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**Institutional and Procedural Challenges to
Generic Production in India:
Antiretrovirals in Focus**

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Abstract

The Indian pharmaceutical industry has played a central role in providing generic antiretroviral (ARV) medicine to national and global ARV therapy programmes over the last two decades. The industry practically, has become the primary supplier of generic medicines, ARV medicines in particular, to the developing world, through both international organizations and nation-level ARV access programmes. Given India's important role as a global supplier, this paper reviews the legal and political situation in India with special attention to adaptations in regulatory procedure and trends in jurisprudence since India's adherence to the WTO-TRIPS agreement in 2005. With a review of the historic role of India as a supplier of ARV medicines, the paper outlines some of the key rulings in Indian courts as the interpretation of the new patent laws are tested. Also presented is an analysis of the recent challenges to the Bolar exception in India. The main objective of the paper is to introduce the reader to some of the most crucial changes in Indian patent law and procedures which are likely to shape production of local ARV medicines.

Keywords : Indian pharmaceutical industry, HIV/AIDS, Antiretrovirals; Intellectual property rights

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1. Introduction

The ability to transform HIV/AIDS from a veritable death sentence into a manageable, chronic disease is largely attributable to two major shifts over the last decade or so: first, the political will to confront the disease and, second, the technical ability to supply antiretroviral (ARV) medicines. Recent gains in the expansion of access to ARVs have been unprecedented. ARV access has expanded remarkably over the last decade, during the period 2003-2007, for example, the number of people in the developing world receiving ARVs increased more than seven times (WHO, 2008). By the end of 2008, more than four million people in low and middle income countries were receiving antiretroviral therapy (ART), up from nearly three million just the previous year. More than a quarter of a million of those receiving ARVs were children (WHO-UNAIDS-UNICEF, 2009). These achievements, however, remain overshadowed by enormous challenges facing the global community. In 2007, 33 million people were living with HIV/AIDS, 2.7 million became infected with the virus and 2 million people died as a result of causes related to the virus. UNAIDS reports that only a third of those in developing countries needing ART are receiving it (UNAIDS, 2008).

For those who have begun treatment, major barriers remain for their continued access. In the developing world, where 95 per cent of the people with HIV/AIDS reside, issues regarding the supply of the first-line medicines have been largely hampered by accessibility and adaptability (MSF, 2008). Although it is now widely accepted that ART programs can be effectively managed in developing countries (Peterson *et al.*, 2006), putting an end to earlier debates about the dangers of ARV access provoking resistances

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(Harries *et al.*, 2001, Wadman, 2001), the rising costs of new first-line and second-line therapies are increasingly prohibitive (Orsi *et al.*, 2010). The average cost of new first-line and second-line ARV regimens are approximately US\$ 610 and \$ 1660 on average per-person per year (respectively) compared to the old generation of first-line treatment US\$ 88 (WHO, 2009). For those patients on ART, access to the second-line treatments will be critical if the gains of the first line-treatments are to be preserved.

The Indian pharmaceutical industry has played a central role in providing generic ARV medicines as national and global ART programs have expanded their operations over the last decade. More than half the drugs used for the treatment of HIV/AIDS patients in the developing world are produced in India. India's role as the so-called "pharmacy of the developing world"¹ and as a key supplier of HIV/AIDS ARVs,² stems from legal and industrial systems, which until 2005, did not recognize product patents. Since 2005, 70 per cent of ARVs purchased by the UNICEF, IDA, the Global Fund (GFATM) and the Clinton Foundation³ are being sourced from Indian producers (MSF, 2007). In addition to supplying generics India is also a major source of active pharmaceutical ingredients (APIs) - those bulk inputs which have been fundamental sources for the generic programs pursued in both Brazil and Thailand.

¹ In addition, over 80 per cent of the stock comprising Medecine Sans Frontier's (MSF), HIV/AIDS treatment programs are supplied by Indian firms. *Doctors Without Borders*, December 18, 2006.

http://www.doctorswithoutborders.org/news/access/novartis_qa.cfm. (Accessed December 28, 2006).

² Unni Karunakara, 'Medical Director of MSF's Campaign for Access to Essential Medicines', <http://www.accessmed-msf.org/> (Accessed February 7, 2007).

