CHAPTER-IV
THE INDIAN PATENT ACT ON DRUGS AND MEDICINES

4.1 INTRODUCTION

Indian Patents act was one of the best act legislated in India keeping in mind the requirements of its people and at the same time protecting the interest of the industrialists and innovators thereby adopted a flexible act which harmonized both societal and industrial interests at minimum interference of each other. Many developing countries like India were forced to take on commitments under TRIPs agreement due to the principle of ‘either take it all leave all’ during the Uruguay Round of trade negotiations.

The Patents Act of 1970 specifically prohibited product patents on “substances intended for use, or capable of being used as food or as medicine or drug” or “relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds)”, while allowing the processes for the making of such substances to be patentable for a short period of between 5 to 7 years. The terms of all other types of patents (for e.g., mechanical devices) were 14 years from the date of the patent. In shaping its first indigenous patents regime, India made a deliberate choice to stimulate domestic manufacturing and reduce the prices of products deemed “essential”, such as food and medicines.

India led the opposition to the inclusion of patent and intellectual property rights in a GATT accord. India and other developing countries viewed the GATT framework as a tool by which wealthy nations would impose strong IPRs as the cost of much needed access for the developing world to western markets.

Members may, of course, choose to give effect to the rules of the TRIPs Agreement by the adoption of national legislation or administrative rules that specifically implement its provisions. However, not all legal systems require that the rules of treaties (or international agreements) be transformed into national law by the adoption of specific legislation. In some national legal systems, the constitution provides that treaties may be given “direct effect” by the regulatory authorities and courts\(^1\) by 1989; India had reversed its anti-TRIPs stance and agreed to serious negotiations over patent protection, while arguing for special provisions

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\(^1\) Treaties that are given direct effect are referred to as “self-executing” treaties, but this terminology is specific to the United States.
to be made within the framework of TRIPs for developing countries. Upon it’s signing the Uruguay Agreement along with 116 other countries in 1994; India became a member of the WTO from January 1, 1995 and became obligated to amend its domestic IP laws. India was given ten years to implement its new laws.

The transformation of India’s patent laws has thus far involved a three-stage process corresponding to the three acts amending the Patents Act of 1970. First, the Patents Amendments Act of 1999 resulted in the creation of a “mailbox” in India which allowed inventors to file patent applications for products invented after 1995. These applications were to be considered for patent protection at the end of India’s ten-year transition period when product patents were to be brought into full effect. Second, the Patents Act of 2002 further amended the 1970 Act by providing the TRIPs-required twenty-year patent term, a reversal of the burden of proof for process patent infringement and modifications to compulsory licensing requirements. Lastly, India finally put product patent protection into full effect as of January 1, 2005.

At the Ministerial conference held at Marrakesh in 1994, the Government of India (GOI) ratified the Final Act of 1986-1994 Uruguay Round of trade negotiations establishing the WTO and it became obligatory for India to implement various Agreements incorporated in the Final Act.

In the TRIPs context, a mandatory rule is one that implementing authorities “must” apply with regard to IPRs holders or those challenging them. A discretionary rule is one that executive authorities or courts “may” apply in these settings. Although there may be certain limits on this principle, it has long been recognized under GATT-WTO dispute settlement practice that only mandatory rules may be challenged in dispute settlement, and that discretionary rules may not be challenged until a Member uses discretionary authority in a way inconsistent with WTO obligations.

While the Members are obliged to enforce the minimum standards of IPR protection prescribed by the Agreement, they have the leeway in framing the working

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2 The Panel in the US – Section 301Trade Act case identified a discretionary rule it considered to obligate the United States to act in manner that created uncertainty regarding its WTO obligations, and found that in such circumstance even a discretionary rule might violate WTO obligations. This panel report was not appealed (see Panel Report, United States – Sections 301-310 of the Trade Act of 1974 (“US – Section 301 Trade Act”), WT/DS152/R, adopted 27 January 2000.) In a subsequent ruling, the Appellate Body affirmed that the mandatory-discretionary distinction forms part of WTO jurisprudence noting, without expressing an opinion on the matter, that the Panel in the US – Section 301 case had “found that even discretionary obligations may violate certain WTO obligations” (Appellate Body Report, United States – Anti-Dumping Act of 1916, WT/DS136/AB/R, DS162/AB/R, adopted 26 September 2000.)
of IPR provisions such as scope of patentability, compulsory licensing provisions, etc.
All the laws on IPRs in India except Patents have been amended without much debate
in the Parliament or protests from the public.\(^3\) TRIPs Agreement provided some
transitional arrangements to developing country Members. Though the provisions of
the Agreements are expected to be in force by 1\(^{st}\) January 1996, developing countries
which had process patent regimes were given time, if they wanted, to extend the period
for further four years, i.e., till 1st January 2000\(^4\).

However, the Agreement required these Members to make provisions for
receiving patent applications\(^5\) and for developing countries which are obliged to
extend product patent protection to areas of technology not so protectable in its
territory on the general date of application of the Agreement, i.e., 1st January 1996,
could delay the application of the provisions for an additional period of five years,
i.e., till 1\(^{st}\) January 2005. India was having process patent regime in pharmaceuticals
and agro-chemicals and had the time till 1st January 2005 to extend product patent
rights in pharmaceuticals and agro-chemical products, though in other areas it had
to meet its obligations by 1\(^{st}\) January 2000.

India complied with its obligations under the TRIPs Agreement in three steps.
The first step was the Patents (Amendment) Act of 1999, which provided for receiving
of patent applications (mail-box applications) and for exclusive marketing rights\(^6\).

The Patents (Amendment) Act 2002 introduced comprehensive amendments
to bring together various provisions of the Patents Act 1970 into conformity with
the TRIPs Agreement.\(^7\) Though many applauded the creation of TRIPs, the
agreement also saw instant backlash, not only by critics who saw this as a move

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\(^3\) There have been concerns expressed from various corners (industry association-Indian
Pharmaceutical Alliance, CSOs, Health Activists, Academics, etc.) in the case of protection of
pharmaceutical test data. GoI appointed an inter-ministerial Committee to study the issue and the
Committee submitted its report in 2007. GoI is yet to take an official decision on the issue.

\(^4\) Article 65.2 of TRIPs Agreement.

\(^5\) Article 70.8 of TRIPs Agreement.

\(^6\) An ordinance was issued on 31st December 1994 amending the Patents Act 1970 to introduce
the mailbox provisions. But the amendment was not passed by the Parliament. The United States
dragged India into a dispute in the WTO (WT/DS50) on the failure of providing mail-box facility
where the decision went against India. Exclusive Marketing Rights brought with them a five-
year, patent-like monopoly for products covered by the product patent applications made under
the mailbox system. The company securing an exclusive marketing right has the exclusive right
to sell or distribute the article or substance covered in a patent application in a country.

\(^7\) It introduced 64 amendments. See Shamnad Basheer, *India’s Tryst with TRIPS: The Patents
away from the WTO’s trade mission\(^8\), but also by human rights activists concerned that this new intellectual property regime would quash certain basic human rights\(^9\), such as the right to health, food security and access to information\(^10\). As a result of these human rights concerns, the WTO adopted the Doha Declaration on the TRIPs Agreement and Public Health in 2001, in which the WTO acknowledged the concerns that some intellectual property protections could harm human rights like access to healthcare and medicines. It therefore created some flexibility in the application of the TRIPs principles by allowing member states to overlook some patent rights that may impinge on access to essential medicines.

Public health laws, national drug policy and the patent system are intensely inter-related. This was explained by the then Prime Minister Mrs Indira Gandhi while speaking at the World Health Assembly in Geneva on May 6, 1981. In her words:

“Affluent societies are spending vast sums of money understandably on the search for new products and processes to alleviate suffering and to prolong life. In the process, the drug manufacture has become a powerful industry.”

She added, on the patent system:

“My idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death.”

In this historic session, the participating countries unanimously adopted a resolution for “Global Strategy on Health for All”. Since then there have been laudable contributions by science and technology to tackle successfully many health problem areas. While there is a substantial unfinished agenda on the health front, new and formidable challenges have been thrown up by an unequal treaty on all-pervasive economic and social aspects by the Final Act embodying the results of the Uruguay Round negotiations. In particular, the TRIPs agreement is the most contentious part of the Final Act. The aim of this agreement is to enforce globally tough standards in respect of several forms of intellectual property, which include patents, trademarks,

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protection of undisclosed information, and so on, forgetting the goals by Indira Gandhi in regard to freeing of medical discoveries from the patent system - B. K. Keayla\textsuperscript{11}

All the agreements of WTO, including TRIPs, came into force on 1 January, 1995. But Article 65.2 of TRIPs permits developing countries, a transition period of five years to implement the provisions of TRIPs. In addition, if a country did not provide product patent protection in any field when TRIPs came into force, then under Article 65.4, she gets another five years (in addition to the five years permissible under Article 65.2) to introduce such protection. But Articles 70.8 and 70.9 of TRIPs put a limitation on the transition periods allowed under Articles 65 for two classes of products - pharmaceuticals and agricultural chemicals. Even though the developing countries, such as India had time till 1 January 2005 to introduce full product patents protection for pharmaceuticals and agricultural chemicals, they were required to introduce “mail box” and “exclusive marketing rights” provisions from 1 January, 1995\textsuperscript{12}.

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

1. Introduction of a facility (“mail box”) from January 1, 1995 to receive and hold product patent applications in the fields of pharmaceuticals (and agricultural chemicals). Such applications will not be processed for the grant of a patent until the end of 2004. But Exclusive Marketing Rights (EMRs) can be obtained for that application if a patent has been granted in some other WTO member country and the application has not been rejected in the country as not being an invention.

2. Compliance, from January 1, 2000 with other obligations of TRIPs, namely, those related to rights of patentee, term of patent protection, compulsory licensing, reversal of burden of proof and so on, and

3. Introduction of full product patent protection in all fields including pharmaceuticals from January 1, 2005. All the product patent applications held in the mail box are also required to be taken up for examination from January 1, 2005\textsuperscript{13}.


\textsuperscript{12} For a discussion of these transitional arrangements under TRIPs, see Ganesan 1999 in the Indian context and UNCTAD-ICTSD 2003; 2004 in the general context.

\textsuperscript{13} “Amendments to the Patents Act, 1970: Background Note,” Department of Industrial Policy and Promotion, Ministry of Commerce, New Delhi. See also the website of the Controller General of Patents, Designs and Trademarks, Government of India (www.patentoffice.nic.in).
Except in three sectors - Food processing, pharmaceutical and agro-chemicals - the Indian patent law allows product patents. In these sectors only process patents were allowed. India had a process patent regime regarding pharmaceutical products. Therefore, the Indian Patent Act, 1970 had to be changed to bring it in line with the international laws on patenting of pharmaceutical (and agro-chemical) products.

Being a developing nation, India had a grace period of five years to change its patent laws under the Agreement on TRIPs. In other words, the Indian Patent Act, 1970 have been amended suitably by 31st December, 1999.

At the same time, developing countries like India were given a grace period of ten years for technologies previously unprotected in its market. During this interim period of ten years, all patent applications will be put in a ‘black box’. However, pharmaceutical corporations can apply for an exclusive marketing right (EMR) for their products for five years only even before the country in question has fully phased into the new patent protection system.

The proviso is that the product must have been registered for a patent and has received marketing rights in any of the WTO Member countries. Thus it is a backdoor method for granting the monopoly rights. Furthermore there is a grey area here too.

From 1971 onwards, Indian Patent Act of 1970 governed the patent system in the country. This act was not in compliance with TRIPs provisions. India being a member of the WTO it was obligatory for India to change its patent act to confirm with the TRIPs Agreement. In principle there were three major changes that were required in the above act. The first deadline was to be adhered on the day the WTO agreement came into force (1st January, 1995): (a) to introduce ‘Mailbox’ protection (providing a means by which product patents in pharmaceutical and agriculture can be filed) and (b) provision of exclusive marketing rights (EMRs) to a pharmaceutical product that has been granted patent in any WTO member country after 1995. These changes had to be made in patent laws of country such as India that did not provide product patents in pharmaceuticals and agro-chemicals. The second major change required was to increase the duration for patent protection to 20 years from the date of filing of a patent by 2000. The third major requirement was to introduce product patents in pharmaceuticals, food and agro-chemicals by 2005. In principle by 2005, Indian Patent Act had to be made complaint with TRIPs requirements.
Apart from meeting the three deadlines, other important changes were required to be incorporated in Indian patent Act by 2005. TRIPs include a number of provisions from other major treaties covering IPR. In framing its rules/guidelines in patents, it has included articles from Paris Convention. Additionally India has also signed PCT (Patent Cooperation Treaty) and Budapest Treaty and thus it was imperative for India to include all the major clauses in its Patent Act that were required by these treaties.

The provisions of the TRIPs Agreement are to be implemented in phases by developed, developing, least developed countries and economies in transition. Further, there is some differential phasing in for provisions relating to certain fields of technology which were earlier exempt from product patents. Developed country members got a general period of one-year, i.e., up to January 1st, 1996 to bring their domestic legislations in line with the TRIPs Agreement. Developing country members are entitled to delay implementation of the Agreement for a further period of four years, i.e., up to January 1, 2000. However, all members would have to implement the provisions on national treatment and most-favored-nation treatment by January 1, 1996.

4.2 DISPUTE ON CONTENTIOUS ISSUES IN IMPLEMENTATION OF TRIPs AGREEMENT

The Indian government has made prompt efforts to introduce legislation to modify the Patent Acts in compliance with TRIPs. It failed to get it passed due to technical problems as the Parliament was dissolved. The new caretaker government responsible for administration, which came after dissolution of the government in November 1995, was not authorized to legislate on any new law. Under these circumstances, the United States called for a consultation with India under Article 4 of the understandings on rules and procedures governing the Settlement of Disputes on 2nd July 1996.

Considering that India had violated the TRIPs obligations the Panel was set up on 20th November 1996 and by September 1997 the Panel ruled that India had failed to comply with its TRIPs obligations.

TRIPs came into force on 1st January 1995. However, the first amendment to India’s Patents Act post-TRIPs did not come into force until 1999. This amendment was introduced after the United States took action before the dispute
settlement body of the WTO in 1997. The issue in United States v India was whether the Indian Patents Act 1970 included a mechanism that adequately preserved novelty and priority of product patent applications in the fields of pharmaceuticals and agrochemicals, given that under the 1970 act substances classified as “foods, medicines or drugs” were entitled only to process patents; product patents in these fields were not granted. The WTO panel concluded that India was in breach of Article 70.8 (a) of TRIPs and had violated its obligation under Article 70.9 to provide EMR during the transition period. The WTO Appellate Board upheld the panel’s conclusion.

The main charges against India were:

a) India did not provide any legal mechanisms for the deposit of applications for product patents for the transition period (i.e. until new legislation allowing product patent was introduced).

b) India did not provide any provision for Exclusive Marketing Rights as required under Article 70 (9) of the TRIPs Agreement.

c) India violated Article 63 (1) and (2) of the TRIPs Agreement, which required a member state to publish the new administrative rulings and legislation pertaining to Intellectual Property to other member states and to the TRIPs Council of the WTO Secretariat.

India’s arguments in defense of these charges were that it allowed applications for biological and chemical patents in the Patent Office thus complying with Article-70 (8)(a) by promulgating an Ordinance, which was in fact a de facto law. India had also the advantage of 5 years grace period as a developing country and it did not need to introduce any legislation to give effect to Article-70 (9) immediately and could delay this for another 4 years.

The Panel supported U.S. charges against India and stated that Ordinance was an administrative notification rather than a law and hence it has violated its TRIPs obligations. The Panel also stated that India’s reading of Article 70(9) was incorrect and under this Article India was required to introduce the transitional system immediately. Aggrieved with the panel decision, India appealed before the WTO Appellate Body.
The Appellate Body upheld the decisions of the Panel and found India to be in default of its TRIPs obligations under Article 70(8)(a) and 70(9), but reversed the Panels alternative findings with regard to Article 63(1) and (2) of the Agreement. The Appellate Body recommended that the Dispute Settlement Body of the WTO should request India to change its Patent Laws to make it TRIPs –Compliant by April 1999. This decision compelled the Indian Government to introduce the amended Patent Bill in 1998 to the Indian Parliament which was passed on 26th March 1999. After a number of meetings and discussions, finally a consensus could be reached and the Patents (Amendment) Bill 2003 was introduced in the Lok Sabha of the Parliament on 23rd December 2003. The Bill brings in the final changes that will make the Indian Patent Act fully TRIPs compliant. It was expected that the third amended Bill 2003 will be passed effective by 1st January 2005.

A case was made out against India for insufficient implementation of the stricter compliance to IPRs. India appealed from certain issues of law and legal interpretations in the Panel Report especially with regard to patent protection with respect to drugs and medicines. The Panel was established to consider a complaint by the United States against India concerning the absence in India of either patent protection for pharmaceutical and agricultural chemical products under Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property (the “TRIPs Agreement”), or of a means for the filing of patent applications for pharmaceutical and agricultural chemical products pursuant to Article 70.8 of the TRIPs Agreement and of legal authority for the granting of exclusive marketing rights for such products pursuant to Article 70.9 of the TRIPs Agreement.

On hearing from both the sides The Panel Report was circulated to the Members of the World Trade Organization (the “WTO”) on 5th September 1997. The Panel reached the following conclusions:

On the basis of the findings set out above, the Panel concluded that India has not complied with its obligations under Article 70.8(a) and, in the alternative, paragraphs 1 and 2 of Article 63 of the TRIPs Agreement, because it has failed to establish a mechanism that adequately preserves novelty and priority in respect of applications for product patents in respect of pharmaceutical and agricultural chemical inventions during the transitional period to which it is entitled under Article 65 of the Agreement, and to publish and notify adequately information
about such a mechanism; and that India has not complied with its obligations under Article 70.9 of the TRIPs Agreement, because it has failed to establish a system for the grant of exclusive marketing rights.\(^\text{14}\)

The Panel made the following recommendation:

The Panel recommends that the Dispute Settlement Body request India to bring its transitional regime for patent protection of pharmaceutical and agricultural chemical products into conformity with its obligations under the TRIPs Agreement.\(^\text{15}\) Based on the arguments that were put forward by the parties against each other on the basis of which the DSB gave the above decisions which were to comply with TRIPs Agreement.

On 15\(^{th}\) October 1997, India notified the Dispute Settlement Body\(^\text{16}\) (the “DSB”) of its intention to appeal certain issues of law covered in the Panel Report and legal interpretations developed by the Panel, pursuant to paragraph 4 of Article 16 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (the “DSU”), and filed a Notice of Appeal with the Appellate Body, pursuant to Rule 20 of the Working Procedures for Appellate Review (the “Working Procedures”). On 27\(^{th}\) October 1997, India filed an appellant’s submission.\(^\text{17}\) On 10\(^{th}\) November 1997, the United States filed an appellee’s submission pursuant to Rule 22 of the Working Procedures. That same day, the European Communities filed a third participant’s submission pursuant to Rule 24 of the Working Procedures. The oral hearing provided for in Rule 27 of the Working Procedures was held on 14\(^{th}\), November 1997. At the oral hearing, the participants and third participant presented their arguments and answered questions from the Division of the Appellate Body hearing the appeal.

India’s contention was that the legal findings and conclusions of the Panel relating to Articles 70.8, 70.9 and 63 of the TRIPs Agreement. India asserted that it has established, through “administrative instructions”, “a means” by which applications for patents for pharmaceutical and agricultural chemical products (often referred to as “mailbox applications”) can be filed and filing dates assigned to them. India contends that, as of 15\(^{th}\) October 1997, 1924 such applications had been

\(^{14}\) Panel Report, para. 8.1.

\(^{15}\) Panel Report, para. 8.2.

\(^{16}\) 5WT/DS50/6, 16 October 1997.

