oct 2013 Oct 2013 Oct 2013
Ritonavir	Norvir	Abbott	5846987 5541206 5948436 5635523 5648497 5484801 5674882 6037157 6232333	Dec 2012 July 2013 Sep 2013 Jun 2014 July 2014 Jan 2014 Oct 2014 June 2016 Nov 2017
Saquinavir	Invirase (Saquinavir mesylate) & Fortovase)	Hoffman La-Roche	5196438 6352717 6008228	Nov 2010 Nov 2019 June 2015
Lopinavir + Ritonavir	Kaletra	Abbott	5914332 5886036 5846987 5541206 5635523 5648497 5674882 5914332 6037157 6284767 6232333 6284767 6458818 6521651	Dec 2005 Dec 2012 Dec 2012 Jul 2013 Jun 2014 Jul 2014 Oct 2014 Dec 2015 July 2016 Feb 2016 Nov 2017 Feb 2016 Nov 2017 Nov 2017
Atazanavir	Reyataz	BMS		
Fosamprenavir Calcium	Lexiva	GSK		

IV: Fusion Inhibitors

Generic Name	Brand Name	Firm	US Patent	Patent Expiry
Enfuvirtide	Fuzeon	Hoffman La-Roche & Trimeris	5464933 6133418 6475491	June 2013 June 2013 June 2017

Annexure I: The Gleevec Case

Gleevec (Beta Crystalline Salt of Imatinib Mesylate) is an anti-cancer breakthrough drug, used to treat chronic myeloid leukaemia (blood cancer). Gleevec is also known to be effective against gastrointestinal stromal tumour (stomach tumours) and other forms of cancers. Gleevec however does not cure cancer but keeps the same under check hence making patients dependent on it for a prolonged period of time.

Although the compound STI571, from which Gleevec was eventually developed, was synthesized by Ciba Geigy, much of the research and development involving the drug was carried out in the laboratory of Dr. Brain Ducker of the Oregon Health and Science University. And when Dr Ducker was developing the drug, the funding pattern of his laboratory was as follows: 50% by the National Cancer Institute, 30% by Leukaemia and Lymphoma Society, 10% by Novartis and 10% by the Oregon Health and Science University.

Imatinib Mesylate is regarded as the most effective drug for Chronic Myeloid Leukaemia, a form of leukaemia. In India, annually around 25,000 people become the victims of Chronic Myeloid Leukaemia.

Novartis holds the patent for the drug and markets it under the brand name of Gleevec. Imatinib Mesylate was granted marketing approval in the US in 2001. Subsequently, the USFDA also approved Imatinib Mesylate for the treatment of gastrointestinal stromal tumours.

Novartis applied for a product patent application in India under the mailbox provisions that India was obligated to introduce in its Patents Act following the country's accession to the WTO. The patent applicant also claimed "Exclusive Marketing Rights", which was included in the first amendment of the Patents Act, 1970 in Chapter IVA, to meet the requirements of Article 70.9 of the TRIPS Agreement.

The Drug Controller General of India (DCGI) gave the marketing approval for Gleevec in 2001. Novartis started the marketing of the drug through importation. In 2003, an Indian firm, Natco Pharma, launched generic version of Imatinib Mesylate. Besides Natco, five other firms Camlin, Cipla, Sun Pharma, Ranbaxy and Intas are also in the market with their generic versions of Imatinib Mesylate.

In November 2004 Novartis obtained an Exclusive Marketing Right (EMR) for Gleevec having applied for it in 1998. In its application, Novartis indicated that Gleevec qualified for the grant of EMRs since it had been granted marketing approval in Australia. Even though Novartis got the patent and marketing approval from the US but did not rely on US approval and patents for EMR in India. The decision to grant EMR was challenged by one of the generic manufacturers in the High Court of Delhi. Meanwhile, Novartis obtained stay from the High Court of Madras and prevented all other generic firms from producing and marketing generic versions of Imatinib Mesylate.