³ The Clinton Foundation HIV/AIDS Initiative (CHAI) supports national governments to expand high-quality care and treatment to people living with HIV/AIDS. CHAI offers reduced prices for ARVs to members of its Procurement Consortium. CHAI has agreements with eight manufacturers of ARV formulations, active pharmaceutical ingredients and/or pharmaceutical intermediates: Aurobindo Pharma, Cipla Ltd., Hetero Drugs, Macleods Pharmaceuticals, Matrix Laboratories, Ranbaxy Laboratories, Strides Arcolab and, Zhejiang Huahai Pharmaceutical Co. The ARVs included in CHAI's pricing agreements are: abacavir (ABC), didanosine (DDI), efavirenz (EFV), emtricitabine (FTC), lamivudine (3TC), lopinavir/ritonavir (LPV/r), nevirapine (NVP), stavudine (d4T), tenofovir (TDF) and zidovudine (AZT).

With India's harmonization of its patent standards with those set by the WTO's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), the Indian pharmaceutical firms will no longer be able to provide generic copies of ARV medicines for which patent applications have been filed according to the new rules set in India's Patent Office. The end of this system will have vast implications for the access to medicine issues around the world, in particular for populations in the developing world, where over 90 per cent of purchases are made through out-of-pocket payments and medicines account for the second largest household expenditure (Chan, 2010).

With this backdrop, this paper explores the post-2005 situation in India with special attention to adaptations in regulatory procedure and legal jurisprudence which could affect the production decisions of Indian generics pharmaceutical companies.⁴ The paper comprises three sections. The first reviews the historic role of India as a supplier of ARV medicine. An analysis of the three areas of patent law currently tested in Indian courts has been presented in the second section. The third and final section reviews debates regarding the implementation of the Bolar exception and so-called "patent linkage" in India. In conclusion, we reflect on how these changes may influence the strategies made by the Indian pharmaceutical firms. The aim of this exercise is not to provide a complete picture of transformations in Indian law, but to focus on those which are most relevant to production by the local industry.

⁴ The larger aim of the project, lasting two years, is to investigate how the production of ARVs has changed since the implementation of TRIPS standards and to identify how it will affect access to ARVs. This research project, directed by Keshab Das and linked in tandem with the grant application coordinated by Benjamin Coriat of University Paris, 13, titled "Production et Apparovisionnement en ARV Generics dans L'après 2005: Une analyse à partir des cas du Brésil et de l'Inde", proposes a three-fold but interrelated set of objectives - namely, legal, industrial and access - towards understanding the consequences of the product patent regime on production of first- and second-line ARVs and their respective active pharmaceutical ingredients by Indian generic firms. The on-going research will benefit from the larger research project directed by Professor Coriat and collaboration with Lia Hasenclever of the Universidade Federal do Rio de Janeiro.

2. “The Pharmacy of the Developing World” in Transformation

A contradiction confronts current efforts at dealing with the HIV/AIDS epidemic. Globally, whereas the political motivation to address the HIV/AIDS crisis has gained momentum,⁵ the future source for procurement of affordable ARVs, in particular, second-line treatments, appears increasingly dubious.⁶ Much depends, at least in the short and medium term, on outcomes in the Indian patent system where issues in the implementation of international patent laws are currently being debated. Throughout the 1990s, while other developing countries experienced a decline in their ability to produce the APIs necessary for ARV production, India’s capacity expanded with growing demand.⁷ During the period 2000-05, Indian generic competition was essential for reducing the first-line AIDS drug prices from approximately \$ 12000 per year to \$ 150 per year. In addition to providing a source of competitive ARVs prices, Indian firms’ ability to innovate on molecules patented elsewhere resulted in a series of technical improvements to ARV therapies. One such critical breakthrough ushered in by the Indian firms was the development of a “fixed-dose combination” drug

⁵ The scaling up of programmes on a global level, from the Global Fund to UNITAIDS, has been compounded by increased focus on the issue at the national level. A recent paper, “Programme Implementation Guidelines for a Phased Scale up of Access to Antiretroviral Therapy for People Living with HIV/AIDS” from the National AIDS Control Organization (NACO) highlights the importance of both global initiatives promoting the use of ARV treatment in addressing the HIV/AIDS epidemic, and the drop in prices for those treatments. See, NACO, http://www.nacoonline.org/guidelines/guideline_1.pdf

⁶ The current production of the first-line ARVs is sufficient, but as the Director General of India’s NACO, Dr. Quraishi, puts it, “the problem will come when we need second line drugs...I’m personally very worried about the second line drugs.” AIDS MAP, “India, China or Brazil, Who will produce the second line ARVs?”, Reproduced from *Health and Development Networks SEA-AIDS Forum Coverage of the 7th International Conference on AIDS in Asia and the Pacific*. July 12, 2005, www.aidsmap.com. (Accessed February 10, 2007.)