\(^{17}\) Pursuant to Rule 21(1) of the Working Procedures.
received, of which 531 were by United States’ applicants. Upon receipt, the particulars of these applications, including serial number, date, name of applicant, and the title of the invention were published in the Official Gazette of India. None of these applications had been taken up for examination, and none had been rejected. On 2 August 1996, the Government had stated in Parliament: “The Patent Offices have received 893 patent applications in the field of drug or medicine from Indian or foreign companies/institutions until 15 July 1996. The applications for patents will be taken up for examination after 1st January 2005, as per the World Trade Organization (WTO) Agreement which came into force on 1st January 1995”\textsuperscript{18}.

India argued that the function of Article 70.8(a) of the TRIPs Agreement is to ensure that the Member concerned receives patent applications as from 1st January 1995 and maintains a record of them on the basis of which patent protection can be granted as from 2005. India asserts that the Panel ruled that Article 70.8(a) comprises two obligations: first, to establish a mailbox to receive patent applications for pharmaceutical and agricultural chemical products and to allot filing and priority dates to them; and second, to create legal certainty that the patent applications and the patents based on them will not be rejected or invalidated in the future. India maintains that the second obligation is a creation of the Panel.

India asserts that the Panel justified the creation of this second obligation by invoking the concept of predictability of competitive relationships that was developed by panels in the context of Articles III and XI of the GATT 1947. India contends that this concept cannot be unquestioningly imported into the TRIPs Agreement. Furthermore, the Panel used this concept to advance the date on which India must give substantive rights to inventors of pharmaceutical and agricultural chemical products. Thus, India concludes, the Panel incorporated into the procedural requirements of Article 70.8(a) the substantive obligations set out in paragraphs (b) and (c) of Article 70.8 and turned an obligation to be carried out in the future into a current obligation.

India asserts that the means of filing provided by India ensures that patents can be granted when they are due. According to India, there is absolute certainty that India can, when patents are due in accordance with paragraphs (b) and (c) of Article 70.8, decide to grant such patents on the basis of the applications currently

\textsuperscript{18} See Panel Report, Annex 2.
submitted and determine the novelty and priority of the inventions in accordance with the date of these applications. India insists that there is no logical link between the theoretical refusal of a mailbox application under current law and the grant of a patent in accordance with paragraphs (b) and (c) of Article 70.8 in the future.

According to India, the Panel interpreted into the TRIPs Agreement the requirement that a Member must eliminate any reasonable doubts that it has met the requirements set out in that Agreement. To India, the Panel’s interpretation of Article 70.8(a) entails a violation of established principles governing the burden of proof.

India argued that the effect of the Panel’s shift in the burden of proof from the complainant to the defendant was exacerbated by the standard of proof which the Panel applied to the evidence submitted by India to demonstrate that the United States’ assertion was based on an incorrect interpretation of Indian law. In India’s view, the Panel did not assess the Indian law as a fact to be established by the United States, but as a law to be interpreted by the Panel. According to India, the Panel’s initiative contrasts with the cautious approach of previous panels to issues of municipal law. The Panel should have followed GATT practice and given India, as the author of the mailbox system, the benefit of the doubt as to the status of that system under its domestic law. The Panel also should have sought guidance on the manner in which the Indian authorities interpreted that law. India contends that the assertion by a Member that a mailbox system exists, and that it has been set up in accordance with its domestic law, may be displaced only by compelling evidence that the mailbox is illegal in domestic law; it is essentially for the Member itself to determine the methodology by which it sets out the mailbox system in terms of its municipal laws.

India argued that the text of Article 70.9 establishes the obligation to provide exclusive marketing rights to a pharmaceutical or agricultural chemical product for which a patent application has been made only after the events specified in the provision have occurred. India maintained that there is nothing in the text of Article 70.9 that creates an obligation to make a system for the grant of exclusive marketing rights system generally available in the domestic law before the events listed in Article 70.9 have occurred.

In India’s view, the Panel did not examine the context of Article 70.9 fully. There are many provisions in the TRIPs Agreement -- including Articles 22.2, 25.1, 39.2, 42-48 and 51 -- which explicitly oblige Members to change their domestic law to authorize their domestic authorities to take certain actions before the need to take such actions actually arises. India also notes that a comparison of the terms of Article 70.9 with those of Article 27, according to which “patents shall be available” for inventions, is revealing. According to India, the Panel examines Article 70.9 only in the context of Article 27, and dismisses the relevance of the distinction between “shall be available” and “shall be granted” in the wording of these related provisions because “an exclusive marketing right cannot be ‘granted’ in a specific case unless it is ‘available’ in the first place”\(^{20}\).

India maintained that Article 70.9 is part of the transitional arrangements of the TRIPs Agreement whose very function is to enable developing countries to postpone legislative changes. Patent protection for pharmaceutical and agricultural chemical products is the most sensitive TRIPs issue in many developing countries. To India, the Panel’s interpretation of Article 70.9 has the consequence that the transitional arrangements would allow developing countries to postpone legislative changes in all fields of technology except in the most sensitive ones.

In India’s view, the Panel did not base its interpretation on the terms of Article 70.9, nor did it take into account the context and the transitional object and purpose of this provision; instead, the Panel justified its expansive approach with the need to establish predictable conditions of competition. India contends that this notion turns an obligation to take actions in the future into an obligation to take action immediately. India notes that there are numerous transitional provisions in the Marrakesh Agreement Establishing the World Trade Organization (the “WTO Agreement”)\(^{21}\) that requires action at some point in the future, either when a date has arrived or an event has occurred. These are all obligations that are, just like those under Article 70.8 and 70.9 of the TRIPs Agreement, contingent upon a date or event.

While it would be desirable if all Members were immediately, to enable their executive authorities to take the required actions even before the dates or events requiring those actions have occurred, India asserts that these provisions

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\(^{20}\) Panel Report, para. 7.56 and note 112

\(^{21}\) Done at Marrakesh, Morocco, 15 April 1994.
cannot reasonably be interpreted to imply the obligation to provide for such conditions in the domestic law in advance of that date or event.

India asserted that, under Articles 3, 7 and 11 of the DSU, panels are to make findings and recommendations only on matters submitted to them by the parties to the dispute. India therefore contended that the Panel exceeded its authority under the DSU by ruling on the subsidiary claim by the United States relating to Article 63 after accepting its principal claim under Article 70.8. If the Appellate Body were to conclude that the Panel was entitled to present findings on the United States’ Article 63 claim, India asks whether the Panel was entitled to recommend simultaneously that India bring its mailbox system into conformity with Article 70.8(a) and Article 63 of the TRIPs Agreement.

On the other hand the arguments put forward from the other side were that the United States endorses the legal findings and conclusions of the Panel relating to Articles 70.8, 70.9 and 63 of the TRIPs Agreement. The United States asserts that the Panel correctly analyzed the text and context of Article 70.8, and focused on the failure of the system described by India to achieve the object and purpose of this provision. The United States contends that the concept of the importance of creating the predictability needed to plan future trade was developed in the context of Articles III and XI of the GATT 1947, as the Panel observed. However, it does not follow that the objectives of ensuring minimum standards of treatment and regulating competitive relationships are mutually exclusive. Protecting legitimate expectations of WTO Members regarding conditions of competition is as central to trade relating to intellectual property as it is to trade in goods that do not relate to intellectual property.

According to the United States, under Article 70.8, reasonable assurances of treatment must be provided for mailbox applications. The United States deems that the Panel correctly interpreted Article 70.8 to require a mailbox system under which patent applications have a secure legal status. This interpretation respects the relationship between paragraphs (a), (b) and (c) of Article 70.8, and the purpose of the mailbox system. The United States insists that the administrative system described by India does not provide a sound legal basis for filing mailbox applications. According to the United States, the Panel correctly placed the burden of proof on the United States, consistent with the Appellate Body Report in United States - Measure Affecting Woven Wool Shirts and Blouses from India ("United
States – Shirts and Blouses”)22. The United States argues that nothing in the Panel’s analysis had the effect of shifting the burden of proof from the United States to India, and that the Panel applied the correct standard of proof. In the view of the United States, the Panel did not require India to prove that its administrative instructions to patent offices were immune from challenge, but rather found that India had not rebutted the evidence presented by the United States regarding the likelihood that mailbox applications and patents ultimately based on them would be invalidated by such a challenge.

The United States asserted that the Panel appropriately considered India’s factual arguments regarding the operation of the Act to Amend and Consolidate the Law Relating to Patents (the “Patents Act”), and that India’s arguments represent an attempt to turn a factual question into a legal issue. While the United States acknowledges the propriety of seeking guidance from Members regarding their domestic laws, it argues that giving a Member the benefit of the doubt regarding matters of interpretation of its domestic law is not equivalent to unquestioning acceptance of the Member’s position. In the view of the United States, India’s argument is inconsistent with the requirement in Article 11 of the DSU that a panel make “an objective assessment” of the facts of the case. On this point, the United States recalls that the panel in United States - Restrictions on Imports of Cotton and Man-Made Fiber Underwear stated, “A policy of total deference to the findings of the national authorities could not ensure an “objective assessment” as foreseen by Article 11”23.

The United States contended that the Panel correctly found that India has failed to comply with Article 70.9. According to the United States, the text of Article 70.9 indicates that the obligation to establish exclusive marketing rights became effective upon the entry into force of the WTO Agreement. The ordinary meaning of the term “granted” is to “give (rights, property, etc.) formally; transfer legally”24.

The definition implies that availability and authority are necessary, but not sufficient, conditions for “granting” something. The United States asserts that the Panel correctly stated: “an exclusive marketing right cannot be “granted” in a

22 Adopted 23 May 1997, WT/DS33/AB/R.
specific case unless it is “available” in the first place\textsuperscript{25}. Moreover, the terms used in other Articles of the TRIPs Agreement reflect the context of each Article, and do not support the conclusion that there is no obligation under Article 70.9 to provide a system for granting exclusive marketing rights before a particular case arises.

The United States maintains that the context, object and purpose of Article 70.9 indicate that it imposes a current, not future, obligation. In the view of the United States, the Panel correctly found that the average period of time required to satisfy the conditions set forth in Article 70.9 is not relevant to the analysis. The United States further argues that India’s argument is factually incorrect: the Panel found that at least one United States’ company had satisfied the steps required for the grant of exclusive marketing rights, but had not applied for them in India because it could not obtain information regarding the appropriate procedure for doing so. In addition, the United States presented evidence regarding the likelihood that various products designed to treat serious medical conditions would be ready for introduction to the Indian market in advance of the timeframe described by India.

The United States argues that the consequence of India’s view of Article 70.9 is that a national of another WTO Member would have to apply for exclusive marketing rights that did not exist under Indian law, and only at that time would India be obligated to enact legislation providing such rights.

There would be at least a temporary violation of a Member’s rights because that Member’s national would have to wait for India to enact legislation making these rights available. According to the United States, such a result is inconsistent with the principle of fostering predictable conditions of competition and does not protect the legitimate expectations of Members under Article 70.9. In the view of the United States, the Panel’s finding on Article 70.9 does not imply that all future obligations under the WTO Agreement should be implemented immediately in Members’ domestic law.

Requiring a system for granting exclusive marketing rights protects the core balance of the TRIPs Agreement with respect to pharmaceutical and agricultural chemical product patents. Under the TRIPs Agreement, the quid pro quo for taking advantage of the extended transition period for granting product patents for pharmaceutical and agricultural chemical inventions was the grant of exclusive marketing rights. The United States asks the Appellate Body to affirm the Panel’s

\textsuperscript{25} Panel Report, para. 7.56, note 112.
decision to make findings on the Article 63 issue submitted to it by the United States. In the view of the United States, the Panel correctly addressed both the issue of India’s failure to comply with Article 70.8 and its failure to comply with Article 63. The United States asserts that Articles 3, 7, and 11 of the DSU establish that the Panel acted within its authority in addressing the United States’ claim: the United States submitted this issue to the Panel in both written and oral submissions and India had an abundant opportunity to respond; and the United States’ characterization of its Article 63 claim is not determinative of the Panel’s authority to address it.

The European Communities endorses the Panel’s findings concerning the failure by India to take the action necessary to implement its obligations under Article 70.8 of the TRIPs Agreement and agrees with the Panel’s interpretation of Article 70.9 of the TRIPs Agreement. The European Communities supports the Panel’s finding that India failed to take the action necessary to implement its obligations under Article 70.8 of the TRIPs Agreement. In the view of the European Communities, India’s arguments about the Panel’s interpretation of municipal law are unfounded: there is nothing in the ruling of the Panel which suggests that it did anything other than treat domestic law as a question of fact to be proved by the party asserting a breach of Article 70.8. The European Communities asserts that the Panel’s findings show that the Panel treated the question of municipal law as a matter of evidence. Moreover, India’s submission that the Panel’s interpretation on this point be treated as a question of fact would result in it being excluded from the remit of the Appellate Body. The European Communities maintains that the Panel’s approach in interpreting Article 70.8(a) was consistent with the provisions of Article 31 of the Vienna Convention on the Law of Treaties (“the Vienna Convention”)

Accordingly, in analyzing the meaning to be given to the term “means” in paragraph (a) of Article 70.8, the Panel considered that term in its context and in the light of the object and purpose of Article 70.8. The European Communities asserts that the setting up of such a mailbox mechanism is clearly not an end in itself. The objective of the mechanism cannot simply be to permit the filing of applications: such a mechanism would serve no useful purpose. The

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objective is rather to ensure that the novelty and priority of such applications is preserved and made available as from the date of application of the Agreement for developing countries. With respect to India’s claims that the Panel effectively relieved the United States of the burden of proof of adducing evidence that a breach of Article 70.8 had occurred, the European Communities asserts that the Panel’s reasoning is correct. According to the European Communities, it is clear, from paragraph 7.37 of the Panel’s findings that India was not able to discharge the burden of proof upon it to demonstrate that its system for mailbox applications was not tainted with a degree of legal insecurity.

In the view of the European Communities, this question relates to the Panel’s appreciation of the evidence before it and is therefore not a question of law. In consequence, it falls outside the scope of the remit of the Appellate Body. The European Communities supports the Panel’s interpretation of Article 70.9 of the TRIPs Agreement. The European Communities maintains that Article 70.9 provides for the granting of a residual right (the exclusive marketing right) to applicants as long as the products are not patentable during the transitional period available to developing country Members. For that purpose, applicants must be able to identify the authority to whom they have to address a request for the granting of an exclusive marketing right. They must also be given the opportunity to know what their rights are with regard to other potential applicants who might request exclusive marketing rights for the same product. In the view of the European Communities, India’s proposed reading of Article 70.9 disregards this aspect of the law on intellectual property rights that concerns the relationship between different actual or potential applicants. It is not possible to regulate this relationship by legislative or administrative action only after the relevant events have occurred, since such subsequent action would not be capable of determining the relationship between several actual or potential applicants. The European Communities insists that the protection of the exclusivity of the exclusive marketing right is a necessary component of the mechanism that is required under Article 70.9. The European Communities contends that India’s attempt to deny the need for a mechanism for the grant of exclusive marketing rights cannot be considered as a good faith interpretation of Article 70.9. According to the European Communities, India’s reference to the sensitivity of the question of exclusive rights for the marketing of pharmaceuticals
and agricultural chemical products in developing countries is not relevant. The European Communities contends that the basic rule of international treaty law is “pacta sunt servanda”, that is, that treaties must be observed. Moreover, treaty provisions must be read in context and treaty interpretation must be carried out in good faith. In the view of the European Communities, the TRIPs Agreement contains many provisions concerning the rights of applicants and right holders with regard to third parties; the context of the TRIPs Agreement requires developing country.

Members that invoke the transitional period to allow, in advance, the grant of exclusive marketing rights under Article 70.9 and to provide the relevant mechanism for the grant of such exclusive marketing rights in order to define the position of applicants and right holders with regard to other persons.

According to the European Communities, India’s argument that this reading of Article 70.9 is not consistent with the scope of the issue relating to the patentable subject-matter in particular pharmaceuticals may be specifically mentioned in the relevant sector. It is important that pharmaceutical substance is also defined in Section 2 of the Act, so as to include ‘drug chemical entity’ or drug molecule or bulk drug involving inventive steps.

Similarly inventions, which are not patentable, should also be clearly provided in an exhaustive manner. Exclusion of all life forms should be placed in this category and no patent claim should be entertained thereof. As regards patenting of microorganisms the issue is still being examined by the WTO as stipulated in Article 27(3)(b) of TRIPs, and as such extending patentability to microorganism at this stage should be avoided. The scope of patentability should also define all technical terms so that ambiguities could be avoided to the maximum extent. All these issues should be adequately covered in the Patents (third amendment) Bill 2003. There has been a mixed feeling regarding the issue of stricter Patent Laws and India’s compliance with the TRIPs Agreement not only in India but also on International level. Many professionals, academics and activists in India as well as abroad feel that if WTO goes into full swing at the instance of big powers, it is a matter of serious concern. They feel that its effect may be disastrous because of the huge difference in the economic and Industrial atmosphere of the developed nations and the developing nations. However, it cannot be denied that there has been a considerable development in the last two decades in India and it
cannot remain ignorant and oblivious to its surroundings when countries across the globe are able to exploit India’s rich biodiversity and herbal medicines and continuously apply for Patents in different countries of the world. Developing countries like India will also be able to meet the challenges in the new IPR regime provided they put in place an Intellectual Property Strategy system and their in-house R&D. The formalization of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) at the conclusion of the Uruguay Round of General Agreements on Tariff and Trade (GATT) negotiations was a direct consequence of the efforts that the commercial interest in this frontier technology has made. One of the compelling reasons why it should be implemented in WTO, which monitors the Agreement on TRIPs, has initiated a process through which attempts are being made to bring the objectives and sustainable development on an even keen to protect the interests of under-privileged and deprived sections of the society. So our global endeavor, embracing all humanity is to create a just world system promotive of economic equity and social egalite, reversing the process, which holds the developing nations as mere markets to be exploited. This can happen only if we raise our concerns at appropriate forums with proper evidences and at the same time speed up our march towards cutting edge frontier technologies.

The Appellate body findings were:

India appealed the panel’s decision. As to the question of interpretation, the appellate body (“AB”) determined that TRIPs 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 light of its object and purpose,” based on the directive in GATT acquis and Article 31 of the Vienna Convention. In doing so, the AB utilized a different spectrum for examining the article and reversed the Panel’s standard of context, object, and purpose-based examination of the individual article (i.e., Article 70.8) in question.

Despite using the Vienna Convention’s terms to interpret the text, the AB’s preferred method of interpretation was on the basis of the legitimate expectations of the parties at the time of signing the treaty (and opposed to an objective-based interpretation of the treaty as required in the Vienna Convention).

Had the appellate body followed a more traditional course of interpretation, it would have examined TRIPs in the light of the goals and objectives espoused in Article 7 and the preamble’s deference to developing states on account of prevailing economic conditions. Instead, the appellate body strictly construed Article 70.8 and held that India had an obligation to establish a legally sound mailbox mechanism.\(^29\)

Having determined the requirements under Article 70.8, the AB proceeded to examine whether India’s administrative orders in fact established a legally sound mailbox mechanism. India objected that the AB was unqualified to determine the soundness of a local implementation mechanism on the grounds that Article 1.1 of TRIPs preserved the sovereign right of members to determine the method and mechanism of implementing TRIPs obligations. India’s argument that the DSB cannot interfere with the choice of legal implementation tools chosen by a nation was rejected by the AB,\(^30\) which found that the “administrative instructions” of India contradicted the provisions of the Indian Patents Act 1970, and hence the assigned priority dates were legally untenable. That is, India’s administrative instructions required the Controller to provide priority dates but defer examinations of mailbox applications until patent amendments were executed. But Section 15(2) of the Patents Act 1970 mandated that the examiner refuse applications for non-patentable inventions. The AB felt that examiners would be obligated by the statute to reject all applications for protecting pharmaceutical and agricultural chemical products. The AB was thus not convinced that administrative orders would survive a legal challenge under the Indian Patents statute. The appellate body rejected India’s position that the scheme was legitimate under the jurisprudence developed by the Indian courts.\(^31\) Instead, like the panel, the AB required precedents explicitly showing that a court will uphold the validity of administrative actions where they


\(^{30}\) Patent Protection Appellate Body Report, 66.