After the third amendment of Patents Act, the affected pharmaceutical firms and public interest groups used the provisions relating to pre-grant opposition to challenge the product patent application on Gleevec. Patent application was challenged on the

following grounds: (i) prior publication, (ii) lack of inventive step, (iii) insufficient description, (iv) last priority date and (v) subsequent patenting of known substance.

According to petitioners, Novartis had disclosed the substance in an application filed in the US in 1994 taking priority from a Swiss patent application filed in 1992. The USPTO granted patent on this application in 1996. The US application stated that owing to the close relationship between the novel compounds in free form and in the form of their salts, including those that could be used as intermediaries, any reference to the free compounds should be understood as including the corresponding salts where appropriate and expedient. Hence, Novartis' claim for beta crystal salt format of Imatinib Mesylate has been anticipated through publication. Further, petitioners also pointed out that the steps stated in the patent application for creating the beta crystal form of Imatinib Mesylate is an obvious step and lacks inventive step. It was pointed out that the patent application failed to describe the steps involved for the manufacture of beta crystal form of Imatinib Mesylate. Patent application was also opposed on the ground of loss of priority date. The application in question was filed in 1998 taking priority from a Swiss application of 1997. However, on the date of filing in India, Switzerland was not recognized as Convention Country in India and therefore the date of application in Switzerland could not be considered as the "priority date". And, finally, under the Indian Patents Act, salts are not patentable unless the applicant the patent claim is not based on the enhanced efficacy. Novartis failed to provide any evidence on the enhanced efficacy of the beta crystal form of Imatinib Mesylate. Considering these objections, Indian Patent Office rejected Novartis' patent application on 27th January 2006.

In response, Novartis in May 2006 took the case to the High Court of Madras, challenging the validity of Section 3(d) of the Indian Patents Act (which makes the patentability of new forms of known substances dependent on the proof of enhanced efficacy of the known substance). In particular, Novartis declaration petitioned before the High Court to declare Section 3(d) of the Patents Act unconstitutional and to direct the Controller General of Patents to allow the patent application filed by it.

Amongst other submissions Novartis submitted that while amending Section 3 of the Act to include Section 3(d), the legislature did not pay heed to the essence of Articles 253 and 51(c) of the Constitution of India. Novartis asserted that when a particular legislation is being amended in pursuance of an international obligation that has been ratified without reservations then such an amendment must comply with the treaty obligations. They extended this assertion to Section 3(d) of the Act to state that it is not in consonance with the provisions of the TRIPS Agreement and submitted that the same is in violation of the constitutional mandate of the Indian government to respect international commitments

In light of the aforementioned submission Novartis submitted that Article 27 of the TRIPS Agreement mandates that patents are to be made available for any inventions in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

In its submission Novartis argued that the provisions of Section 3(d) are narrower than those of Article 27 of the TRIPS Agreement. The same is true because section 3(d) mandates that a new form of a known substance is an invention only if it results in the enhancement of the known efficacy of the substance. Therefore, the petitioners contend

that Section 3(d) contravenes Article 1(1) of the Agreement which requires members to give effect to the provisions of the TRIPS Agreement and prohibits members from providing protection that contravenes the provisions of the agreement.

Novartis further contended that while the discovery of a new property of a substance is understandable, the discovery of a new form is not. They assert that the discovery of a new form is a contradiction in terms as something, in order to be 'discovered', must already exist. Section 3(d) is alleged to allow the patenting of a discovery of a new form of a known substance, provided it satisfies the efficacy test. This is in direct conflict with the definition of an invention in Section 2(1)(j) which requires a 'new product or process involving an inventive step and capable of industrial application'. Therefore, Section 3(d) is alleged to render Section 2(1) (j) redundant in determining the patentability of inventions falling under Section 3(d), leaving 'enhanced efficacy' as the only criterion for the patentability of such inventions. The petitioners contended that as the term 'efficacy' has not been defined in the Act, its inclusion in the language of the statute is arbitrary. This, the petition argued, would give uncontrolled as well as unguided powers to the Controller of Patents in India. The arbitrary exercise of powers by the Controller of Patents would violate the right to equality under Article 14 of the Constitution of India. A challenge to the constitutional validity of a statute is maintainable only on two grounds in India, viz. legislative competency and violation of fundamental rights.