⁷ Kaul (2004) shows that Indian exports of pharmaceutical chemicals have been steadily growing over the last decade. In contrast, while Brazil is heralded as a successful case in its ability to negotiate with multinationals for lower ARV prices, its national pharmaceutical chemical base has witnessed a contraction in the already small number of companies producing ARVs. Brazilian laboratory Labogen, for example, has discontinued production of ARV APIs and Cristália has reduced production to three (Ritonavir, Saquinavir, and Saquinavir Mesylate).

compounding three ARVs in a single dose.⁸ During the 1990s, Asian manufacturers, largely Indian and Chinese bulk producers, played a critical role in the respective national government's ability to scale up programmes for universal access (Grace, 2004 and 2005; and Possas, 2005).

India's role as a global supplier of low-cost medicines is rooted in the nation's early policies to foster national industrialization in the pharmaceutical sector. In 1970, the Indian National Congress enacted a Patent Act which sought to address the low level of local production. The 1970 Act provided for patents for pharmaceutical processes but eschewed the granting of monopoly ownership for pharmaceutical products.⁹ This distinction opened the door for reverse engineering by Indian firms; and harboured the growth of one of the world's largest generic drug industries.¹⁰ Despite the achievements of Indian firms during 1970-95 in developing high skills of adaptation and growth, they face steep difficulties competing in innovation and remain a highly generic industry with comparatively meagre success in new molecule discovery.¹¹

During the Uruguay Rounds (1984-96), which culminated in the formation of the World Trade Organization, India was an avid negotiator for the

⁸ This was orchestrated by Cipla in the so called (D4T+3TC+NVP) combination.

⁹ It is important to note that process patents were granted for a period of five years from the date of the patent grant or alternatively, seven years from the filing date of a patent, whichever was earlier. Additionally, the 1970 Patent Act included multiple provisions for compulsory licensing of process patents. Three years after the sealing date of the patent, any party interested in working on the patented invention could apply for a compulsory license. Finally, the Patent Act included a clause for "licenses of right" enforceable three days after the sealing of the patent should the government believe that the invention was not available to the public at a "reasonable" price (FICCI 2003: 5).

¹⁰ According to Verma (2005: 436) Indian generic medicines account for 22 per cent of generic medicines worldwide. There is some disagreement about the actual source of Indian pharmaceutical development. A report from the Chemicals & Pharmaceuticals division of the Federation of Indian Chambers of Commerce and Industry (FICCI) concludes that the 1970 Indian Patent Act has been the "single most important factor pushing the growth and development of the domestic pharmaceutical industry" (FICCI 2003: 4).

¹¹ Srinivas (2004) outlines three core challenges for Indian firms in entering innovative areas: finance, experience and institutional environment.

rights of its generics industry, negotiating a transition period for the implementation of the new TRIPS standards which many developing countries hastily enacted (Jawara and Kwa, 2003). Over the following decade, several stages marked the transformation of Indian law from a process to product patent regime (Chaudhari, 2005).¹² Two of the most significant legislative changes took place in the last year of the transition. On the eve of the TRIPS implementation deadline, the Indian Parliament enacted the Indian Patent Ordinance (codified on December 26, 2004). The Ordinance was widely viewed as multinational enterprise-friendly, with the patent process lessening requirements for patent applications and terminating a clause for procedures for contestation of applications during the pre-grant period. In terms of trade impacts, the Ordinance constrained Paragraph 6, regulating export and provided for export only to those countries which had issued compulsory licenses. Finally, the Ordinance did not specify the procedure for issuing compulsory licenses.