\(^{31}\) India offered case laws in support of its assertion. India cited the two Supreme Court cases to confirm the Indian position that its reliance on an administrative practice regarding the handling of pharmaceutical and agricultural chemical product patent applications is not unconstitutional, *see* State of Haryana v. Mahendra Singh and Others, A.I.R. 1988 S.C. 1681. *See also* Union of India v. H.R. Patankar and Ors. A.I.R. 1984 S.C. 1587 (holding that statutory rules cannot be amended by Executive instructions but “if the rules are silent” on any particular point, the Government can fill up the gaps by issuing executive instructions, in conformity with the existing rules). *See generally* INDIA CONST. art. 73 s1.
arguably contradict legislation. Thus, the AB refused to defer to a nation’s interpretation of its own legislation and held that India violated Article 70.8.

Similarly, applying a line of analysis that treated Article 70.9 as operating in tandem with Article 70.8, the AB held that India violated Article 70.9 by not establishing a system for granting EMR after the lapse of the President’s Ordinance. India’s argument that a violation of the Article does not occur until an applicant makes an actual demand on the government of India for a grant of an EMR was rejected. The appellate body report of December 19, 1997, which concluded that India had a legally unsound mailbox mechanism, was adopted by the DSB in January 1998. Following the report, India agreed to act on the recommendations to comply with TRIPs by April 19th, 1999. Consequently, the Indian Parliament passed the Patents (Amendment) Act of 1999.

Consequently, the Patent Act 1970 was amended in 1999 to bring it into line with Articles 70.8 and 70.9 of TRIPs. Section 5(2) of the 1999 act provided for mailbox applications, while a new Chapter IVA introduced EMR. The amendment had retroactive effect from 1st January 1995. All applications filed under Section 5(2) – known as WTO applications or mailbox applications – were not considered for grant until 31st December 2004. However, applicants could seek EMR to sell or distribute the substance covered in the patent application if the criteria specified in Sections 24A and 24B were satisfied. The EMR lasted for five years from the date of grant or until the date of grant or rejection of the patent application, whichever was earlier. The grant of EMR did not guarantee the subsequent grant of a patent, as the application could be rejected at a later stage if the invention failed to meet the criteria for patentability laid down in the act. Thus the new era for granting patent in

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32 “Article 70.9 refers to Article 70.8, and they operate in tandem to provide a package of rights and obligations that apply during the transitional periods contemplated in Article 65. It is obvious, therefore, that both Article 70.8(a) and Article 70.9 are intended to apply as from the date of entry into force of the WTO Agreement.” Patent Protection Appellate Body Report, Appellate Body Report on India’s Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/9 (Jan. 27, 1998).

the field of drugs and medicines through EMR to the present product patent regime was implemented\textsuperscript{35}.

4.3 MAIN PROVISIONS OF INDIAN PATENT AMENDMENT ACT ON PHARMACEUTICAL PRODUCTS AND CHEMICALS

On 26\textsuperscript{th} March, 1999, Patents (Amendment) Act, 1999 came into force retrospective effect from 1\textsuperscript{st} January, 1995. The main provisions were\textsuperscript{36}:

1) Sec 5(2) was introduced which provides for filing of application for patent in the field of drugs medicines and agro-chemicals. These applications were kept pending in the mailbox or black box. This mailbox was to be opened on 1\textsuperscript{st} January 2005.

2) Provision of Exclusive Marketing Rights (EMR) was brought in by way of chapter IV A. Thus Pipeline protection was provided for pharmaceutical and agro-chemical manufacturers whose application for product was lying in the black box.

3) Section 39 was omitted from the Act, thereby enabling the Indian residents to file the applications for in an outside India simultaneously.

4) Chapter II (A) was inserted in the Indian Patent rules dealing with International Applications under PCT.

The second phase of amendment was brought in by the patents amendment act 2002 which came into force on 20\textsuperscript{th} May 2003. The main features with regard to pharmacy patents were:

1) The term of patent was extended to 20 years, wherein the date of patent was the date of filing of complete specification. Also the difference in term of drug and food patent and other patent was removed.

\textsuperscript{35} India’s patent regime was amended 1999 to provide that applications claiming pharmaceutical inventions would be accepted and put away in a mailbox, to be examined in 2005—these applications are commonly referred to as ‘mailbox applications’. This amendment was in pursuance of Article 70.9 of TRIPS and a WTO dispute filed by the United States against India for a failure to comply with this TRIPS provision. See WTO Appellate Body, \textit{India: Patent Protection For Pharmaceutical And Agricultural Chemical Products}, WT/DS50/AB/R (Dec. 19, 1997), <http://docsonline.wto.org/imrd/directdoc.asp?DDFDocuments/t/WT/DS/50ABR.WPF>.

2) The definition of invention was made in conformity with the provisions of TRIPs Agreement by introducing the concept of inventive step, thereby enlarging the scope of invention.

3) Deferred examination system was introduced.

4) Introduction of the provision of publication of application after 18 months from the date of filing thereby bringing India at par with the rest of the world.

5) Microorganisms became patentable, whereas inventions relating to traditional knowledge were included in the list of ”what are not inventions”.

6) The concept of unity of invention in accordance with EPC and PCT.

7) Section 39 was reintroduced thereby prohibiting the Indian residents to apply abroad without prior permission or first filing in India.

8) Provisions of Appellate Board were brought in by inserting section 116. All appeals to the decision of the Controller would be appealable before the Appellate Board. The Head Quarter of the Appellate Board is to be in Chennai.

9) Section 117 provided for Bolar provision for the benefit of agrochemical and pharmaceutical industry.

The third and final amendment to the Patents Act, 1970 came by way of Patents (Amendment) Ordinance, 2004, which was later replaced by The Patent (Amendment) Act, 2005, and Patents (Amendment) Rules, 2006 with retrospective effect from 1st January, 2005. With the third amendment India met with the international obligations under the TRIPs. Significant achievements of this amendment were:

1) Deletion of section 5, opening of mailbox and grant of product patents. Thus this amendment led to the dawn of the “product patent regime” in India.

2) Abolition of Exclusive Marketing Rights (EMR).

4.4 CURRENT POSITION OF INDIAN PATENT LAW ON GRANTING PATENTS IN THE FIELD OF DRUGS AND MEDICINES

The present Indian position in respect of patent law is governed by the provisions of the Patents Act, 1970 as amended by the Patents (Amendment) Act,
2005 (hereinafter referred to as the Act) and Patents Acts Rules, 2006 (hereinafter referred to as the Rules).

The Head Patent Office is located at Kolkata and its branch offices are located at Delhi, Mumbai and Chennai. Patent system in India is administered by the Controller General of Patents, Designs, Trademarks and Geographical Indications. Each office has its own territorial jurisdiction for receiving patent applications and is empowered to deal with all sections of Patent Act.

The jurisdiction for filing the patent application depends upon:

1) Indian applicant(s): determined according to place of residence, place of business of the applicant or where the invention actually originated.

2) Foreign applicant(s): determined by the address for service in India.

3) The Act provides for the definition of the invention, which is now compliant with the provisions of TRIPs. The criteria for patentability of an invention are novelty, inventive step and industrial applicability.

4) Section 2(1)(j) of the Patent Act, 2005, defines the "invention" as a new product or as process involving an inventive step and capable of industrial application.

5) Under the Act "New invention" is defined under section 2(1)(l) of the Patents Act

6) “New invention” means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art.

7) Thus, according to this definition of new invention, Act talks of absolute novelty, i.e. the invention should have neither been used anywhere in the world nor published in any part of the world. However, the later sections of the act for the purpose of anticipation and opposition proceedings deal with the relative novelty i.e. not used in India and not published in any part of the world. Further, entire Act refers to the word invention and not new invention. Therefore, for all purposes relative novelty is the criterion.
8) Exceptions to the Novetly Rule: There are a few exceptions where the rule of novelty is not applicable. These cases are as follows:

a) Subject matter published without the consent of the inventor.

b) The invention was published in consequence of the display in an exhibition notified by the Government or reading the paper before a Learned Society. Grace period of 12 months is given in such cases to file the patent application.

c) Previous communication to Government of India.

d) Public working for reasonable trials.

“Inventive Step” is defined under Section 2 (1) (ja) of the “Act”. Prior to the Amendment of 2005, inventive step meant a feature that makes the invention not obvious to a person skilled in the art. The new Act of 2005 defined inventive step more precisely.

“Inventive step means a feature of an invention that involves technical advance as compare to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.”

Thus, in addition to the non-obviousness criterion two other conditions were added i.e. it should also involve technical advancement as compared to the existing knowledge or having economic significance, or both, in addition to being non-obvious. The terms “technical advance” and “economic significance” have not been defined clearly and are unambiguous. It cannot be left to presumption “economic significance” is synonymous to the phrase “capable of industrial application” in section 2 (1)(ac) or in footnote 5 to Article 27. The meaning of the phrase “technical advance” cannot be presumed either, in absence of a specific definition or reference.

The Patents Act 1970 had a very limited scope of protection wherein the essential elements of invention were new, useful and manner of manufacture. Even though manufacture was not defined in the old Act, the Patent Office established the practice of interpreting manufacture as process resulting in a tangible product. The landmark decision of Calcutta High Court on the process of production of Bursitis virus containing vaccine (Dimminaco AG vs Controller of Patents, 2002) changed the practice and now the definition of invention is interpreted keeping in mind the term ‘industrial application’ as under section 2(1)(j).
The Act defines ‘capable of industrial application’ in relation to an invention as capable of being made or used in an industry.

An invention is capable of industrial application if it satisfies the three conditions cumulatively:

1) can be made;
2) can be used in at least one field of activity;
3) Can be reproduced with the same characteristics as many as necessary.

Section 3 of the Indian Patents Act deals with non-patentable inventions which are as follows:

a. Inventions which are frivolous or contrary to well established natural laws. For example: inventions relating to perpetual motion alleged to be giving output without any input is not patentable as it is contrary to natural law. Merely making in one piece, articles, previously made in two or more pieces is frivolous. Mere usefulness is not sufficient (Indian Vacuum Brake co. Ltd vs. Laurd (AUR 1962 CAK 152)).

b. Inventions whose primary or intended use or commercial exploitation could be contrary to public order or morality (such as something against accepted norms of a culture in a society), or which causes serious prejudice to human, animal or plant life or health or to the environment. For example terminator technology which involves inserting a gene sequence in a seed to stop germination or growing recombinant plants leading to disappearance of butterflies.

c. The mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature. However isolation of living thing or non-living substances is patentable as it involves human technical intervention.

d. 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 mere discovery of any

new property, or new use of a known substance, or mere use of known process, 
machine, or apparatus unless such known process results in a new product or 
employs at least one new reactant.

Explanation to Section 3 (d): “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.It 
may be seen from section 3(d) that new use of a known substance is not 
permissible. It means that claims for second medical use are not allowed in India. 
Further, derivatives of known substances are considered to be the same substance 
unless they “differ significantly in properties with regard to efficacy”.

The term “efficacy” under section 3 (d) has been held vague, as it does not 
indicate the kind of efficacy required under the provision. It is also ambiguous 
because it is unclear whether the phrase “enhancement of known efficacy” is the 
same as the phrase “technical advance” under section 2 (1), (ja).

However, the explanation provided to section 3 (d) does not rule out the 
grant of patent to derivatives, complexes, combinations, isomers and so on, if 
enhancement of its efficacy as a consequence of its properties can be shown38.

e. Substances obtained by mere admixture such as physical admixture are not 
patentable under the Act.

1) However, compositions consisting of combination preparations comprising 
of two or more known active ingredients are patentable if “synergism” or 
super additive effect is shown clearly, for example pharmaceutical 
compositions or any other chemical compositions.

2) The mere arrangement or re-arrangement or duplication of known devices 
each functioning independently of one another in a known way.

Methods of agriculture or horticulture

For example a method of producing a new form of a known plant even if it 
involved a modification of the conditions under which natural phenomena would
pursue their inevitable course is not patentable. (N.V. Philips Gloeiammpenfabrieken’s Application 71 RFC 192).

f. Processes for medical, surgical, curative, prophylactic, diagnostic, therapeutic, or other treatment of human beings or animals or plants that would render them free of disease or to increase their economic value.

g. In United Kingdom, a method for treating an old animal with an enzyme two hours prior to butchering was allowed to be patented as the treatment increased the economic value of the animal by making the meat soft (Swift Application RPC 37, 1962). Such a process would not be patentable under the Indian Patent system.

The words ‘diagnostic and therapeutic’ has to be read as diagnosis of diseases in human beings and animals. Accordingly, method of screening antibodies for a specific activity is permissible.

h. Plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals. For example clones and new variety of plants are not patentable. But process/method of preparing genetically modified organisms is patentable subject matter.

i. Computer program per se, a mathematical method or a business method or algorithms.

j. Literary, dramatic, musical or artistic work or any other aesthetic creations including cinematographic works and television productions are not patentable as they are covered under the copyrights, design and entertainment laws.

k. Scheme/rule/method of performing a mental act or method of playing a game.

l. Presentation of information.

Unfortunately neither the Act nor the Rules defines a mathematical method, or a business method or a computer program per se or algorithm. Under such circumstances, one has to rely on the practices built up under Articles 52(1), 52(2) and 52(3) of the EPC, where similar provisions corresponding to the Indian Act under section 3(k), 3(m), and 3(n) exist.

A program producing technical effect or program having technical character is permissible in EPO as it is not program per se. Accordingly, software related
inventions may be patentable if accompanied by a novel and non-obvious technical effect which adds to the art of technology.

m. Topography of integrated circuits.

n. An invention falling within the scope of traditional knowledge such as the use of herbal medicines.

Inventions relating to atomic energy are not patentable under section 4. Such applications are referred to the Department of Atomic Energy. The decision of the Department of Atomic Energy is final and no appeal lies to the decisions of the Department of Atomic Energy.

With the amendments effected patents are now granted for inventions relating to both product and process. The invention must relate to a machine, article or substance capable of industrial application, or the process of manufacture of an article. A patent may also be obtained for an improvement of an article or of a process of manufacture. Further, with regard to medicine or drug patent is now granted for the product and process of manufacturing the substance.

1) Procedural Aspect

An application for a patent for an invention can be made by any of the following persons either alone or jointly with another:

i. true and first inventor

ii. his /her legal assignee

iii. legal representative of deceased inventor or assignee

Foreign Filing License:

No person resident in India shall, except under the authority of the written permit can file any application outside India for the grant of a patent unless:

i. An application for a patent for the same invention has been made in India not less than 6 weeks before the application is filed outside India, and

ii. Either no secrecy direction has been given under Section 35(1) in relation to the application in India or all such directions have been revoked.

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A request for foreign filing license may be filed on prescribed form with
detailed description of the invention and the drawings, if any, and the prescribed fee.

Publication:

Every application is ordinarily published after the expiry of 18 months
period from the date of filing of the application or the date of priority of the
application whichever is earlier.

The applicant can request publication of his application prior to the normal
period under a request through a prescribed form and fee.

The early publication rule however does not apply if:

i. Secrecy directions are imposed under Section 35 of the Act.
ii. Application has been abandoned under Section 9(1) of the Act.
iii. The applicant has withdrawn his application three months prior to the expiry of
    said prescribed period of 18 months.

Early publication can result in acceleration of substantive examination of
application and in early grant. Also, early publication is important for obtaining
provisional protection in cases where the applicant anticipates infringement.

Provisional Protection:

On and from the date of the publication of the application for patent and
until the date of grant of patent in respect of such patent, the applicant will have like
privileges and rights as if the patent for the invention have been granted on date of
publication of application. However, the applicant cannot institute the infringement
proceedings unless the patent is granted. This provision is advantageous to the
applicant for the purpose of claiming damages from the date of advertisement.

Applications for patent under section 5(2) relating to pharmaceuticals and
agrochemicals are exceptions to this system and will have protection from the date
of grant of patent and not from the date of publication of the invention. Further, the
Indian manufacturers who have made significant investment and were producing
and marketing the product in respect of the application filed under section 5 (2)
prior to January 1, 2005 will continue to manufacture the product, even after the
grant of patent on said application (pharmaceuticals and agrochemicals) and no
infringement proceedings will be instituted against the manufacturer. The patent holder will be entitled to receive reasonable royalty from the manufacturer.

2) Request for Examination

The request for substantive examination by applicant or any other interested person has to be filed on prescribed form, with the prescribed fee, after the publication of patent application, but within 48 months from the priority date of the application or from the date of filing the application whichever is earlier.

The applications shall be examined only on filing the request for substantive examination. Thus the applicant can defer the examination of the application by at least 48 months from the date of priority. If the request is not filed the application shall be deemed to have been withdrawn by the applicant.

3) Patent Procedure

On receiving a request for examination, the Controller refers the application and specification and other documents to the Examiner, ordinarily within 1 month from the date of its publication or 1 month from the date of request for examination whichever is later. The examiner submits the report to the Controller ordinarily within one month but not exceeding 3 months from the date of reference of the application by the Controller.

The Controller would then dispose off the report ordinarily within one month from the date of receipt of such report and issue the first examination report. The first examination report is issued ordinarily within 6 months from the date of the request for the examination or 6 months from the date of publication whichever is later. Time for putting the application in order for grant under section 21 is twelve months from the date of receipt of first examination report. No extension of time is permissible. Therefore, it is necessary to comply with all the requirements and objections rose by the patent office within twelve months from the date of first examination report.

Once all the requirements are met with and the examiner is satisfied with the arguments and amendments of the applicant, the application proceeds for grant. The grant is notified in the Patent Journal, published weekly by the Indian patent office. The post grant opposition proceedings may follow within one year from the date of said notification.
4) Opposition Proceedings\(^{40}\)

The Indian Patent system provides for two opposition proceedings, one before the grant of the patent and one after the grant of the patent.

The grounds for Pre and Post Grant Opposition are the same namely:

i. wrongful obtaining,

ii. prior publication,

iii. prior claiming,

iv. prior public knowledge and use,

v. obviousness,

vi. not an invention,

vii. insufficiency,

viii. failure to file the information regarding foreign filing under Section 8

ix. convention application not made within 12 months,

x. not disclosing or wrongly mentioning the source and geographical origin of biological material in the complete specification,

xi. Complete specification was anticipated having regard to the knowledge, oral or otherwise available within any local or indigenous community in India or elsewhere (traditional knowledge).

5) Pre-grant Opposition Procedure

The pre-grant representation may be filed by any person within six months of date of publication of the application or before the grant of the patent whichever is later. It may be noted that the Controller is empowered to grant the patent soon after six months from date of publication.

The pre-grant opposition proceeding may be carried out in parallel with the Examination proceeding. The opponent is required to submit statement and evidence, if any, in support of the representation and request for a hearing if he so desires. However, the representation is not considered by the Controller unless a request for examination is filed by the applicant.

\(^{40}\) Anand and Anand, Article by Jaya Bhatnagar and Vidisha Garg, India: Patent Law in India, 13 December 2007, Available at www.mondaq.com
On receipt of the request for examination from the applicant, the Controller initiates Examination proceeding and also issues a notice to the applicant along with the copy of the statement and evidence filed by the opponent.