The court refused to examine whether Section 3(d) violates the obligations under the TRIPS Agreement and held that " …this court has no jurisdiction to decide the validity of the amended section, being in violation of Article 27 of TRIPS, we are not going into the question whether any individual is conferred with an enforceable right under TRIPS or not. For the same reason, we also hold that we are deciding the issue namely, whether the amended section is compatible to Article 27 of TRIPS or not". In fact, the court urged the Novartis AG (Switzerland) to approach the dispute settlement mechanism provided under WTO framework. The very next day the Federal Councilor, Department of Economic Affairs for the Swiss Confederation stated, "we must have a reliable TRIPS system and the one in India is good enough. The Swiss government never gets involved in any judicial pronouncements of other countries". This effectively ruled out the possibility of Switzerland approaching WTO dispute settlement body.

On the issue of Section 3(d) being violative of right to equality owing to the arbitrariness and vagueness of the phraseology, the court held that "… in sum and substance what the amended section with the explanation prescribes is the test to decide whether the discovery is an invention or not is that the patent applicant should show the discovery has resulted in the enhancement of the known efficacy of that substance and if the discovery is nothing other than the derivative of a known substance, then , it must be shown that the properties in the derivatives differ significantly with regard to efficacy". The court also clarified the meaning of the term efficacy. According to the court "… the meaning of the word efficacy and therapeutic effect …. What the patent applicant is expected to show is how effective the new discovery made would be in healing a disease /having a good effect on the body?" Thus the court equated the meaning of efficacy with the therapeutic effect on the body. While doing so the court also accepted the argument of the respondents that "… petitioner is not a novice to the pharmacology field but it, being pharmaceutical giant, cannot plead that they do know what is meant by enhancement of a