The Ordinance provoked a great deal of concern among both the public health community and in intellectual rights law circles. In contrast, the final version of India's domestic application of IP law, the Patents (Amendment) Act of 2005 (henceforth, "the 2005 Act") which was passed in March, provided for a comparatively flexible framework and addressed some of the core issues which had not been addressed in the earlier Ordinance. The key change brought about by the 2005 Act was the extension of product patents in the area of pharmaceuticals and chemical inventions. The drug pricing and access implications of this change have triggered widespread anxiety among public health activists. The pharmaceutical companies, on the other hand, welcomed the change for its innovation-promoting implications. The Act defined new invention and patentability on the basis of three attributes – a novelty standard, inventive step and industrial applicability (Basheer, 2005). The Act also expanded on the exception provided under Section 3 (d) of the Patents Act 1970 and provided that any discovery of a new form of a known substance is not patentable unless it results in the enhancement of the known efficacy of that substance (*Ibid.*). Section 3 (d) was introduced as a measure to prevent the ever greening of patents, this rather liberal – and vague according to legal experts

¹² Mueller (2007) provides a thorough review of the key transformations in the three stages of the Indian patent system, arguing that the emerging system has taken on a "mosaic" nature, incorporating western standards and Indian norms.

- provision paved the way for a prolonged legal battle between Novartis and the Union of India, a case dealt with later in the paper. Another significant change was the introduction of the post-grant opposition mechanism and revocation mechanism to complement the pre-grant mechanism that the 1970 Act was already endowed with. This again is considered as a strategic provision that can effectively discourage frivolous patent applications.

One of the most significant changes in the Act, and the most promising in terms of use of TRIPS flexibilities, has been in the area of compulsory licensing. In pursuance of a TRIPS obligation, the 1999 amendment of the Patent Act provided for a mail box, where patent applications during 1995-2005 were to be put away to be reviewed in 2005 (Joseph, 2009). The Act provided that the generic companies that made significant investment and were producing and marketing drugs covered by the mail box applications prior to January 1, 2005 would be granted automatic compulsory licenses subject to payment of a reasonable royalty. This way the Act ensured that generic producers of such drugs continued their business even after the Act came into effect.

A number of scholars have attempted to understand how the Indian case reflects trends in the “harmonization” of international legal standards to a developing country (Kapczynski, 2009; Basheer, 2007) and what the quantitative effects of the TRIPS implementation in India might be (Fink, 2000; Chaudhuri *et al.*, 2003; Fink and Maskus, 2005; and Adams, 2008). Yet little consensus has emerged on how India’s adoption of the patent regime has affected the supply of medicine in great part, because the implementation of the standards continues to be undergoing a process of definition.¹³

One of the most important areas of flexibility which remained in place in the 2005 Act was a system of pre-grant and post-grant patent opposition channels.¹⁴ Patent decisions in India are administered by the Patent Office, which has four branches, in Kolkata (head office), Chennai, Mumbai and

¹³ Oxford’s Carolyn Deere-Birbeck (2009) has called this process the “Implementation Game.”

¹⁴ Discussion regarding “flexibilities” has garnered increasing attention in the legal and public health communities. One important contribution was a study published by the South Centre, see, Musungu and Oh (2006).

New Delhi.¹⁵ Patent applications in India could be routed through the national application system or, for foreign applicants, through the Patent Cooperation Treaty (PCT). In the year 2006-07, the conventional national applications were 3165, a 10 per cent increase over that of the previous year. The total applications through the PCT route were 19768, about 28 per cent higher than that of the previous year at 15467. In the specific category of medicines, the number of applicants for patents was 3239, an increase of 46 per cent from that of the previous year. The number of patents registered was 787, an increase of 72 per cent over that of the preceding year. Based on these statistics, revealing the immediate post-implementation trends, a rise in the general patent applications is visible, and particularly so in the sphere of medicines. Importantly, in terms of patent oppositions during the same period, the Indian Patent Office recorded 44 pre-grant oppositions and 27 post-grant oppositions. Despite receiving a relatively low proportion of applications for which there are oppositions in process, almost all applications for ART or cancer drugs face pre- or post-grant oppositions from national, or international groups.