The applicant may file his statement and evidence in support of his application within three months from the date of the notice. Thereafter, after the Controller has considered the submission and the representations made, the patent is either granted or rejected. The acceptance may be with or without amendment to the specification. The decision is issued ordinarily within one month from the date of the completion of the proceedings. It may be noted that no fee is required to be paid for entering into pre-grant opposition. An appeal can be filed in the appellate board against such decision.

6) Post-grant Opposition Procedure

The process of post grant opposition initiates with a notice of opposition filed by the opponent (who is an ‘interested person’) within 1 year from the date of publication of grant along with full written statement and evidence to the Controller. The patentee is required to file a reply statement and evidence within two months failing which, the application will be abandoned. This time period is extendible by one month provided the request for extension is filed within the two-month period. Reply evidence filed by opponents is to be strictly confined to patentee’s evidence. Further evidence may however be filed with the leave of the Controller.

All the documents are handed over to the Opposition Board constituted by the Controller for recommendation. Controller takes decision after a hearing along with the members of the Opposition Board. An appeal may be made against the decision before the Appellate Board within three month from date of the order.

7) Term of Patent

The term of every patent granted under the Act is twenty years from the date of filing. The patents in force on 20th May 2003 stood extended for the term of 20 years. The term of patent in case of International applications filed under the PCT, designating India, is twenty years from the international filing date accorded under the PCT. Renewal fee is required to be paid annually to keep the patent in force. Restoration of patents is possible if applied within 18 months from the date of lapse.
8) Appeal Procedure

Section 117A provides for appeals to the Appellate Board. Sub-section (1) of section 117A makes it clear that no appeal will lie from any orders apart from those mentioned under sub-section (2) of section 117A.

While there is a provision for appeal from the order in a post-grant opposition under section 25 (4), there is no provision for appeal under section 25(1). The Controller can, under the Rule 55, sub-rules (5) and (6) of the Patents Rules, as they stand presently, refuse to grant the patent or require amendment of the complete specification.

In a significant development, the Intellectual Property Appellate Board (IPAB) has come into force with effect from April 2, 2007. All appeals relating to patent cases pending at the High Courts have been transferred to the Appellate Board except the infringement suits and counter suits for revocation. The appellate board comprises a bench of three members including a technical expert.

9) Patent Rights

The Act provides for patent protection for inventions relating to both processes and products. In case of patents relating to product, the grant provides exclusive right to prevent unauthorized persons from making, using, offering for sale, selling or importing the product in India.

In case of patents relating to process, the patentee receives an exclusive right to prevent unauthorized persons from using the process and offering for sale, selling or importing for those purposes the product obtained directly from the process in India. Product produced by the process is also protected.

10) Registration of Assignment

Registration of assignment etc. is compulsory under the Act, though no time limit has been specified for registration of assignment. However, the registration dates back to the date of execution of the instrument. Unless licensee or assignee is entered in the register of patents they cannot file a suit for infringement. The license Agreement has to be registered under section 69 of the Patents Act at the appropriate Patent Office by filing prescribed form with the prescribed fee. After it is registered, the licensee name is entered in the Register of Patents.
11) Commercial Working of Patents

Section 146(2) provides every patentee and licensee to furnish to the Controller periodical statement of the extent to which the patented invention has been worked on commercial basis in India. Such statements should be furnished in the manner prescribed under Rule 131. Therefore, filing a statement regarding the working of patented invention on a commercial scale in India is a mandatory requirement. Failure or refusal by the patentee or licensee calls for penalty provisions. Further, submission of false information is punishable by imprisonment up to six months or fine or both. Most important is that failure to work the invention in India is attracted under section 84(c) for the grant of compulsory license.

Importation of the patented article/product does not amount to working of the Patent in India. Any working of the patent for the production of the patented article or the use of the patent process in the production of any articles for sale to the public would appear to amount to working on a commercial scale. The working on a commercial scale is that the demand for the particular article in India is met at a reasonable price.

If the patentee has granted license to company ‘A’ in Japan to manufacture the patented product in Japan and export and sell them to India, it does not amount to working the patented product in India. Company ‘A’ is therefore not required to submit information on prescribed form. Accordingly, the patentee has to submit the information. If the patentee provides technical assistance for manufacturing the patented product in India to an Indian based affiliate duly licensed to manufacture the patented product in India, the Indian based affiliate can file Form 27. If the patentee submits the form 27 without mentioning that a license has been issued to the Indian based affiliate, then the patentee is attracted by penalty provisions under section 122(2) of The Patents Act, as the information furnished in Form 27 is knowingly false. The co-owners can submit form either jointly or separately.

Thus either the patentee or the licensee may submit information of commercial working of the patent. If there is no licensee in India, the patentee will be punished if he fails to submit the information or furnishes false information. In case there is a licensee in India and he is authorized by the patentee to furnish the information to the patent office and if he fails to furnish such information or submits false information, he is liable to be punished under section 122(2).
All or part of the information submitted in a statement of working may be published by the Controller. A statement of working would remain confidential till such time and if at all it is published by the Controller.

12) Compulsory License\(^4\)

Sections 84 to 94 of the Patents Act relate to compulsory licensing of patented products. A person may apply for a compulsory license three years after the grant of a patent on the following grounds:

a) The reasonable requirements of the public have not been satisfied, or

b) Patented invention is not available at a reasonable affordable price or

c) The patented invention is not worked in India.

Compulsory license may also be granted on notification by Central Government on exceptional circumstances related to public interest namely national emergency, extreme urgency example scarcity of petroleum products, earthquake etc, and public non-commercial use the Controller will notify and grant licenses without any consideration as in other cases in respect of patents on such terms and conditions that the article is available to the public at lowest price.

The Compulsory license provisions is aimed at curbing the practice of meeting the demand for patented articles solely by importation from abroad thereby discouraging

i. transfer of technology,

ii. development in existing trade and industry,

iii. non-establishment of new trade and industry,

iv. refusal to grant licenses to work the patent locally,

v. imposing unreasonable terms on licenses thereby discouraging voluntary licensing and imposing restrictive conditions on the use,

vi. Sale or lease of the patented articles thereby prolonging the patent monopoly rights even after the patent has expired.

vii. Revocation of the patent for non-working has been adopted in almost all countries.

In considering the application for the grant of compulsory license, the Controller shall take into account the nature of the invention; the time which has elapsed since the sealing of the patent; the measures already taken by the patentee or any licensee to make full use of the invention; the ability of the applicant to work the invention to the public advantage; capacity of the applicant to undertake the risk in providing the capital and working the invention; whether the applicant has made efforts to obtain a license from a patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period (6 months) as the Controller may deem fit.

Where the Controller is satisfied that a prima facie case has been made, the Controller will direct the applicant to serve copies of the application on patentee and any other person appearing in the Register of Patents and upon hearing the parties may give his decision. An appeal lies to the appellate board. The Controller can terminate the compulsory license when circumstances that gave rise to the grant no longer exist.

Further, in determining royalty Controller shall keep in mind the nature of the invention; the expenditure incurred in making and developing the invention; expenditure in obtaining patent and its maintenance; patented invention is worked and the licensee gets reasonable profit; patented article is available to public at reasonably affordable price; license granted is non-exclusive; the right of the licensee is non assignable; that the license is for a balance period of the term of the patent or shorter term;

13) **Bolar Provision**

Section 107 A (a) of the Patents Act provides that any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information for regulatory approval will not amount to infringement. This provision is helpful for persons who wish to exploit the patent after the expiry of the terms of the Patent as they can obtain the marketing approval before the term of patent expires and can immediately manufacture after the expiry of the term of Patent.

14) **Parallel Importation**

Section 107 A (b) provides for Parallel Importation of patented products. The provision declares that importation of patented products, by any person from a
person who is duly authorized under the law to produce and sell or distribute the product, would not be considered as infringement.

The phrase “duly authorized under the law” was inserted in place of “duly authorized by the patentee” by the Patent (Amendment) Act, 2005. Effectively, this provision refers to and relies on the applicable local laws of the country exporting the goods to India. The provision allows export from a country where there is no protection of the article patented in India. Parallel Importation provision has been introduced as a mechanism to help in price control through the act of competition. The Principle of exhaustion of right is also applicable in this provision.

15) Cross Border Licensing

Grant of Compulsory License to manufacture and export patented pharmaceutical products to any country having insufficient or no manufacturing capacity by an Indian manufacturer is possible either through the importing country granting compulsory license to the Indian manufacturer or through allowance of importation of the patented pharmaceutical products from India by notification. This provision is based on Para 6 of DOHA Declaration on TRIPs Agreement.

Around 9,000 mailbox applications were filed in India. Of these, 973 concerned agrochemicals and the remainder drugs and pharmaceuticals. A majority of 7,520 applications were filed by multinational corporations, while Indian drug companies filed 1,406 applications. Fourteen applications requesting the grant of EMR were filed between 1995 and 2005, four of which were successful (Novartis for Glivec, Eli Lilly and Company for Cialis, Wockhardt for Nadifloxacin and United Phosphorus for the fungicide Saaf).

On 1st January 2005 Parliament passed the Patent (Amendment) Act, which repealed Chapter IVA. Under Section 78 of the amendment act, all pending applications for EMR made under Chapter IVA were to be treated as claims for patent under Section 5(2) of the 1999 act and were to be deemed requests for examination for the grant of patents under Section 11(B)(3) of the amendment act.

The new patent regime generated lively debate upon implementation. Following its repeal Chapter IV A was almost forgotten; but interest in this provision has since been revived by the recent Supreme Court decision in \textit{Glaxo Smith Kline LC and others v Controller of Patents and Designs and others}. This
case clarifies the effect of the repeal of the EMR provisions on the litigation of pending and decided applications for the grant of EMR.

In early 2005 the Indian Parliament passed the latest amendments to the India Patents Act 1970. It was the third amendment to the Patents Act aimed at conforming India’s patent laws to the requirements set forth by the World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). TRIPs set down minimum standards for many forms of intellectual property protection that its member countries must provide. Notably the new amendments allow for product patent protection for pharmaceuticals. The Supreme Court ruling in GSK\(^{42}\) where (GSK) filed two mailbox applications under Section 5(2) of the Patent Act 1970 on 28\(^{th}\) August 1998 based on this application, GSK filed an application for the grant of EMR for its anti-diabetes drug Rosiglitazone on 30\(^{th}\) June 2000. The examiner issued an examination report as regards the EMR claim on 28\(^{th}\) July 2000. In May and June 2002 the Patent Controller refused GSK’s applications for EMR.

Dissatisfied with this decision, GSK filed two writ petitions (WP No 20469 (W) and WP No 20407 (W) of 2004) with the Calcutta High Court. In an order dated 16\(^{th}\) December 2004, the High Court set aside the rejection by the Patent Controller (order dated 3\(^{rd}\) May 2002) and directed the Patent Controller to consider the application for EMR afresh, keeping all points open. On 28\(^{th}\) December 2004 the Patent Controller rejected the EMR application for a second time. On 9\(^{th}\) June 2005 GSK filed another writ petition before the Calcutta High Court challenging this second rejection. By this time the Patents (Amendment) Act 2005 had come into force and the provisions relating to EMR applications had been repealed. In an order dated 10\(^{th}\) February 2006, the High Court ruled in favour of GSK.

The Patent Controller and Union of India each appealed the ruling. Two other appeals were filed by a third party to the proceedings that wanted to be added as party-respondent in the writ application. The appellants’ preliminary objection concerned the maintainability of the writ petition under circumstances where the legislative amendments had come into operation from 1\(^{st}\) January 2005. According to the appellants, there was no scope for any further consideration on the question.

\(^{42}\) Article by Nupur Maithani and Priyanka Vyas, India: Exclusive Marketing Rights Revisited In India,04 March 2009 Originally published in IP in The Life Sciences Industries 2009.
of EMR, as Chapter IVA of the act had been repealed with effect from 1st January 2005, and Section 78 of the amendment act made clear that all pending applications for EMR filed under Chapter IVA were to be treated as requests for examination under Section 11(B) 3 of the amendment act. In their rejoinder, the appellants stated: “It was not possible to give any retrospective effect as well as any prospective effect in absence of the provisions of EMR.”

The appellants thus took the position that after 1st January 2005, there was no scope to consider pending applications for EMR and further there was no scope to revive for further consideration any such EMR applications which had already been decided. On the other hand, the writ petitioners argued that on 1st January 2005 there was “no pending application” made by them for the grant of EMR. Section 78 of the amendment act applied only to “pending applications” and not to EMR applications that had been rejected. Therefore, Section 78 did not apply to the facts of the case. The application for EMR had been disposed of at a point in time when the amendments had not yet come into force, as a result of which there was a vested right to challenge the order before an appropriate forum in accordance with the law.

The Division Bench of the High Court, headed by Justice H K Seema, accepted the preliminary objection regarding the maintainability of the writ petition, thus allowing the appeal. The Division Bench was of the opinion that EMR were granted for a temporary period as there was a “prohibition created by law”, and EMR could not be granted afresh since the “embargo” had been lifted. The merits of the third parties’ appeal were not considered.

GSK challenged this ruling before the Supreme Court. It contended that a crystallized right had accrued because of Sections 24A and 24B, and that the original orders dated 3rd May 2002 and 16th December 2004 were under challenge. GSK further referred to Section 24(B) 1 to show that the right had accrued. Counsel for the Patent Controller submitted that the intention of the statute appeared to be to the contrary, and that the transitional provision clearly applied even if the impugned application were treated as pending under Section 11B(3) of the amendment act. Counsel for GSK relied on Section 6 of the General Clauses Act 1897, which discusses the effect of repeal as follows:
Where this Act, or any Central Act or Regulation made after the commencement of this Act, repeals any enactment hitherto made or hereafter to be made, then unless a different intention appears, the repeal shall not

a. Revive anything not in force or existing at the time at which the repeal takes effect; or

b. Affect the previous operation of any enactment so repealed or anything duly done or suffered there under; or

c. Affect any right, privilege, obligation or liability acquired, accrued or incurred under any enactment so repealed; or

d. Affect any penalty, forfeiture or punishment incurred in respect of any offence committed against any enactment so repealed; or

e. Affect any investigation, legal proceedings or remedy in respect of any such right, privilege, obligation, liability, penalty, forfeiture or punishment as aforesaid;

And any such investigation, legal proceeding or remedy may be instituted, continued or enforced, and any such penalty, forfeiture or punishment may be imposed as if repealing act of Regulation had not been passed.

One of the important decisions cited in this case was M/s Hoosain Kasam Dada (India) Ltd v The State of Madhya Pradesh and Ors (AIR 1953 SC 221), where it was held that if a pre-existing right of appeal continues to exist, then by implication the old law which created the right of appeal also exists to support the continuation of that right, and hence the old right must govern the exercise and enforcement of that right. In the absence of a stated intention to the contrary in repealing the enactment, the rights under the old statute are not destroyed.

A second judgment of relevance was M/s Gurcharan Singh Baldev Singh v Yashwant Singh and Ors (1992 (1) SCC 428), where it was observed that the right to proper consideration of an application by a statutory authority remains alive even after repeal of the enactment under which the consideration was sought.

Based on these facts, the Supreme Court held that the High Court ruling disregarding the application of Section 78 of the amendment act to proceedings which had been concluded before the appointed day appeared to be correct. Since Chapter IVA was merely repealed, the situation was to be dealt with under the
provisions of Section 6 of the General Clauses Act, which specifically states that repeal affects no right, privilege, obligation or liability acquired, accrued or incurred under any enactment so repealed. The provisions of Section 78 were conditional and did not apply to cases where the application for EMR had already been rejected. Thus, the order of the Division Bench could not be sustained. The appeal was allowed with no order as to costs.

It will take years to truly evaluate the full impact of India’s new patent regime on the pharmaceutical industry. It is clear that it will change, and has already changed, the businesses of the indigenous generic pharmaceutical industry. With regards to foreign investment in pharmaceutical research and development, however, it is less clear whether the recent growth can be primarily attributed to the new patent regime, or whether it is more the result of India’s low-cost, highly skilled scientific human resources.

Under the former Patent Act, patents were not available for pharmaceutical products. Only processes to create these substances were protected, and even then for a limited period of time relative to other inventions. In accordance with its TRIPs obligations, one of the most important changes India had to make to its patent laws was making patents available for pharmaceutical products. During the 10-year transition period provided by the WTO for India to become TRIPs-compliant (1995 to 1st January 2005), India provided for so-called 'mailbox applications', which provided a way for patent applicants to file their applications immediately and receive a filing date. Such applications would be examined once the 10-year transition period expired or whenever the Patent Office could get to them in due course.

The Dunkel Draft - the foundation of the World Trade Organization (WTO) proposed that countries which did not offer product patents for pharmaceuticals and agricultural chemicals as of 1st January 1995 should provide a pipeline system for accepting product patent applications (the “mailbox provision”) and grant exclusive marketing rights (EMR) on certain mailbox applications. Article 65.4 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) provides that developing countries which did not grant patents for pharmaceuticals and agrochemicals would be required to introduce a product patent regime within

43 India became a member of the WTO on 1 Jan 95; only pharma products invented after this date are patentable.
10 years. In the interim, these countries were expected to provide pipeline protection to product patents, allowing product patent applications to be filed during the transition period and granting EMR as proposed in the Dunkel Draft.

During the debate, Parliamentarians voiced their concern on the impact of a product patent regime on the prices of drugs. They identified “ever greening” of patents – where an innovator company that has obtained a patent on a new chemical entity seeks to enlarge its monopoly by seeking and obtaining patents on new forms or by claiming new uses for that entity – as a problem that would result because of the product patent protection for pharmaceuticals. Parliament, therefore amended, the patent law to attempt to prevent ever greening. At the same time, the Government assured Parliament that it refer two contentious issues restricting patenting of pharmaceutical substances to only new chemical entities and patenting of microorganisms – to a Technical Expert Group to be appointed by the Government.

The patent law contains several substantive safeguards to check ever greening of patents. Section 3 of the Indian Patents Act, 1970, enumerates lists out what are not considered “inventions” and therefore cannot be granted a patent. Firstly, section 3(d), even before the 2005 amendment, excluded mere discovery of new properties or new uses of known substances from patentability. Thus, second medical uses of

46 The government constituted a technical committee, with Dr Mashelkar, a reputed scientist, as Chairman to determine whether restricting the grant of patents for pharmaceutical substance to only new chemical entities (NCEs) would be in compliance with TRIPS. See Dr. R. A. Mashelkar et al., Report of The Technical Expert Group on Patent Issues (2007) http://ipindia.nic.in/ipr/patent/mashelkar_committee_report.doc. The Mashelkar Committee Report was however withdrawn due to certain technical inaccuracies in the report namely the fact that certain sections of the report had been reproduced from a paper prepared by Basheer Shamnad, without proper acknowledgement of the same. See generally Pallava Bagla, ‘Plagiarism’ in his panel’s report, Mashelkar tells Govt. to withdraw it, Indian Express, Feb 22, 2007 available at http://www.indianexpress.com/story/23941.html. Accordingly, a Technical Expert Group, chaired by Dr. Mashelkar, was set up by the Government in April 2005. After a series of hearings, the Technical Expert Group submitted its report to the Government in December 2006 recommending that it would not be TRIPS compliant to restrict patenting of pharmaceutical substances to new chemical entities. The Report was criticized for various reasons, including a lack of legal reasoning. Following a revelation of plagiarism of the Report’s key findings from the submissions of a foreign multinational pharmaceutical-industry funded group, the Report was withdrawn. A revised Report reiterating the same conclusions was submitted to the Government in March 2009.