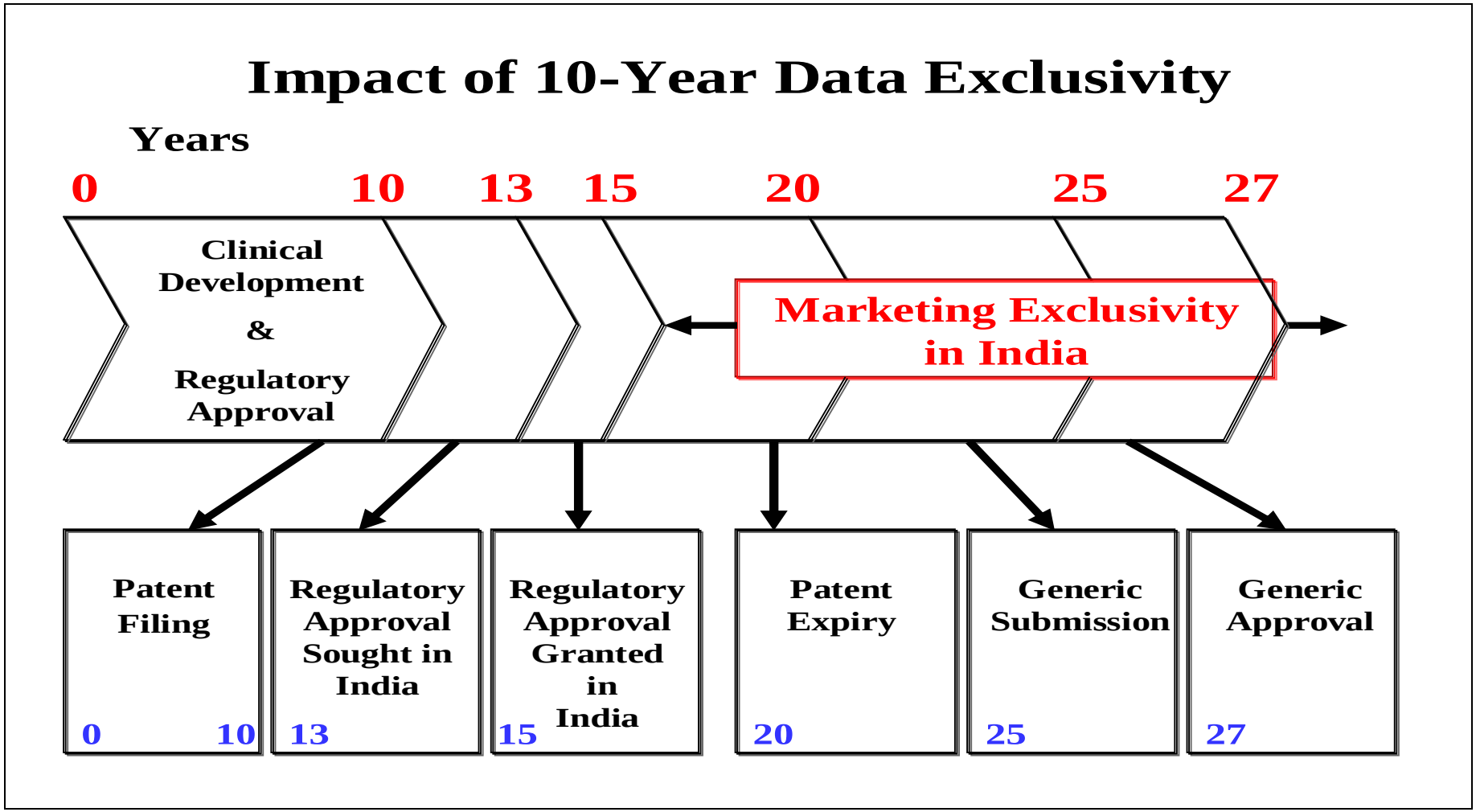
known efficacy and they cannot show the derivatives differ significantly in properties with regard to efficacy". Hence it was held that the patent applicant has to show enhanced therapeutic effect in order to obtain a patent for a new form of a known substance or for its derivatives. Therefore the court held that Section 3(d) is not violative of Article 14 of the Constitution of India.

The Gleevec case has attracted attention of the public interest groups essentially because the case would have deep rooted implications for access to medicines at affordable prices in countries like India. The case will decide whether the citizens of this country would see Novartis charge an unaffordable $ 2727 for a month's supply of the drug or whether generic firms would be able to sell the drug at a considerably lesser price.

Annexure II: Issues for comments by the Pharmaceutical Industry

1. Comments on Section 3(d)
    a. Assessment of the position in light of the KSR case
2. Views on research exception
    a. Does the Patents Act promote or hinder R&D
3. Views on pre-grant opposition
    a. Should pre- and post-grant opposition be existing together
4. Disclosure of source and origin of genetic material etc
    a. How acceptable is revocation as a remedy for non-disclosure
5. R&D strategies
    a. Working around patented products – ANDA
    b. Focus on new products
    c. Focus on neglected/orphan diseases
6. Section 11A
    a. Does it help/impede current operations
    b. Would you consider it a disincentive to operate in India
7. Compulsory Licensing
    a. Would CL hinder or facilitate their operations
    b. Are the existing grounds for the grant of CL adequate, if not what are the deficiencies
    c. Procedures for the grant of compulsory licence
    d. Interpretation of "economic value of licence"
    e. Section 92A (Para 6): how effective are the provisions for meeting the objectives for which it has been included (i.e. supplying to countries having little or no capacity to manufacture pharmaceuticals)
8. Government use
9. Bolar exceptions
10. Remedies for anti-competitive practices (Section 90)
    a. Are they adequate
11. Parallel imports

Chart 1


Impact of 10-Year Data Exclusivity
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10
13
15
20
25
27
Clinical Development & Regulatory Approval
Marketing Exclusivity in India
Patent Filing
0
10
Regulatory Approval Sought in India
13
Regulatory Approval Granted in India
15
Patent Expiry
20
Generic Submission
25
Generic Approval
27