3. Legal Turf Wars: Interpreting and Applying the Patent Law in India

Over the past 5 years, a number of cases in Indian jurisprudence have begun to shape the legal interpretation of intellectual property standards with direct results for the amendment's implementation. In this section, three cases have been presented with discussions on their preliminary implications for the Indian generics industry. These include: 1) a case testing the infamous Section 3 (d) clause setting a standard for levels of minimum innovation; 2) consideration of public interest; and 3) withdrawal of patent applications and the granting of voluntary licenses by multinational enterprises. The aim here is not to provide a complete review of trends in Indian patent jurisprudence, which is beyond the scope of this paper, but

¹⁵ Prior to the 2005 Act, the period for consideration of patents was approximately six years but now the Patent Office has undergone a series of steps to modernize the process, and suggests that this average has been reduced to three years. As part of the modernization process, the patent office has begun to computerize its systems. All applications filed after January 1, 2005 have their information held electronically (with a classification of the application, name of application, country type, etc.). The ability to track patents and their stage in the application process is of paramount public interest.

to focus on some of the key, recent political and legal issues emerging for the production of some life-saving medicines. Many of these cases are still under consideration; for those in which judgements have been released, appeals may leave the door open for debate for years to come.

a) Testing the Constitutional Validity of Section 3 (d): Novartis and Glivec

In 2006, the Patent Office in Chennai rejected the Swiss-based Novartis' patent application for the anti-cancer drug Glivec.¹⁶ The rejection of Novartis' application set into motion a series of rulings with implications reaching well beyond the question of the Glivec application. Novartis' response was not merely to appeal the rejection, but to question the constitutionality of Section 3 (d). As briefly discussed earlier, Section 3 (d) prohibits the granting of patents for what are considered negligible modification of existent drugs, defining such substances as a "mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance."¹⁷ This clause is considered critical in preventing firms from engaging in evergreening, or for firms' seeking extensions to monopoly rights for insignificant molecular adaptations. The Madras High Court rejected Novartis' claim, and found that Section 3 (d) was constitutional.¹⁸

Novartis, the Swiss pharmaceutical company, filed an application in 1998 claiming a patent over Glivec, a life-saving cancer drug to treat patients suffering from Chronic Myeloid Leukemia (CML). Glivec is the b-crystalline form of imatinib mesylate. Imatinib, the free base molecule, was invented by Novartis in 1992 and the 1993 US patent for imatinib discloses imatinib mesylate (US Patent No. 5521184). Despite this, Novartis filed the patent application in India in 1998 and argued before the Patent Controller that they had invented two compounds - imatinib mesylate and its b-crystalline form. Novartis had been granted patents on corresponding patent applications in over 40 countries including China and Russia. The Cancer Patient Aid Association filed a pre-grant opposition, claiming that Glivec could not be

¹⁶ Sold in the United States under the commercial name Gleevec.

¹⁷ The Patents (Amendment) Act 2005, Office of the Controller General of Patents, Designs and Trademarks, Delhi, India.

¹⁸ It also held that it did not have "jurisdiction" for evaluation of TRIPS, which has been artfully challenged in Basheer and Reddy (2008). For an excellent discussion on this case, see, Raju (2007).

patented. The Association claimed the grounds of (1) prior publication in an earlier patent, (2) obviousness, (3) lack of enhancement of efficacy, and (4) incorrect claim of priority.¹⁹

As India did not recognise product patents for pharmaceuticals at the time of this application, it was to be examined only after 2005. In the meantime, in 2003, Novartis obtained the exclusive marketing right (EMR) for imatinib mesylate based on its patent application. Based on the EMR, Novartis obtained orders from the Madras High Court to stop several generic pharmaceutical companies from manufacturing generic versions of imatinib mesylate, while the Bombay High Court did deny the same. While generic versions were available at a cost of around Rs. 8000 (US \$ 160) to Rs. 12,000 (US \$ 240) per month, Novartis sold its version at Rs. 120000 (US \$ 2400) per month. The court order resulted in the reduction of the supply of generic versions, and consequently impacted patients suffering from CML.

In 2006 the Indian Patent Office rejected the application on the ground that the product claimed by Novartis lacked a sufficient level of novelty and failed to show an increased efficacy over the known substance.²⁰ The base substance known at the time of application was not imatinib but imatinib mesylate; thus, Glivec being only a b-crystalline form of imatinib mesylate was deemed to be only a new form of a known substance and not an enhancement of efficacy. Rejecting Novartis' argument that it was 30 per cent more bio available in rats, the controller held that there had been no enhancement of efficacy.²¹ With the rejection of patent the EMR came to an end.