47 Section 3(d) of the Patents Act, 1970, as it now stands, reads as follows: “The following are not inventions within the meaning of this Act,—.(d) 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. Explanation: 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 substances, unless they differ significantly in properties with regard to efficacy.” (emphasis supplied).
known substances cannot be patented in India. Secondly, section 3(d), as amended in 2005, states that discoveries of new forms of known substances are not inventions, unless there is a significant enhancement in the known efficacy of the known substance. To this extent, section 3(d) draws a distinction between “evergreening” and incremental innovation.\textsuperscript{48} By making derivates with added efficacy patentable, section 3(d) encourages sequential developments of existing products or technologies that help bring in improved products to the market, capable of addressing unmet public health needs. For example, if a patent applicant wishes to patent a polymorph of a known salt (A), the patent applicant must show that the particular polymorph is significantly more efficacious than the known efficacy of the known salt (A). The explanation to section 3(d) clarifies that salts, esters, ethers, polymorphs, combinations, etc are deemed to be new forms of known substances.

Thirdly, section 3(e) of the Patents Act, 1970 disallows patenting of admixtures, which result merely in the aggregation of the properties of the components\textsuperscript{49}.

Interestingly, India also amended the definition of inventive step to make it more stringent. Section 2(1)(ja) of the Patents Act, 1970 requires a patent applicant to show that the invention constitutes technical advance or economic significance or both \textit{and} it is not obvious to a person skilled in the art\textsuperscript{50}.

The law also contains procedural safeguards to prevent frivolous patenting. The Patents Act, 1970 allows any person to file a pre-grant opposition before a patent is granted\textsuperscript{51}. There is also several provisions to challenge patents that have been granted. Firstly, a post-grant opposition can be filed within one year of the publication of grant of a patent\textsuperscript{52}. Secondly, a revocation proceeding can be initiated at any time after the grant of a patent\textsuperscript{53}.

\textsuperscript{48} Classifying all ‘incremental innovations’ as tantamount to ‘evergreening’ is misguided. See Shamnad Basheer \textit{Limiting the Scope of Pharmaceutical Patents and Micro-organisms: A TRIPS compatibility Review}, (Intellectual Property Institute, London, 2005.)

\textsuperscript{49} Section 3(e) of the Patents Act, 1970 reads as follows: “The following are not inventions within the meaning of this Act,—…(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance.” (Emphasis supplied).

\textsuperscript{50} Section 2(1)(ja) of the Patents Act, 1970 reads as follows: “2(1) In this Act, unless the context otherwise requires—...(ja)”inventive step” means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art” (emphasis supplied).

\textsuperscript{51} Section 25(1) of the Patents Act, 1970.

\textsuperscript{52} Section 25(2) of the Patents Act, 1970.

\textsuperscript{53} Section 64 of the Patents Act, 1970.
Thus, the Indian patent law has certain provisions that can prevent frivolous patents from being granted. It remains to be seen whether the Indian Patent Office applies the patentability standards in a strict manner to ensure that the public health interest is safeguarded. However, the spate of patents granted to pharmaceuticals in India raises questions as to how public health is being implemented.

With the advent of product patent regime, effective from January 1, 2005, India witnessed a surge of patent applications, in particular chemical and pharmaceutical patent applications. The future will be extremely promising with many more milestones to be conquered in the journey of the Indian pharmaceutical industry.

Currently, in India filing patent applications is on a rise. The number of drug applications filed between 2001 and 2004 was 2,728 and between 2004 and 2010 that number was 21,300. The patent amendment has acted as a major catalyst in this sharp growth and thus product patent regime, in consonance with international laws, has significantly impacted the Indian Pharmaceutical Machinery industry.

Despite the substantial changes incorporated in the Patent law, India’s patent system still differs in various aspects vis-a-vis other member countries. Given the fact that limited case laws are available in the field of patent, therefore, understanding of various aspects is essential for the applicant to avoid the various pitfalls associated with patent filing and prosecution in India. An overview into these areas will assist the applicant in formulating a robust strategy for smooth and economic pharmaceutical patent allowance in India. Pharmaceutical inventions are not resonant with the triple criteria of novelty, inventiveness and applicability alone. Some unique requirements exist in India.

4.5 UNIQUE REQUIREMENTS OF THE INDIAN PATENT SYSTEM

Indian Patent laws are in the process of evolution. On one hand the system complies with international obligations, yet it has some unique features for safeguarding national interests\(^5\). Till the time there is more clarity, the applicant has to be judicious in filing pharmaceutical patent application in India. While filing pharmaceutical patents, some unique requirements may be considered to secure the allowance of patent in India.

\(^5\)www./emr23/html/Pharmaceutical%20patents%20the%20curious%20case%20in%20India%20%20Info media%20Yellow%20Pages%20Blog.htm
Currently, six sections of the Indian Patent Act are to be borne in mind before preparing and prosecuting pharmaceutical applications in India, i.e., Section 3 (b), 3(c), 3(d), 3(e), 3(i) and 3 (j). Section 3(a):

Inventions which are frivolous or which claims anything obvious contrary to well established natural laws are considered as a ground for rejecting the patent. e.g. a drug capable of transforming a new born baby into adult within six months shall be considered frivolous, hence not patentable under Section 3(a) of the Indian Patent Act.

Section 3(b): An invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment.

Recently, this provision has been held against patent of Swiss drug maker Novartis for cancer drug Glivec by Intellectual Property Appellate Board (IPAB)\(^5\), citing that the price quoted for the drug creates public disorder among other things, since Glivec costs ₹ 1.2 lakh per month, against the generic versions that cost ₹ 11,000. The pertinent part of the order reads as below:

“We are fully conscious of the Appellant’s benevolent GIPAP program for free distribution of GLEEVEC to certain cancer patients. But as per information furnished in its written counter-argument by R 3 that when the Appellant was holding the right as EMR on GLEEVEC it used to charge ₹ 1, 20,000 per month for a required dose of the drug from a cancer patient, not disputed by the Appellant, which in our view is too unaffordable to the poor cancer patients in India. Thus, we also observe that a grant of product patent on this application can create havoc to the lives of poor people and their families affected with the cancer for which this drug is effective. This will have disastrous effect on the society as well. Considering all the circumstances of the appeals before us, we observe that the Appellant’s alleged invention will not be worthy of a reward of any product patent on the basis of its impugned application for not only for not satisfying the requirement of section 3(d) of the Act, but also for its possible disastrous consequences on such grant as stated above, which also is being attracted by the provisions of section 3(b) of the Act which prohibits grant of patent on inventions, exploitation of which could create public disorder among other things”.

\(^5\) See <http://www.ipab.tn.nic.in/> for more details on the IPAB.
This decision has been challenged by Novartis AG before the Supreme Court of India\(^56\). The patent rejection of Novartis key cancer drug, Glivec, under Section 3(b) of the Indian Patent Act was attributed its high price and was judged to be against ‘public order.’ However, on the other hand, Novartis has held that that Section 3(b) is not applicable to Glivec, citing that in no other country, price is bar for acknowledging the patentability of the invention. Novartis has argued that pricing of the drug must be independent of patentability criteria.

In another matter, Roche vs. Cipla, for product Erlotinib – Tarceva, the Delhi High Court denied injunction to Patentee. The Court order reasoned that between the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for the people to a life saving drug, the balance has to be tilted in favor of the latter.

India being a developing nation, affordable drug availability to public is of prime importance. Therefore, in order to avoid rejection under Section 3(b), affordability of the drug by differential pricing option must be considered, although said section does not seem to have been interpreted in consonance with the essence of this Section.

Section 3(c) A Mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature. This section is of relevance for drug patents, including genetically engineered pharmaceutical product. The wording of the claims must indicate the substantial human intervention involved, so as to come out of the realm of discovery. Section 3(d) 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.

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.

Section 3(d) has been drafted keeping in view the public health safeguard. This Section aims to block ‘ever greening’ of patent by acting a check valve against additional patents on insignificant improvements, thus paving way for introduction of generics on expiry of the original patent. In January 2006, the Patent Controller in Chennai refused to grant Novartis a patent, in view of being obvious, and being not patentable under section 3(d). Thereafter, Section 3(d) has drawn considerable attention of intellectual property attorneys, policy makers, academicians, pharmaceutical firms, non- governmental organizations and has been in limelight ever since 2005. In short, patentability criteria have not been defined under TRIPs; a deeming provision such as section 3(d) can be made and sustained, provided it is not entirely arbitrary. This section aims to weed out frivolous patents by creating a credible “efficacy” barrier. It is very difficult to see how a WTO panel might strike this down as being in contravention of TRIPS. Of course, if the term “efficacy” is construed in so narrow a manner that the Indian patent regime effectively protects only New Chemical Entities, this may tantamount to a TRIPS violation\(^\text{57}\).

4.6 ISSUES OVER INDIAN POSITION ON DRUG PATENT

There is an issue over the Indian position for the grant of Patent specifically granted under Sec 3(d)\(^\text{58}\), as very few numbers of cases were reported in respect of the grant of patent on drugs. Of which very important one regarding the non-patentable subject matter and the Indian position in granting pharmaceutical patent was Novartis AG v. Union of India\(^\text{59}\).

The facts of the case itself will explain the procedure for availing drug patent in India and the link between pricing and public interest. In this case the Novartis, a Switzerland based pharmaceutical company engaged in manufacturing anti-cancer drug- Glivec (known as Gleevec in USA) and got it patented in many countries from 1994. It started selling Glivec in India in the year 2002 after obtaining marketing approval, though it filed patent application in the year 2002 after obtaining marketing approval, though it filed patent application in the year 1998 before the Chennai (madras) patent office\(^\text{60}\).

\(^{58}\) (2007) 4 MLJ 1153.
\(^{60}\) Application No. 1602/MAS/1998.
After hearing the oppositions from many domestic industries like Ranbaxy, Cipla and considering the then amended Patent act, 1970 the Assistant controller of patents and designs passed order of refusing the grant of patent in the year 2006. Aggrieved by the order, the Swiss company filed writ petitions before the High Court of Madras61.

The main prayers of the appellant are to declare section 3(d) of the Patent Act as unconstitutional and to direct the controller to allow their patent applications. Then the court converted the part of the case, the challenge to the patent office’s decision to not grant a patent for Glivec from a writ petition to an appeal. During the pendency of the writ and the appeals, the central government brought into force the provisions of the patent act on appeals regarding the grant of patent, by establishing the Intellectual Property Appellate Board (IPAB) in the year 2007. The court then transferred the Novartis’s appeals matter on the Glivec patent to the IPAB. The high court started hearing the writ on constitutional validity of S.3 (d) of the Act and the IPAB62 on the appeal matter. Novartis challenged the s.3 (d) on grounds, one, it is not compatible to the TRIPs and it is arbitrary, illogical, vague and offends article 14 of the Constitution of India. The madras high court, very well, observed that the courts in India cannot check or the validity of the amendment section or stuck it down, in the backdrop of such alleged violation of TRIPs. On deciding the second issue, the court considered the main grounds of attack to the validity of the amended section that it is vague, arbitrary and confers encarnalized power on the statutory authority. Finally the court came to a conclusion that the amended section of the Act is constitutional as the patent controller, the statutory authority in the case, is exercising a quasi-judicial function. According to the act, he considers the patent claim application in the context of the objections received; hears parties on both sides and then passes an order, either granting the patent or rejecting the patent application, by giving reasons. The Court also stated “we have borne in mind the object which the amending Act wanted to achieve namely, to prevent ever greening; to provide easy access to the citizens of this country to life saving drugs and to discharge their constitutional obligation of providing good health care to its citizens…

61 Writ Petition No. 24754 to 24758 of 2006.
The judgment of Madras High Court\textsuperscript{63} rejecting Novartis patent case enabled Indian companies to manufacture cheaper generic medicines, providing patients from India and third world countries an affordable medicine and treatment for blood cancer. At the same time, the appeal against the refusal to grant patent for Glivec was also heard by the IPAB with Z. S. Negi as the Chairman and Dr. P. C. Chakraborti as a technical member. There are many arguments made by both the appellant and respondents and five main issues were framed by the appellate board, most of the issues are based on s.3 (d) of the Act. The IPAB after considering the Madras high court’s explanation given to the said section, held that the appellant’s invention is novel and possesses inventive step, which is additionally satisfied by way of inventive selection, but the enhanced bio-availability of 30% was not same as the therapeutic efficacy as required under section 3(d) and by not satisfying s.3 (d) the claims are not patentable, because the invention was termed as same (known) substances. The appellate board also observed that the different public interest provisions permissible under TRIPs which gives India the right to protect public health and to promote access to medicine for all. On the Exclusive Marketing Right (EMR) over Glivec, the appellant used to charge Rs.120000 per month for a required dosage\textsuperscript{64}, which was remarked by the board as too unaffordable to the poor cancer patients in India\textsuperscript{65}.

On this observation it notes that granting patent for Glivec will cause ‘public disorder’. The order was praised by many developing nations and tends to get support from article 27(2) which permits members to exclude certain inventions which is necessary to protect public order or morality and to protect human .Another major reported case which attempting patent linkage, which is the practice of linking drug marketing approval to the patent status of the originator’s product and not allowing the grant of marketing approval to any third party prior to the expiration of the patent term, unless consented to by the patent owner.\textsuperscript{66}

\textsuperscript{64} The same in case of generic version was Rs.10, 000 only.
\textsuperscript{65} Order No.100/2009 of the IPAB, Chennai.
In case of *Bayer Corporation and Others v. Cipla*, UOI and others\(^{67}\) the petitioner Bayer was a corporation which got patent on its renal cancer drug ‘Sorefenib tosylate’\(^{68}\). filed a petition to restrain grant of license to Cipla to manufacture, sell and distribute its drug ‘soranib’. The Delhi high court in this case has framed two issues, one on the patent linkage and the other on the generic drugs and spurious drugs. The Court held that the system of patent linkage could not be read into the provisions of the Drugs Act and the Patents Act and such system is undesirable in the Indian Context. The Delhi high court indicated its strong disapproval of Bayer’s intention to use the judiciary to sneak in a drug patent linkage mechanism by imposing costs of Rs.6.75 lakhs. This cost was awarded to both Cipla and the Union of India and was to be shared equally between them. Bayer Corporation filed a special leave petition before the Supreme Court against the order of the Delhi high court and the same was dismissed by the Supreme Court, taking into account that the Drug Controller General of India had already granted marketing approval to Cipla and the Bayer’s infringement suit was pending before the high court. At a time when India is negotiating Free Trade Agreements (FTA) with several countries, the Supreme Court’s observations sends a good signal and could boost the Indian government’s position particularly since some regions were pushing for patent-linkage to be included in the FTA. The Supreme Court order also appears to have effectively put a lid on the patent-linkages controversy would have delayed entry of generic versions of medicines in the market, there-by adversely affecting access to medicines.

As like Bayer, Novartis also filed a petition for special leave to appeal against the order of the IPAB before the Supreme Court\(^{69}\) which was lastly heard on 4\(^{th}\) February, 2011 and was posted for final disposal on April 19, 2011. Recently Indian Patent office rejected a patent applications filed by Abbott Lab, a US based company, for the anti-HIV drugs Lopinavir, Ritonavis and Atazanavir. Primarily this application was challenged by Cipla, Matrix and IMAK, that Abbott has a history of pricing this drug much higher in developed countries that it should\(^{70}\).

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\(^{67}\) 2009(41) PTC 643 (Del).

\(^{68}\) Bayer sells it for Rs.2,85,000 for one month dosage.

\(^{69}\) SLP(civil) No. 20539-20549/2009(Supreme Court, India).

This decision shows how India’s patent law, which prevents routine improvements from being patented, works in favor of public health by only granting patents for drugs that are truly innovative. These decisions also illustrate the need to safeguard India’s role as ‘pharmacy of the developing world’. Abbott is also expected to challenge the patent rejection. Indian patents act contains a number of provisions that allow generic manufacturers to produce affordable medicines, including rigorous standards to ensure that only new medicines are granted a monopoly. Affordable medicines produced in India have played a major role in helping expand AIDS treatment to more than five million people across the developing world71.

4.7 ANALYSIS OF THE CASE IN RELATION TO SECTION 3

The Primary contention in its challenge to the constitutional validity of section 3(d) was that the use of the term ‘efficacy’ in Section 3(d) is vague and ambiguous, and therefore violates the equality provision (Article 14) of the Indian Constitution.

Novartis filed its case with Indian court at Chennai and sought patentability of its product Gleevec filed under EMR provisions on the grounds alleging: (I) illegality in procedure adopted and also the text of 3(d) of The Act which was in violation of Article 27(1) and 27(2) of TRIPs Agreement; (ii) arbitrariness by the Controller General of Patents and Designs, Chennai and ignoring rationality underlying Articles 253 and 51(c) of the Indian Constitution whereby national laws are required to be harmonized with International treaties; (iii) Provision relating to discovery of “new form” contained in 3(d) is illogical and against the concept of patents which encourages innovation and intervention by rewarding the person associated with such acts beneficial for society; (iv) Deliberate incorporation after approval of its product Gleevec under the earlier prevailing EMR provisions resulted in disturbing the level playing field laid under the Act in compliance with conditionality under TRIPs Agreement. Novartis has asked the Chennai High Court to strike down this section as inconsistent with the WTO’s Agreement on Trade-Related Aspects of Intellectual Property (TRIPs).

Moreover, Section 3(d) of India’s patent law does not necessarily impose stricter requirements than are used elsewhere; it may be seen as simply creating a

general presumption of non patentability for modifications of known chemical compositions – and shifting to patent applicants the burden of rebutting this presumption in each particular case.

The Chennai High Court considered these issues of sufficient importance to merit referral to a two-judge panel. By late January 2007, the panel had not issued a decision. NGOs were disappointed by the court’s refusal to dismiss Novartis’s challenge outright. But the Indian judiciary must analyze and rule on the viability and uncertain contours of the new patentability test. Until it does so, the patent office retains virtually complete discretion in its application of Section 3(d). The court must also determine whether the patent office followed correct administrative procedures in rejecting Novartis’s application. The company contends that among other errors, patent examiners ignored data demonstrating that Gleevec has greater manufacturing stability than does the imatinib free-base form, as well as 30% greater bioavailability. But after a court case and four months of deliberation, two High Court judges concluded that the Indian courts have no jurisdiction to decide whether the National law is compliant with this international treaty. They also rejected an additional charge that Indian patent law was unconstitutional, vague and arbitrary. The Government of India and other opponents argued that section 3(d) is not in violation of the equality provision of the Indian Constitution as the concept of efficacy is well-known to people in the pharmaceutical industry to mean ‘therapeutic efficacy’. Dismissing the petition, the Madras High Court held that72 “We have borne in mind the object which the Amending Act wanted to achieve namely, to prevent ever greenling, to provide easy access to the citizens and therefore did not violate the Indian Constitution.”

The Patent application was subsequently heard by IPAB and it rejected the application on the ground of providing insufficient data to show that beta crystalline form of imatinib mesylate exhibited enhanced therapeutic efficacy over known imatinib mesylate. This decision has been challenged in Supreme Court of India.

The Novartis’ Glivec matter has created an impression that because of Section 3(d), any kind of incremental innovations will not get patent in India, however, Section 3(d) has stood the test of time and many patents have been granted in recent past for innovation wherein the improvements were significant.

The Indian Patent Office has uploaded on July 28, 2011, a detailed list of granted pharmaceutical patents on its website. The data provided therein clearly indicates during the last five years alone, the Indian Patent Office has granted 3,588 patents relating to pharmaceutical innovations rebutting the notion that Section 3(d) was against incremental innovations. Thus, Section 3(d) of the Patents Act is not a bar for patenting of significant incremental innovations, since the patents granted are not only for new molecules but also for new processes as well as new uses, combinations and dosage forms.

While many cases have been refused on the ground of insufficient data to show the increased efficacy of the claimed drug, however, many drugs have also been allowed after submitting sufficient data, e.g., in the matter of Hoffmann La Roche AG vs Wockhardt and Sankalp Rehabilitation Trust, the Patent office has upheld the Hoffman patent. In this patent, the Controller has considered the experimental data which showed decreased antiviral activity and increased anti-proliferative activity of PEG conjugated interferon as ‘therapeutic effects’. Thus, a derivative of known compound having enhancement in known efficacy has been allowed. Similarly, other matters which received a favorable response in favor of the Plaintiff are Gilead Sciences vs. Cipla; Hoff man La Roche and Pfizer products vs. Cipla Ltd; Pfizer Ltd vs. Natco Pharma.

As per Section 3(d) new forms of known substances are patentable, provided the enhanced therapeutic efficacy is established in comparison to known substance. As regard inventions related to pharmaceutical, incorporation of comparative data in the specification to show enhanced efficacy in terms of therapeutic effects will assist in securing the allowance of patent. Though it is not essential to present final clinical trial data, details of initial laboratory data or test results of compound/composition in comparison to base or known form of compound, which support the arguments for the enhanced therapeutic effect, must be disclosed in the specification.

Section 3(e) A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance.

In an Indian patent application, compositions claims should provide unique ratio or percentage of the components and should be supported by teaching of
surprising effect or synergy to prevent the rejection of claims under Section 3(e) on the ground of being admixture. To claim a composition, wherein no chemical reaction is taking place, it is imperative to show that combination of ingredients claimed is a synergistic composition exhibiting surprising or synergistic properties not exhibited by components individually. In case of composition claims, at least two active components are required to claim; mere addition of recipients and carriers is considered obvious by the examiner, resulting in rejection of composition claim. The claimed composition should show synergism in comparison to individual components, e.g., an Indian Patent application was allowed as the claims related to a synergistic composition with proof of synergism in the examples including bio availability data and clinical data. On the other hand, another application was rejected in spite of description showing considerable increase in the therapeutic effect, since data pertaining to the synergistic effect of the combination and individual drug(s) was absent.

Section 3(i) Any process for the medicinal, surgical, curative, prophylactic diagnostic therapeutic or other treatment of human being or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products in India, claims related to method of treatment and diagnosis per se are not patentable. However, as per the practice followed in India, ‘in vitro’ methods are considered patentable, provided the method has industrial application. Also in general, claims directed to composition for treatment, medical devices and diagnostic kits per se are considered patentable. Reference is made to J N Mitra vs. Kesar medicaments for device for detection of antibodies to Hepatitis C, wherein Delhi High Court granted injunction, reasoned the order on the basis that the use of patent being limited, irretrievable prejudice will be caused to the plaintiff if interim orders are not granted. The balance of convenience lies in favor of the plaintiff as the plaintiff’s patent cannot be permitted to be infringed.

Thus, the applicant has the option of securing allowance of such matter by appropriately re-wording the claims as compounds, composition and applications claims, instead of treatment method per se. However, Swiss type claims or use claims worded as per current European practice are not allowed.
Section 3(j) Plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.

Microorganisms per se are patentable in India. Clones and new variety of plants/animals are not patentable. However, process/method of preparing genetically modified organisms (GMO) is patentable subject matter. Recombinant proteins and method of preparation of such proteins are also patentable.

In spite of limitations set forth by the Sections discussed above, the past few years have witnessed exponential rise in pharmaceutical patent filing and grant of applications in this area. By keeping the few considerations in mind, applicants have been successful in securing allowance of Pharmaceutical Instrument patents in India.

In India, the patent office has considered that the Patent Act denies claims to compositions obtained by mere admixture resulting in the aggregation of the properties of the components there from. Thus, a novel pharmaceutical composition with a single active ingredient (known or novel) with an inert carrier is not patentable in India as there is no synergy between the components viz. the active compound and the inert carrier.

The existence of synergy, however, should not be considered per se as demonstrating inventive step, if the composition is obvious to a person skilled in the art.

1) Pharmaceutical Compositions

1. The pharmaceutical compositions other than mere admixtures resulting in the aggregation of properties of the ingredients, but having synergistic effect may normally be patentable.

2. The known pharmaceutical compositions in different new dosages and different form such as capsules, tablets, syrups, suspensions etc, are not patentable under sections 2(1)(j), 3(d) and 3(e) of the Act.

3. New use of known substance or its new use in a pharmaceutical composition is not normally patentable.

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4. Any method of using pharmaceutical composition is not patentable. Combinations Claims are sometimes directed to combinations of previously known active ingredients. In some cases, the specific covered compounds and quantities are indicated, while in others they generally refer to a category of therapeutic compounds, such as antacids. If claims on combinations are accepted subsequent to a patent on the relevant active ingredient/s, the patent owner may be able to indirectly extend the term of protection granted under the basic patent.

In some countries, combinations claims are rejected unless the combination generates a new and non-obvious synergy or distinct effect. If a synergistic effect is to be relied on to allow patentability, it must be possessed by everything covered by the claims, appropriately described and proven in the patent specification (for instance, on the basis of biological tests) and be the manifestation of an inventive step. A new synergy need not be considered, as such, as inventive, since it may be obvious for a person skilled in the art. Moreover, the synergy between two or more drugs may be deemed a ‘discovery’ rather than an ‘invention’, since the synergy takes place in the body and is found through clinical trials.

It is also to be noted that, in some cases, combination claims may in practical terms be equivalent to claims over medical treatments (the patentability of which is excluded in most countries), to the extent that they only provide a method of administering a combination of existing drugs. Also, combining drugs to avoid resistance is normal practice in pharmaceutical development and should generally be seen as evident to a person with average skills in the field. The Indian patent office has issued draft guidelines specifically providing criteria for the examination of applications relating to hydrates, salts and other derivatives. The amendment introduced to the Indian Patent Act in 2005, moreover, incorporated a specific provision with regard to claims regarding salts, esters and other ‘forms’ of existing products.

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75 For instance, CIPLA, the Indian pharmaceutical firm, filed a PCT application for the combination of three antiretrovirals: efavirenz (EFV), zidovudine (AZT) and lamivudine (3TC) and their analogues. Another example is the application filed by GlaxoSmithKline for the tablet formulation of the combination of zidovudine (AZT) and lamivudine (3TC), also known under the brandname ‘Combivir’.

76 For instance, claims on the combination of aspirin 325 mg + carisoprodol 200 mg + codeine phosphate 16 mg were granted in the USA, with expiry date 13/08/2002

It may be possible in cases where the required dosage for a new medical use is markedly different from that for the known use, to allow a claim to a unit dosage form containing the known active ingredient in such an amount that the unit dosage form is novel and not obvious to have been made up in that amount for the prior art use. Thus if the new medical use requires a dose of, for example, ten times (or one tenth) that for the prior art use, then a claim to a unit dosage form might be judged to be novel and inventive and allowable. In assessing the inventiveness of such claims it should be remembered that dosages required are usually related to body weight so that children’s doses are smaller than those for adults.\textsuperscript{78}

2) Guidelines for Hydrates and other Substances Etc\textsuperscript{79}

Hydrates, acid addition salts and other derivatives, which are routinely prepared prima facie, lack inventive step. However where there is a problem, like stability, absorption etc., and there is a long standing problem in preparing the derivatives, patentability of such process may be considered. The clear objective of the amendment to the Indian Patent Act is to limit the proliferation of patents around existing pharmaceutical products. It provides in section 3(d) that the following shall not be treated as an invention within the meaning of the Act: 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.

Explanation.—for the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, and mixtures of isomers, complexes, combinations and other derivatives of known substance shall be

\textsuperscript{78} Box 3: Examination Guidelines for Patent Applications relating to Medical Inventions in the UK Patent Office (March 2004), Claims to pharmaceutical compositions, Claims to unit dosage forms, Paragraph 120.

considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

Any special claims made by an applicant regarding, for instance, a faster therapeutic response of a new salt, should be supported by clinical data that demonstrate this effect. The more special claims that are made, the more data should be required to examine the viability of the application. It is critical that the new data be properly assessed. Health regulatory authorities have the appropriate expertise in these matters; hence, an articulated cooperation with patent offices in examining these applications might, as discussed below, facilitate the task of the patent offices and improve the quality of their decisions.

3) POLYMORPHS

1. Some compounds present in polymorphic forms, i.e., they crystallize in diverse forms. Such forms can be deemed within the prior art and therefore not patentable. However, process patent may be allowed for the new polymorph, if the polymorph is prepared by a novel process involving inventive step.

2. Some therapeutically active ingredients present polymorphic forms, that is, they may crystallize in diverse forms, which may have different properties that are more or less significant in terms of their therapeutic use. Such forms can be deemed within the prior art – and therefore non patentable- if they were inevitably obtained following the process of the basic patent on the active ingredient or were covered by a previous product patent. Polymorph claims are accepted in many countries. For instance, the EPO regularly grants patents on newly identified polymorphic forms, in line with the

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80 Some comments on this provision seem pertinent here. In accordance with this provision, if not significantly different in properties with regard to efficacy, salts, esters and ethers are considered to be the same substance and, hence, no separate patent could be granted. Establishing such differences with regard to efficacy (which is not a technical effect, but the result of the use of the substance in the body) would not be sufficient, however, to obtain a patent, since in any case the novelty, inventive step and utility requirements should be met. In other words, an increased efficacy would only prove that the substance is different, and not that it is patentable. An important issue is how a difference in efficacy is to be determined, since at the time of filing a patent application the results of clinical tests are generally not yet available. In the USA, for instance, the Court of Appeals for the Federal Circuit reversed in re Brana (51 F.3d 1560, Fed. Cir. 1995) a decision of the US Patent and Trademark Office (USPTO) holding that a compound was useful enough to be granted a patent, even without the approval of the FDA at that stage (the USPTO had rejected the patent application as it had not yet been approved by the FDA for Phase II clinical trials). In a more recent case, the Court held that where there is “no indication that one skilled in [the] art would accept without question statements [as to the effects of the claimed drug products] and no evidence has been presented to demonstrate that the claimed products do have those effects” the applicant has failed to demonstrate sufficient utility and therefore cannot establish enablement (Novak, 306 F.2d at 928; Rasmusson and Reynolds v. SmithKline Beecham, June 27, 2005).

practice of the German Patent Office and the Federal Patent Court. According to the “Kristallformen” case, products of the same chemical formula are not identical if they differ in some reliable parameter. Patents over polymorphs have been rejected, however, in other jurisdictions. The Indian draft guidelines for patent examination, for instance, provide specific criteria for assessing claims of such forms.

Solvates, including hydrates, were originally considered as “pseudo-polymorphs”. Nevertheless, according to the International Conference of Harmonization (ICH) of 1999, they are to be deemed ‘polymorphs’. Hydrates/solvates will rarely be inventive, as they are obvious to produce in most situations. Hence, claims relating to changes in the content of water in known molecules (deriving in mono-hydrates, bi-hydrates, etc.) should generally be considered non-inventive and not patentable.

It should also be noted that for most solvates and polymorphs, like for new salt forms, only data on quality and, where required, bioequivalence are needed, that is, no more data than for the approval of a generic product. This is the reason why in many jurisdictions these variants of a substance are deemed to be the ‘same’ substance for health regulatory purposes.

4) Patentability of various forms of chemical substances

(i) Isomers

1. Isomers are different compounds that have the same molecular formula which may be broadly divided into two kind’s namely structural isomers or positional isomers and stereo isomers.

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83 Substances that can be described as polymorphs of each other have the same chemical composition, whereas a solvate and a non-solvate do not. Indeed different solvates have different chemical compositions.
84 “Polymorphic forms: Some new drug substances exist in different crystalline forms which differ in their physical properties. Polymorphism may also include solvation or hydration products (also known as pseudopolymorphs) and amorphous forms. Differences in these forms could, in some cases, affect the quality or performance of the new drug products. In cases where differences exist which have been shown to affect drug product performance, bioavailability or stability, then the appropriate solid state should be specified” (Specifications: Test Procedures and Acceptance, Criteria for New Drug Substances and New Drug Products: Chemical Substances Q6A, ICH 1999).
85 As quoted above, the recent reform of the Indian Patent Act provides that polymorphs, inter alia, ‘shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy’ (Section 3 (d)).
2. Structural Isomers or positional isomers may be structurally similar or
dissimilar compounds. The simplest examples are butane and isobutane and
ethanol and dimethyl ether. In the former case the compounds are having
structural and functional similarity.

In the second set of compounds, although they have the same molecular
formula but are structurally and functionally different. Such isomers even having
close structural similarity may be considered to be novel over the prior art. But
when such chemical compounds have close structural similarity, similar functional
similarities and if it is found that the enabling methods are available, a case of
obviousness may be made.

3. Isomers having the same empirical formula but having structural differences
may be considered novel and may not normally offend “obviousness” as they
are structurally different.

An example is that cyclohexylstyrene is not considered prima facie obvious
over prior art isohexyl styrene.

4. Stereo Isomers are prima facie obvious. Once a racemic compound is known, its
enantiomers are obvious because a person skilled in the art knows that a
compound having a chiral center exists in two optically active forms. Hence
product patent may not be granted for the enantiomers. When a new compound
is claimed for the first time in its optically active pure form, product patent may
be granted. In a case (S)-enantiomer of a compound, capable of producing anti
diabetic effects was claimed. The cited prior art disclosed the racemate of the
same compound which was claimed for the same purpose and was not allowed.

(ii) METABOLITES

Metabolites are the compounds that are formed inside a living body during
metabolic reaction. The types of metabolites are-

(i) Active metabolites formed from inactive precursors (e.g Dopa and
Cyclophosphamide)

(ii) Active metabolites formed from precursors that show mechanism of action that is different from that of parent compound (e.g. Buspirone and 1-pyrimidyl piperzine Fenflouromine and norfenfleuromine)

(iii) Active metabolites which contribute to the duration of action of the parent compound (e.g. Hexamethylmelamine and Clobazam)

(iv) Active metabolites that show antagonistic effect on the activity of the parent compound (e.g. Trezodone and m-chlorophenyl pierzine, Aspirin and salicylate)

A metabolite is unpatentable since giving the drug to a patient naturally and inevitably results in formation of that metabolite.

(iii) PRO DRUGS:

1. Pro-drugs are inactive compounds that can produce an active ingredient when metabolized in the body. Hence pro-drugs and metabolites are interlinked. When metabolized in the body, inactive compounds (pro-drug) can produce a therapeutically active ingredient. It must be determined whether the patent on the compound covers the pro-drug and the extent to which claims relating to certain compounds should also be allowed to include their pro-drugs. The inventive aspects of pro-drug may be decided based on the merits of the case.

2. However, if there is a marked improvement over the primary drug, pro drugs may be patentable 88.

Based on the guidelines and merits of the claim the patent may be granted. Allegations are made against India for not granting patents for new use of known substance as many of the claims are rejected on the ground that the claim does not fit to the guidelines and this is a set back for multinational companies as they would not be interested in making investments and transfer of technology in our country. But we still find examples that in few cases patent has been granted if the criteria for the grant of patent are full filled. The Section 3(d) acts as a safety valve and keeps a check on the evergreening of Patents on new use of known substances this is how the Indian Patents Act has curtailed patenting of frivolous innovations and protecting the general public from the clutches of corporate monopolization.

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<td>22.01.2003</td>
<td>16.05.2007</td>
<td>206969</td>
<td>A Pharmaceutical Composition Comprising Lipase Inhibitor and Bile Acid Sequestrant</td>
<td>**</td>
<td>M/s F Hoffmann-La Roche AG</td>
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<td>24.11.2004</td>
<td>01.12.2008</td>
<td>225905</td>
<td>A Combination Comprising A DPP-IV Inhibitor</td>
<td>**</td>
<td>Novartis AG</td>
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<td>11.03.2004</td>
<td>13.11.2007</td>
<td>211844</td>
<td>A Combination Comprising 4-Pyridylmethyl-Phthalazine Antiangiogenic Agent and Platinum Compound</td>
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<td>Novartis AG</td>
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<td>19.04.2004</td>
<td>24.10.2008</td>
<td>224913</td>
<td>Composition Comprising Bisphosphonate, Cox-2 Inhibitor and Taxotere for Growth Inhibition of Cancer Cells</td>
<td>Zoledronic acid + COX II inhibitor + taxol**</td>
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<td>16.06.2003</td>
<td>09.11.2007</td>
<td>211807</td>
<td>Pharmaceutical Composition Comprising Benazepril and Amlodipine</td>
<td>Amlodipine + benazepril</td>
<td>1986 + 1983</td>
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** indicates that either the abstract does not give clear idea or the drug is not identifiable or a new chemical entity # indicates that the year of grant is based on the specific product patent granted; based on the Merck index data or IMS Patent database

4.8 DIFFICULTY IN UTILIZING THE TRIPS FLEXIBILITY

Indian Patent Act was questioned due to the reason that India has failed to comply with the strict implementation of the Patents Act especially with respect to granting of Patents under Section 3 (d) and utilization of the flexibilities, when ever

Source: T C James, Patent protection and innovation, Section 3(d) of the Patents Act and Indian Pharmaceutical Industry. Director, National Intellectual Property Organization, New Delhi, and former Director, Intellectual Property Rights (IPRs) Division, Ministry of Commerce and Industry, Government of India
India rejected a patent application on the grounds of new use of known substances and in the utilization of flexibilities even though done in legal manner and after complying with the provisions of the law, India was posed with the several questions based on the following decisions of the court and with reference to the various case laws and blamed India that it was lagging behind in proper implementation of the Patents Act and has deviated from the TRIPs norms a proper analysis would clarify what was the contentions of the parties with regard to the issue of granting the patent U/s 3(d) and Compulsory Licenses.

In a move welcomed by many in the international community, India has granted an application, its first, from a homegrown generic drug maker to manufacture and sell a patented cancer drug under a compulsory license. In an order dated 9 March 2012, the Controller of the Indian Patents Office ruled against the patent owner German pharmaceutical giant Bayer Corporation. With the ruling, Indian generic drug manufacturer Natco Pharma Ltd. has received a green light to start manufacturing and selling in India Bayer’s patented drug “Sorafenib tosylate.” The compound, used for the treatment of advanced stages of kidney and liver cancer, is sold by Bayer under the brand name Nexavar. Natco has already developed a process to manufacture the drug and received a license to manufacture the drug in bulk and to market it in April 2011. It is expected that Bayer will make an appeal against the decision.

Bayer launched the drug in 2006. It received a license to import and market the drug in India on 1st August 2007. The Patent Office found that Bayer did not import the drug at all in 2008 and only started importing in small quantities in 2009 and 2010. Seeing that Bayer was not making the drug accessible to more people, Natco applied for a compulsory license. Compulsory licensing is one when a government allows someone else to produce a patented product or process without the consent of the patent owner, but under strict terms. It is one of the flexibilities on patent protection under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).

In its defense, Bayer argued that the operation of another pharmaceutical company, Cipla, which is selling a similar drug, is the reason why it could not maximize the distribution of the drug in India. Bayer, in a separate case, has sued Cipla for infringement.
“According to the decision, Natco must pay a quarterly royalty at 6 per cent of the net sales of the drug. This was lower than Bayer’s asking royalty of 15 per cent of net sales.

A royalty of 6 per cent is aligned with the United Nations Development Programme recommendation of a 4 per cent royalty, which can be adjusted upwards as much as 2 per cent for products of particular therapeutic value or reduced as much as 2 per cent if development of the drug made use of public funds. Under the terms of the compulsory license, Natco shall provide the drug for free to at least 600 needy and deserving patients per year; sell the drug at no more than 8,880 Indian rupees (about US$178) for a pack of 120 tablets; and is prohibited from outsourcing the manufacturing of the drug.

Non-governmental groups have welcomed the landmark decision and opined that: “We hope this will lead to more standardized policies for the grant of compulsory licenses when products are so expensive that access is limited to only the wealthiest patients,” said James Love of the Knowledge Ecology International in a statement posted on his group’s website. Médecins Sans Frontières (MSF, Doctors without Borders) said the ruling ends Bayer’s monopoly in India on the drug and could set precedent for making more expensive patented drugs available for compulsory licensing.

This grant of CL is a remarkable decision for the Indian scenario since it is one of the measures taken by the government in the interest of public health. But this decision marks a precedent that offers hope: it shows that new drugs under patent can also be produced by generic makers at a fraction of the price, while royalties are paid to the patent holder. This compensates patent holders while at the same time ensuring that competition can bring down prices.90

This is the first time that an Indian company has been granted a compulsory license, a legally recognized means to force patent holders to grant licenses to generic drug makers, thus ensuring that the poor can afford life-saving medicines.

4.9 UTILIZATION OF COMPULSORY LICENSING IN INDIAN SCENARIO TO MAKE DRUGS AFFORDABLE

The decision by PH Kurian, the controller general of patents, designs and trademarks in India, to allow a local company to manufacture Sorafenib, a drug

90 Tido von Schoen-Angerer, director of the MSF Access Campaign, said in a statement. Maricel Estavillo, for Intellectual Property Watch, Published on 12 March 2012 @ 9:02 pm
used to treat advanced kidney cancer and liver cancer that supports the access of poor people to cheap life-saving drugs\textsuperscript{91}.

Bayer, a German multinational, has been selling Sorafenib, under the brand name of Nexavar, for $5,600 a month. (The average per capita income in India is a little under $100 i.e. two percent of the price of the drug) Natco Pharma, an Indian company which applied for permission to manufacture and sell the drug, will now be able to sell the drug for $176 a month. Kurian’s decision is based on an Indian law which is aimed at keeping prices from skyrocketing beyond patients’ reach and World Trade Organization rules that allow compulsory licenses for drugs for public health reasons. Few countries do this, however, for fear of the legal challenges that the companies can bring against them. To reinforce his decision, Kurian also noted that Nexavar was often hard to buy in major Indian cities even at the inflated price. Bayer has made billion from Sorafenib, and made little effort to sell the product in India, where its price is far beyond the means of all but a few persons.\textsuperscript{92}

This is the first time that the Indian law has been used since 2005, when India ended three decades of refusing to recognize international patents on essential drugs in order to keep prices affordable. Another key decision on this matter is expected soon when the Indian Supreme Court hears a case brought by Novartis, a Swiss company, to force Indian companies to stop selling generic versions of Gleevec which is used to treat a deadly form of leukemia. Novartis sells Gleevec for $70,000 a year in the U.S. versus the Indian version which retails for roughly $2,500 a year.

India is not the first country to act on this matter. Between November 2006 and January 2007, Thailand issued compulsory licenses for two AIDS drugs (efavirnz and the combination of lopinavir+ritonavir) and one antihypertension drug (clopidegrel). Several other countries - Ethiopia, the Congo, Tanzania and Uganda – are also considering similar action.

Indian activists have long lobbied the government to take action in support of cheap generic drugs. Amit Sen Gupta from the Indian Peoples Health Movement was one of three groups that put out a press release in 2009 to underscore the importance of the Sorafenib case: “The Bayer case has implications for drug access, not just for patients


\textsuperscript{92} James Love of Knowledge Ecology International, an activist group in Washington DC in support of India’s move to grant CL. www.kei.org
in India, but for poor people in large parts of the world. It would mean giving sanctity to higher standards of patent protection than what is required even by the TRIPs agreement. Bayer not only seeks to safeguard its own monopoly right, the company also wants to set a precedent that other corporations can benefit from. In essence it would mean that the entry of generic versions of life saving drugs would be delayed.”

Philipp Mimkes\(^{93}\) opined that: “The interest of patients is at risk if marketing approvals are linked with patents. Countries like India must have the possibility to issue compulsory licenses to generic companies or to impose price controls in order to make available affordable drugs safeguarding public health must take precedence over patents and monopoly profits of drug companies”

 Others have noted that such precedents may also help AIDS patients. “As the HIV crisis continues to escalate, patients cannot continue to be denied access to life-saving drugs,” “The burden on people living with HIV and on the Indian government’s own health resources will be unbearable if prices escalate.”\(^{94}\)

Ironically many major pharmaceutical companies take advantage of cheap labor in India to help them boost their profits. “India took (China’s) place as the world’s pharmacy, and in recent decades has been the largest provider of cheap, lifesaving medicines in poor countries across the globe,”\(^{95}\) Doctors without Borders estimates that 80 percent of the generic AIDS drugs that it distributes to 170,000 patients in Africa are made in India.

KEI (Knowledge Ecology International)\(^ {96}\) has provided an affidavit in an India compulsory licensing dispute involving Natco and Bayer, for patents on the cancer drug sorafenib (sold by Bayer under the brand name Nexavar). The Bayer price for sorafenib/Nexavar in India is $47 per 200 milligram tablet. At a daily dose of 4 tablets, this comes to $5,637 per month, or more than $68 thousand per year. In 2010, per capita income in India was $1,330.

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The Natco case will test the new Section 84 of the India patent act, and in particular, set a precedent for a reasonably affordable price. KEI has some background information on sorafenib on the web at http://keionline.org/drugs, including data on research and development, orphan drug designations and global pricing. The KEI affidavit covers three topics: the standards for determining if a price is reasonably affordable, the research and development that contributed to the development of sorafenib, and the calculations of a reasonable royalty for sorafenib.

Issuing CL floats hope for liver and kidney cancer patients who find the available patented medication unaffordable and out of reach based on this reason the Compulsory license can be granted. The drug is sold by German drug maker Bayer at a whopping Rs280, 428 a month. Granted a patent in 2008, it is the only brand of sorafenib legally allowed for sale in the country. However, two years ago, Mumbai-based Cipla launched at-risk generic sorafenib for Rs28, 000 for a month’s treatment, following which Bayer filed an infringement suit against it. Hyderabad-based Natco Pharma requested Bayer for a license to manufacture the generic version and sell at more affordable Rs 8800, per month.

But the German firm turned down the request, and Natco applied for a compulsory license in the patent office. If granted, the compulsory license would allow Natco to legally sell the generic (it already has manufacturing and marketing approval from the drugs controller), while paying royalties on sale to Bayer. According to experts, compulsory licensing is a flexibility provided in the TRIPs Agreement of the World Trade Organization, of which India is a signatory, and can be applied when the patented drug is unaffordable or unavailable. “Rs2,80,428 per month is an incredible amount for most Indians. And the medication has to be taken life long. This makes it a clear case for compulsory licensing, as the drug is unaffordable”. Estimates suggest liver and kidney cancers affect around 30,000 Indians every year, with 24,000 succumbing to them every year. Over 1 lakh Indians are suffering from the two cancers. The patent expert said that since 2005, when the product patent regime rolled out, several important drugs with stupendous prices have been granted patents. “Generic versions are needed to bring prices down to make the drugs affordable as it is a matter of life and death of the poor patients.”

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According to the experts, compulsory licensing has been granted in the past by not just poor countries like Cameroon, Mozambique, Zimbabwe and Ghana, but also by several developed and developing countries. However, the Organization of Pharmaceutical Producers of India, the lobby of MNC drug makers, feels that for innovator companies, the ability to recoup the value of their products through patents is vital if they have to continue research and development. The TRIPs agreement says as much. According to it, granting a compulsory license does not tear apart the patent, as the patent owner still has rights and gets royalties on sale.

India has an interesting relationship with pharmaceutical patents. In 1970, India did away with drug patents entirely, believing it would help create a domestic drug industry. And it worked. As it is evident from the past: 2,237 licensed drug manufacturers in 1969-1970 grew to 16,000 by 1991-1993, production of drugs grew at an average rate of 14.4% per year from 1980 to 1993, India became a net exporter of pharmaceutical products, and the market share of foreign multinational corporations (MNCs) dropped from 80-90% to 40%. In 1995, six of the top ten pharmaceutical firms in India were domestic, and employment in the sector had reached half a million people.

Many companies were producing generic versions, but not all of them were. Despite all of this success, the international community, pressured by the big pharmaceutical firms, cracked down on such practices, and demanded that if anyone wanted to join the WTO - an important organization for large countries to be a part they had to recognize pharmaceutical patents as per the TRIPs agreement. India finally did so in 2005.

However, one key point in TRIPs that developing countries such as India and Brazil have paid close attention to is the fact that they can force a compulsory license on a drug patent holder in the interest of public health.

For the first time since re-instating patents on pharmaceuticals, India has granted just such a compulsory license, covering a kidney and liver cancer drug marketed under the name Nexavar. Indian generic drug company Natco requested a license, noting that Nexavar was in short supply in India and exceptionally

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expensive. A typical dosage costs around $70,000 per year in India -- something Bayer says is necessary to recoup the drug’s R&D costs. However, reports show that it cost less than $300 million to develop this drug (not to mention that the US government subsidized the process) and Bayer has already made billions selling the drug around the world. In a detailed ruling (embedded below), India’s Controller of Patents granted Natco the right to make the same drug, requiring it to sell it at a significantly lower price than Bayer sells Nexavar for, and then pay back to Bayer a 6% royalty rate (which is actually at the high end of what the UN recommends). Natco has to make the drug itself and can’t name it Nexavar, make it look the same or even state that it’s the same as Nexavar -- but it can make its own version of the drug and sell it, and the license lasts the life of the patent. Bayer can and almost certainly will appeal, but this is going to be interesting to watch for a few reasons as it is to look as how U.S and other countries would react.

The US government blames that the kind of ruling would be a “problem” and how India isn’t “respecting” international patent law by granting CL without taking into considerations the companies claim. It is expected to see diplomatic pressure placed on India to put limits on its compulsory licensing program, and potentially even noises about how India has to change its patent laws to “update” them and “harmonize” them with the world. Also don’t be surprised if stuff like this leads India to jump up the charts on next year’s Special 301 reports from the USTR, which list “naughty” countries. American controller on Trade agreements (ACTA) knows that is entirely about ratcheting up enforcement, without any exceptions for things like this where something as important as saving lives comes into play.

Compulsory licensing amounts to government permission for a drug maker to manufacture a copy of a patented drug provided if the patentee fails to ensure that market requirement is adequately met in terms of access and affordability within three years of the original patent grant. Bayer India was granted a patent for Nexavar in 2008 and imports the drug from its parent’s facility abroad. Both Bayer and Natco declined to comment as the matter was subjudice. The liver and kidney cancer drug costs about Rs.2.8 lakh for a month’s treatment. Natco said in the application that only 1% of 100,000 patients had access to sorafenib, sold by Bayer as Nexavar, because of the cost, and said it could sell the drug at Rs.8, 880 for one month treatment.
The Controller General of Patents had asked the patentee—Bayer HealthCare—to submit cost data, including research and development (R&D) expenditure on Nexavar, to justify the price. The German firm had argued it would be difficult to sell the drug at a lower price because of the amount invested in its development. Experts said the disclosure may result in other overseas companies being forced to reveal the pricing strategy for drugs sold in the country.

“Foreign drug makers, while launching patented drugs in the local market, typically price it high, though no questions are asked about the actual cost and margin. They don’t even disclose it”. Natco’s application to the patent office was made on the basis of high cost and affordability. “Since affordability was at the centre of the matter in this case, a balanced view on the price of the drug is important to a take decision on it,”100 “So the patent office’s decision to look at the cost of Bayer as well As the claim of Natco was quite appropriate in this matter.”

Bayer’s disclosure will be critical in the light of Natco’s lawyer alleging in the first hearing that Nexavar was developed as an orphan drug101. Such drugs normally receive government grants and other concessions, lowering R&D costs. “The cost disclosure by Bayer will expose the pricing of many other patented drugs launched by both multinational and local companies in the market,” Natco had earlier unsuccessfully approached Bayer for a voluntary license to allow it to manufacture and sell a generic version. Bayer’s has refused the voluntary license as Natco’s “approach was not appropriate” and the correspondence in this regard implied “a tone of a threat” that it may seek a compulsory license. According to Natco’s lawyer, Bayer imported only 200 bottles of the drug, which was insufficient to meet market demand. A compulsory license applicant has to prove that it’s capable of selling the product at a lower cost to meet the demand. Bayer’s working status filing to the patent office for fiscal 2010 showed that it posted sales of Rs.16 crore for the drug. - (C.H. Unnikrishnan)

Natco, India’s first generic drug makers seeks compulsory license to supply medicines to a least developed country, also plays a major role opposing patent

100 Gopakumar Nair, director of Gopakumar Nair Associates, a Mumbai-based patent law and services firm
101 An orphan drug is one that addresses a tiny patient population that’s normally ignored by researchers and manufacturers as it doesn’t make commercial sense for them.
applications of Multinational pharmas and applying for grant of compulsory license. Developed World’s criticism on Doha declaration and Indian Patent system\textsuperscript{102}.

There are so many criticism coming from the developed fronts that the Doha declaration which permits the compulsory licensing for different reason, as they think of much important, to protect their multi-national pharmaceutical companies. While developing countries have pressed for a broad interpretation of the Doha Declaration, and thus a large list of diseases for which patent rules will be relaxed, drug companies and their respective governments have advocated for a narrow interpretation of the Declaration\textsuperscript{103}.

Some of the arguments put forth by Developed countries against the grant of compulsory licensing, particularly against India, who is the top manufacturer and exporter of generic drugs. One of the arguments against the Doha declaration is that it has not served countries most in need of inexpensive medications: least developed countries with high rates of HIV/AIDS. The terms of the Doha Declaration are too broad, allowing countries to issue compulsory licenses for medications that do not treat life-threatening illnesses, such as Viagra and Plavix. Many countries have seen a dramatic drop in Foreign Direct Investment (FDI) as a result of extensive compulsory licensing of patented pharmaceuticals, making least developed countries hesitant to invoke the terms of the Doha Declaration for fear of similar losses in FDI\textsuperscript{104}.

The discussion on the effect of compulsory licensing provisions against the inventor of a product in economic aspect, but they failed to consider the health of the globe and how can the poor section of the globe purchase such a high cost medicines to save their lives. It cannot be denied that the research and the investment made by the inventor should enjoy its benefit, but when the same drug available at low price why can’t the inventor himself provide it at an affordable price, which may bring economic progress for him, instead of selling it in an inflated price. Some of the western scholars went on the check the legal status and the applicability of the Doha declaration. Their argument is that the Doha

\textsuperscript{103} Collen Chien, “Cheap Drugs at what price to innovation does the compulsory licensing of pharmaceuticals hurtinnovations”\textsuperscript{18}, BERKELEY TECH. L. J. 853 (2003).
Declaration captures the middle ground between the positions adopted by developing and developed countries. It embodies commitment to patent protection for the development of new drugs and to availability of these drugs for indigent populations. The fourth paragraph of the Declaration fortifies this middle ground by affirming that the “TRIPs 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” This language cast in terms of member’s rights to protect public health introduces an interpretation not expressly provided in the TRIPs Agreement. Hence these rights are not expressly derived from the TRIPs Agreement, but are exercisable in light of contemporary international concern regarding the HIV/AIDS pandemic.\textsuperscript{105}

In India’s pharmaceutical industry\textsuperscript{106}, there is sparring over the prickly issue of Compulsory licenses’, a mechanism by which a government allows a domestic company to manufacture and sell a generic version of a patented drug with or without the consent of the patent-holder, who receives compensation.

Compulsory licensing (CL) is one of the major flexibilities allowed under World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). Multinational pharmaceutical companies see great potential in selling drugs in India but once again are faced with the bald truth that there are challenges. Once again, there is a polarising discourse pitting patients against patents. The Indian media reported that the Union Health Ministry had recommended three anti-cancer drugs for compulsory licensing. The recommendation is the outcome of suggestions by an expert committee, and was sent to the Department of Industrial Policy and Promotion (DIPP) which comes under the Union Ministry of Commerce and Industry. Though it is not known exactly when the CL will be notified, the move signals that the Indian government has started the process of issuing compulsory licences for the three commonly used anti-cancer drugs: trastuzumab (or Herceptin, used for breast cancer), ixabepilone (used for chemotherapy), and dasatinib (used to treat leukemia).


In a country where the vast majority of citizens pay for their medical treatment from their pocket, the move has been predictably cheered by public health advocates and cancer patients. For a month’s treatment, drugs like trastuzumab, ixabepilone and dasatinib are reported to cost on an average of US$ 3,000 to 4,500, or Rs 1.64 to 2.45 lakh for each patient in India.

The analysis of how India is making the use of Compulsory Licenses involves Bayer’s Nexavar (sorafenib tosylate)\textsuperscript{107}, a drug for liver cancer is still a costlier affair as to affordability is concerned. The patent on the cancer drug sorafenib tosylate was granted to Bayer in March 2008. Indian generic company Natco applied for a CL on the drug in July 2011 and it was granted by the Indian Patent Controller in March 2012. The CL allows a more affordable version of sorafenib tosylate to be produced and marketed. This brought the price of the patented drug down from over $5,500 per month to $175 per month a reduction of 97 percent. Under the terms, Bayer is being paid a 6 percent royalty on sales by Natco. The question as to what will the impact of CL would be on pharmaceutical companys development and what do the recent developments related to CL portend? The reactions are mixed. This step by the government to use CL was long overdue,\textsuperscript{108} “The prices of cancer drugs remain exorbitant even after the Natco compulsory licensing decision and a number of Indian patients are unable to access the drug. Further, even from a WTO dispute standpoint, terms such as “national emergency” and urgency have not been defined under TRIPs and a WTO dispute resolution panel is likely to accord India plenty of flexibility in interpreting these terms given that India is the most privatized healthcare market, it is high time the government began playing a more active role in promoting public health. It cannot simply rely on generic companies to fill the gap, particularly since generic prices of cancer drugs are also unaffordable to a vast majority of Indians,\textsuperscript{109} showed that after the Natco CL, “not a single generic company applied for compulsory licenses under Section 84 of the Patents (Amendment) Act 2005”.

“Perhaps generics are averse to pursuing this risky legal route, as evidenced by the fact that Natco is spending considerable sums of money defending the license

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\textsuperscript{108} Shamnad Basheer, professor of IP law at National University Juridical Sciences in Kolkata, Intellectual Property Watch.opined on India’s stand to utilize the flexibilities.
\textsuperscript{109} Basheer, Sai Vinod research associate under the Right to Information Act filed a recent petition seeking information about the information seeking CL. http://www.ip-watch.org/2013/01/22/2013-india-battles-for-right-to-use-compulsory-licences-to-make-medicines-affordable/
before the intellectual property appellate tribunal (IPAB),’. ‘The government’s initiative to therefore assume the legal risk itself by issuing a notification under Section 92 is therefore a very welcome move.’ The Organization of Pharmaceutical Producers of India (OPPI), which describes itself as a ‘premier association of research and innovation driven pharmaceutical companies in India, and a scientific and professional body’ is anxious about the emerging CL scenario in India.

In an emailed response to questions from Intellectual Property Watch, OPPI Director General Tapan Ray opined that the grant of compulsory license for Bayer’s Nexavar to Natco by the Indian Patent Office last year had already raised serious concerns across the world on the robustness IPR ecosystem in India. Recent news reports on the same issue will vindicate those concerns.’ ‘It is rather impractical to envisage that routine grant of compulsory licenses by the Indian Patent Office will be able to resolve the critical issue of improving access to patented medicines on a long term basis’, Ray argued that ‘there is a greater urgency to attend to basic healthcare infrastructural and delivery issues, besides providing universal healthcare coverage as recommended by the High Level Experts Group\(^\text{110}\) (HLEG) constituted for this purpose by the government. Far encompassing critical decisions like grant of compulsory licenses should be taken only after exhausting all other access improvement measures.

‘The previous grant of a compulsory license and recent news reports on the possibility of further grant of three more compulsory licenses coupled with several instances of product patent infringements, have made the pharmaceutical business environment for the innovator companies in India extremely uncertain. Predictability of an innovation-friendly environment is critical for the economic growth of India, which the government should not lose sight of.’ ‘Bayer has been very aggressive, challenging just about everything you can imagine,’\(^\text{111}\). Among the issues to be decided, will be ‘how companies can claim R&D cost bear on the issue of an affordable price, and if they even have to provide evidence of what they actually spend on R&D for a particular product.’

\(^{110}\) For details see http://www.hlegphfi.org/

\(^{111}\) James Love, director of Knowledge Ecology International (KEI), a non-governmental organization with offices in Washington, DC and Geneva, told Intellectual Property Watch, Intellectual Property Watch emailed Bayer’s India office for its comments on the issue and also for the company’s reactions to the government’s latest move to start the process of issuing CL for three other cancer drugs. See also James Love, Compulsory Licensing: Models for State Practice in Developing Countries, Access to Medicine and Compliance with WTO TRIPS Accord paras. 35–42, available at http://www.cptech.org/ip/health/cl/recommendedstatepractice.html,
“Bayer has not disclosed its outlays on Nexavar, but rather points to a number of general studies, or very aggregate figures from its overall RandD spending, most of which was completely unrelated to Nexavar.’. “Bayer claims India cannot issue a CL on the issue of a reasonably affordable price unless the Patent Office determines what that affordable price is. Bayer is asking for a 15 percent royalty on a price that is higher than the actual generic price, citing some out-of-context UK cases that are outliers in the case law.’

Love concludes that: “Bayer claims its obligations to work the patent have been satisfied by CIPLA, because CIPLA made its invention available at a lower price. Bayer claims that India cannot require local manufacturing of the drug, under the TRIPs agreement. One concerning point during the IPAB hearings on the Bayer-Natco case was the interpretation of the term reasonably affordable price’ in the CL provision (section 84) of the Indian Patents Act.

The Indian government’s latest moves on CL and the IPAB hearings are significant, especially seen in the backdrop of the evolving IPR scenario in India. The setting up of the expert committee signals the recognition within government that patents are a huge barrier to access to treatment,’ The response from government indicates that we have been able to make a strong collective case for prioritizing constitutional rights of citizens over markets and profits.112,” the expert committee has made its recommendation, to forward to a notification under Section 92 of India’s patent act inviting manufacturers to come forward to manufacture a biosimilar of trastuzumab,’ The outcomes of the IPAB hearings will have huge implications for the campaign as well as for the overall drug patent scenario in India.

However, activists and patients’ groups do not expect things to be all smooth sailing in the coming days. They point out that the story about the expert committee’s decision to recommend the CL route for the three cancer drugs was leaked’ to the media prematurely and could subject the government to pressure from within and outside. Médecins Sans Frontières,113 the international medical and humanitarian NGO, has welcomed the government’s recent moves. Leena Menghaney, India manager for the Access Campaign at MSF told Intellectual Property Watch that the group welcomes the steps the Indian Ministry of Health is

112 Kalyani Menon-Sen, Delhi-based coordinator for the Campaign for Affordable Trastuzumab, told Intellectual Property Watch.
113 MSF, Doctors without Borders. www.msf.org
taking to identify patents on drugs that are exorbitantly priced and face no generic competition. They opined that they are aware that there may be resistance to the CL option within the government. The influence exerted by big pharma in the process of policy-making on such issues should not be underestimated. ‘Our position is clear with 100,000 new cases of breast cancer being recorded every year even by very conservative estimates, 25 percent cases being positive, breast cancer is a public health emergency that government cannot afford to ignore. The government must use every possible means at its disposal including CL to address patent barriers that lead to the loss of so many precious lives.

‘Eight years after India amended its Patent law to implement the international trade rules enshrined in the TRIPs agreement, new medicines, including drugs to treat HIV and hepatitis, are now patented in the country and are too expensive and unavailable for those who need them most,’ ‘MSF’s Mumbai clinic pays as much as US$1,775 per person per year to access just one patented drug for HIV, raltegravir, for example. MSF hopes that India will continue to use all the means at its disposal including compulsory licenses to address patent barriers and bring down high prices on the medicines that are vital to many in India and the developing world.’

The recent developments on CL in India could potentially have international ramifications. ‘Other countries are waiting eagerly for India to produce cheaper versions of drugs like trastuzumab,’ ‘This could well be a huge boost for our domestic manufacturers, including public sector firms, who have outstanding technical capacity and manufacturing infrastructure, and who are looking for policy support to expand their operation.’

‘The international ramifications of the IPAB hearing are huge for the whole world, as India plays such an important role as the source of low-cost generic drugs,’. Indeed, the unfolding events in India are being watched carefully in cities across the world. For instance, the Geneva-based International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) warned against overuse of compulsory licenses\textsuperscript{114}.

\textsuperscript{114} IFPMA Press Release, Geneva, 20 December 2001. Source: www.ifpma.org/pdf/ifpma/CMH%20report-news%20release.pdf. Although patent status is not a consideration in selecting medicines for the list, the total cost of treatment and cost-effectiveness are criteria for inclusion so some therapeutically important patented medicines may
“The IFPMA recognizes that developing countries may use compulsory licensing provisions in certain limited circumstances, but their use is clearly not a sustainable solution and should be seen as a last resort115, “Systematic issuance of compulsory licenses sets a negative precedent and can reduce the incentive to invest in the research and development of new medicines that address unmet medical needs,’ Jenner said. ‘We believe that negotiated approaches, such as tiered pricing or voluntary licensing, are generally more effective and sustainable, both medically and economically.’

Significantly, last year, China, India’s powerful neighbor, amended its intellectual property laws in order to allow the government to issue compulsory licenses for local generics makers to produce drugs which are still in patent. It is difficult to predict what the future holds. But one thing is certain: India is now at the centre of the global debate pitting patents versus patients and is likely to remain that way for some time116.

The United States has maintained that Doha was a political declaration with no legal authority. The United States Trade Representative’s Fact Sheet summarizing the results of the Doha meeting refers to the Doha Declaration on TRIPs and Public Health as a political declaration. From this perspective, the Declaration is not a fait accompli for countries seeking to facilitate access to essential medicines. Rather, it is an implicit reciprocation by the West to developing country governments for their implementation of the TRIPs Agreement and their acquiescence to a new round of WTO talks117.

The reason given by the western countries is that encouraging innovation by rewarding innovators will only help to ensure that new and useful inventions are widely produced and the exclusive rights are necessary to incentive research and development of medications. But the authentic reason is that the United States economy relies on profits from innovation. Thus, the United States pushed heavily to pass a system of intellectual property protection that embodied their strong private property rights in patents and ensured its adoption worldwide by linking it to the benefits of the WTO. The TRIPs agreement, as adopted, reflects the broad property

115 Andrew Jenner, director of innovation, IP and trade at IFPMA, which represents research-based pharmaceutical industry, told Intellectual Property Watch.
116 IPW, Public Health, 18 September 2013
117 Collen Chien, “Cheap Drugs at what price to innovation does the compulsory licensing of pharmaceuticals hurt innovations”18
rights of the American intellectual property system. In fact, the agreement parallels American law almost exactly\(^\text{118}\) that’s why the western countries oppose the Doha declaration on public health. Further the developed countries, particularly the United States and Switzerland, have argued that the only flexibility in the TRIPs Agreement is the staggered implementation period’s developing countries enjoy under the Agreement. Most of these countries have warned the use of compulsory licensing provisions to allow local companies to produce low-cost variants of patented essential medicines can adversely impact the flow of foreign direct investment in the pharmaceutical sector\(^\text{119}\) and their primary concentration is only on their economy. Pharmaceutical Research and Manufacturers of America (PhRMA) is an association which often cautioned the issuance of compulsory licenses only on the reason that the companies which are creating a medicinal product will be denied on their research investment and they will have less incentive to develop new lifesaving treatment options. They also warned that the compulsory licensing provisions may lead to a way to stop research by pharmaceutical manufacturers and the patients will be forced to use old drugs only. Many governments were also warned by the WTO on their decision to allow a generic drug producer to manufacture a lower cost version of patented drug, based on the emergency concepts. From the patent holder’s perspective, a consumer who does not pay for the use of his invention has stolen his invention. From a developed nation’s perspective, such consumers undermine the governmental authorities of all of the WTO member nations, which guarantee patent rights to inventors. This is true regardless of whether the consumer is a government or a Patient. But all the things are about then developing and least developed nations that have only a little or no pharmaceutical infrastructure and thus do not have the manufacturing capabilities to produce sorely-needed medicines. From a pharmaceutical company’s perspective, a life-saving medicine is a more worthy invention than a household device; therefore it should be given more incentives and protections. From a patient’s perspective, a life-saving medicine is of foremost


importance as well to the opposite conclusion: that the drug should therefore be readily available to all in need.\textsuperscript{120}

Well said by the then Prime Minister of India Dr. Manmohan Singh in his speech that “We have affirmed our commitment to the protection of intellectual property rights. But, the global economy, the global community cannot afford the complete privatization of research, of knowledge generation, especially in fields like medicine. We need to evolve mechanisms that protect intellectual property and at the same time, address the needs of the poor”.\textsuperscript{121}

4.10 INDIA QUESTIONED BY WTO AS TO THE ISSUE OF UTILIZING COMPULSORY LICENSING AND GRANTING PATENT U/S 3 (D)

On 14\textsuperscript{th} September 2011 and 16\textsuperscript{th} September 2011, the World Trade Organization (WTO)\textsuperscript{122} undertook a trade policy review of India. All members of the WTO are subject to review under the Trade Policy Review Mechanism (TPRM). The TPRM takes place in the “Trade Policy Review Body which is actually the WTO General Council — comprising the WTO’s full membership — operating under special rules and procedures”\textsuperscript{123} In October 2011, the WTO released the records of the meeting including WT/TPR/M/249, WT/TPR/M/249/Add.1 (containing advance written question posed by WTO members and replies by India) and WT/TPR/M/249/Add.2 (containing additional advance written question posed by WTO members and replies provided by India).

The questions rose by WTO members relating to patents and pharmaceuticals include such topics as compulsory licensing, exhaustion, patentability criteria and the protection of test data. The following piece is a walkthrough of the trade policy review of India in the context of IPRs and health technologies. Although the activities of the WTO TRIPs Council receive much scrutiny during discussions of controversial issues such as ACTA, public health and tobacco plain packaging, the WTO’s trade policy reviews have not traditionally attracted the same level of attention. While discussions within the Trade Policy Review Mechanism are often routine in nature, this is not always the case – as this post will highlight. Perhaps a more diligent

\textsuperscript{121} at Fortune Global Forum, New Delhi in October 30, 2007.
\textsuperscript{122} http://www.September%202011%20Spotlight%20on%20India%20at%20the%20WTO%20Trade%20Policy%20Review%20Knowledge%20Ecoloc.html.
examination of the goings-on of the WTO’s Trade Policy Review Mechanism is merited, to provide more insight into how TRIPs flexibilities are treated in the WTO system. From September 2012 to December 2012, the WTO will undertake trade policy reviews of the following countries: Korea, Norway, Bangladesh, Israel, Iceland, East African Community (Kenya, Tanzania, Uganda, Burundi, Rwanda), Nicaragua and the United States of America.

According to the WTO, The Trade Policy Review Mechanism was an early result of the Uruguay Round, being provisionally established at the Montreal Mid-Term Review of the Round in December 1988. Article III of the Marrakesh Agreement, agreed by Ministers in April 1994, placed the TPRM on a permanent footing as one of the WTO’s basic functions and, with the entry into force of the WTO in 1995, the mandate of the TPRM was broadened to cover services trade and intellectual property. The objectives of the TPRM, as expressed in Annex 3 of the Marrakesh Agreement, include facilitating the smooth functioning of the multilateral trading system by enhancing the transparency of Members’ trade policies.

All WTO Members are subject to review under the TPRM. The Annex mandates that the four Members with the largest shares of world trade (currently the European Communities, the United States, Japan and China) be reviewed each two years, the next 16 are reviewed each four years, and others be reviewed each six years. A longer period may be fixed for least-developed country Members. WTO members that raised questions related to India’s IPR regime in the context of pharmaceuticals include Australia, Brazil, Chile, Chinese Taipei Costa Rica, European Union, Japan, Switzerland and the United States. The following extracts are taken from WT/TPR/M/249/Add.1 unless specifically noted. WTO members that raised questions related to India’s IPR regime in the context of pharmaceuticals include Australia, Brazil, Chile, Chinese Taipei Costa Rica, European Union, Japan, Switzerland and the United States. The following extracts are taken from WT/TPR/M/249/Add.1 unless specifically noted.

4.11 CONCLUSIONS

By going through the chapter one can easily make out a large number of loopholes in the Indian Patent Act especially the amendments made to the patent law by India have been ostensibly to comply with its WTO obligations on intellectual property, the amended law represents a compromise between opposing
interests. This compromise has resulted in a complicated and confused law with potential negative consequences with regard to the patenting of medicines and drugs in patenting them on the issue of sec 3(d) new use of known substances. Patents on Pharmaceutical are for inventions, and not medicines per se. Thus patents may be granted for: a chemical compound or molecule; a medical indication or therapeutic effect of the molecule; the combination of products (e.g., a fixed dose combination of 2 or more molecules); or the manufacturing process (known as a process patent). There could be more than one patent for a single medicine, viz. the chemical compound as well as the process to make it can both be patented. It needs to be kept in mind that while above are the possible kinds of patents that can apply to medicines, national laws may restrict the kind of patents to be granted for medicines, viz. some laws can explicitly bar the grant of patents for drug combinations. There is huge cry from all the parts of the world as to its efficacy is concerned and India was questioned from all the parts of the world including the W.T.O that India has not complied in the strictest sense of complying the TRIPs Agreement on the other hand when it tries to issue compulsory licenses there is again opposition as to India has failed to take a correct decision in implementing the compulsory licensing proper interpretation has not been made in utilizing the flexibilities and hence has caused a great loss to the companies especially pharmaceutical companies which in turn withdraw their supply and manufacture of medicines in India which would affect greatly on research and development as the companies would stop spending money on the research activities in life sciences and pharmaceuticals in the light of the decision made by the Indian Supreme court on the subject matter of patentability and utilizing the flexibilities. There is no sufficient means to address the requirements as to fixing of the prices of patented products and their marketing is concerned the Indian Patent Act does not have sufficient provisions to find way as to how the procurement of the patented medicines by the government can be made in an effective manner to meet the local needs of the general public as regards to supply of medicines are concerned the Patent Act nowhere speaks about the public health policy in the light of Indian Patents Act. The utilization of CL and the multinational companies questioning it and WTO seeking explanations on the efficacy of the main provisions as to Patentibility and CL are questioned. The Patent holder has no duty whatsoever as a matter of public policy in addressing the health issues the act speaks only about the
protection of Patent holder and ignores health issues of the poorer section. Usually the Patents are utilized by the multinational companies and are involved in large scale manufacturing gets the advantage of least cost of manufacture moreover the companies setting up the business in India utilize the Income tax provisos. The companies purchase the patent rights from the patent holder by paying a particular consideration and that amount is shown on the asset side of the Balance sheet as intangible asset against which depreciation is claimed. The Government of India has currently made a provision for tax concession both to manufacturers and consumers of rich class as well for example the manufacturing industries are provided to allow deductions from their income or net profits on investments made on R andD, u/s 35 of the Income tax act expenditure on in-house Scientific research conducted in house both capital and revenue expenditures and prior period expenditure of three years are allowed as deduction, similarly u/s 35(1)(iiia) any contribution made to an Indian company for scientific research an amount of 125% of contribution made shall be allowed as deduction provided the approval shall be given by the chief commissioner of Income tax, Contribution made to the research association for scientific research u/s 35(1)(ii) the amount of deduction allowed is 175% of the contributions made and contribution made to a national laboratory/university etc 175% of the contribution made is allowed as a deduction and the conditions for claiming the deductions are the research institution should maintain the details of the of the work undertaken summary research articles published in the national or international journals should be made any patent or other similar rights applied for or registered during the year and future programmes should be detailed to the income tax authorities. Similarly for rich class persons or the assesses are provided the deduction for making an expenditure on payment of medical insurance or health care insurance u/s 80 D, to the extent of Rs 15000/-, Deductions for physical disability of the assessee u/s 80 u, a general deduction of Rs 50000/- and special deduction for severe disability the deduction is Rs 1, 00,000/- and the disability should be certified by the general surgeon, psychiatrist or an Oculist. Deduction u/s 80DD, an amount of Rs50, 000 in general cases and in special cases Rs 1, 00,000/- is given, again the deduction u/s 80 DDB provides for a deduction of Rs 40,000 or an amount actually incurred, whichever is less for senior citizens it is Rs 60,000/- and the expenditure should be in relation to the diseases such as neurological disease, Cancer, AIDS, Chronic renal failure, Haemophilia and
thalassaemia. All the benefits are provided are to the rich but on the other side the persons who are of low income class or persons of below poverty line are the real sufferers where in they have no earnings assessable by the tax authorities.

For the issue on consumer’s rights the same U.S which has forced to adopt strict compliance to the IPR regime advocates the rights of consumers and has identified the rights. The UN general assembly adopted the guidelines on protecting the human rights on 9th April, 1985, and is also called as “Chapter of Human rights” which includes Right to Safety, Right to information, Rights to choose, Right to be heard and Right to consumer education. The rights clearly shows that a person should not be discriminated or exploited unfairly and charge an exorbitant prices from the consumers on the product they offer moreover the consumers should be provided an opportunity to choose the alternatives this can be done only if there are availability of alternatives where as the grant of patent on products ensures that the consumers have no choice to choose. In case of the product patent regime when it provides the patent holder an exclusive right to manufacture and sell the product at a price fixed at his discretion again it is nothing but a violation of human rights. So efforts should be made to address the issue in a serious manner. The Indian Patent Act ignores the social cost benefit with regard to poorer sections and companies should come by their own in doing social service be reducing the prices of their medicinal products by corporate social responsibility.

The right to life and health is a fundamental right guaranteed to every person living in India and is not negotiable. But in new patent regime, product patent protection for medicines and agrochemicals creates monopoly and eliminates competition in the pharmaceutical market. Drug companies often abuse the patent monopoly and fix exorbitant prices for the patented medicines. The introduction of product patent thus reduces accessibility and affordability of drugs. The populations specially the down trodden and the poor do not have access to the medicines that could save lives is because the price of health is high, as many medicines are owned by pharmaceutical corporations that either sell their products at high prices, or request that the developing countries purchase licenses to produce or import those medicines. The result of this system is an obvious discrepancy between the prices of the medicines and the possibility of those who need them to acquire these required medicaments. Thus access to essential drugs is a key
ingredient for good public health. “The essential drugs” as defined by WHO are drugs that individuals can afford.” An unnoticed feature of this definition is the conflict between need and affordability of a drug. Whether or not a drug is considered essential must not depend on its price.

Given the large benefit that accrues to a patent holder through the temporary monopoly that it enjoys, it is legitimate to question what amounts to a good invention to deserve this reward. Patents are a public policy tool - to be balanced against other public policy needs and governments have the power to keep this balance. Ideally health considerations should play a decisive role in defining which inventions deserve protection.

The government acting on interest of consumers should use more often compulsory licenses in case the prices rise is beyond the reach of consumers and also if the medicines are not accessible to common citizens in numbers. The government on the other hand needs to also see the interest of producers whom we are given to understand invests substantial money in researching and bringing new drugs to the market. It makes sense for giving them (producers) protection in the form of patents if the producers are authentically involved in bringing abstract ideas into practice and are not pursuing their interest for maintaining monopoly positions. Therefore, Government has a larger regulatory role to play in context of the latter and they need to further see that the medicines reach out to the needy. The Government needs to deliver on the efficient delivery mechanisms. In context of global governance, India should support not only public private programs of RandD in dealing with the accessibility and affordability of medicines related to life style diseases (diabetes, blood pressure problems, among others) and malaria, polio, tuberculosis etc but also diseases pertaining to those of the developing countries.