¹⁹ For a discussion of this case, see, points made by the Lawyers' Collective <http://www.lawyerscollective.org/hiv-aids/activities/legal-services-access-to-medicines-patents>

²⁰ It was noted by the Patent Controller that the 1993 patent claimed all salts related to the free base that was being patented. Since Glivec was a salt of that free base, and was obtained in the customary manner and was the form that the salt normally exists in, Glivec was a known salt and could not be patented. Since Glivec's salt form was the most thermodynamically stable and also the form that the salt normally assumes, it was obvious. In other words, the application only claims a new form of a known substance

²¹ <http://www.lawyerscollective.org/node/1042>

Subsequently, Novartis filed multiple challenges in the Madras High Court. It challenged not only the decision of the Patent Office rejecting its patent application, but also the Section 3 (d) of the Patents Act - a crucial public health safeguard introduced in the law by the Parliament to prevent evergreening. The company argued that Section 3 (d) was vague and not compatible with the Constitution of India and was not compliant with the TRIPS Agreement. Its position was that since the free base of imatinib was never patented in India, there was no question of extending the life of the patent and thereby engaging in evergreening.

In 2007, the Madras High Court rejected Novartis' challenge to Section 3/ (d) and held that it had no jurisdiction to determine the issue of TRIPS compatibility. In determining the issue of constitutional validity, the court held that the word "efficacy" used in Section 3 (d) had a definite meaning in the pharmaceutical field.

The set of appeals filed by Novartis challenging the Chennai Patent Office's decision was transferred from the Madras High Court to the Intellectual Property Appellate Board (IPAB). After the hearings over two months concluded in December 2009, the IPAB finally passed its order in June 2009. The IPAB too held that Novartis was not entitled to a patent on imatinib mesylate as its claimed product did not meet the requirement of increased therapeutic efficacy. The IPAB, however, reversed the findings of the Patent Controller on novelty and inventive step. It held that imatinib mesylate was novel and not obvious to a person skilled in the art. It also allowed Novartis to proceed with certain process claims.

Novartis approached the Supreme Court on August 28, 2009 arguing that the IPAB had wrongly relied on the interpretation of Section 3 (d) by the Madras High Court - that a patent applicant has to show an increase in therapeutic efficacy. In a statement justifying legal arguments, the company declared that "Section 3 (d) of the Indian patent law will limit pharmaceutical research and development in India because it limits the ability to patent incremental innovation". The company contended that "Acknowledging innovation by granting a patent is unrelated to the access to medicines issue. Improving access to medicines is a matter of making medicines available. Medicines can be made available through access safeguards in international agreements and, in the case of essential and life-saving

medicines, special pricing arrangements in developing countries can, and must, be made".²²

What are the implications of Novartis' legal challenge of Section 3 (d), a clause hailed as symbol of responsible use of public health safeguards? Any compromise with this section would eventually help pharmaceutical companies with deep pockets to patent incremental changes to the existing drugs. This would hamper competition in generic drugs which has been largely responsible for the reduction of drug prices and increased affordability and access. More specifically, access to recently developed second-line generic ARV drugs by people living with HIV/AIDS (PLHA) all around the developing world would be seriously affected by any weakening of Section 3 (d).²³ Mass scale treatment programmes for other diseases like tuberculosis too would also face rapid shortages of low-cost generic medicines.

b) Consideration of Public Interest: Roche and Tarceva

One of the fundamental characteristics of the Indian patent system is that while patents are valid for a period of 20 years, calculated from the date of filing/priority of the patent application (whichever is earlier), patents may be challenged through systems of pre-grant and post-grant opposition. Post-grant opposition was originally outlined in India's 1970 Patent Act, in Section 25 (2) and was brought forth in the 2005 Act. Procedures for post-grant opposition allow any interested party, be they representatives of civil society, or generic producing competitors, to challenge the validity of a patent as far as one year from the date of publication of the patent issuance.²⁴

The process of how post-grant oppositions are reviewed and what issues are taken into consideration during their review have been illustrated in a

²² http://www.novartis.com/downloads/about-novartis/Novartis_position-Glivec_Gleevec_patent_case_india.pdf. (Accessed September 26, 2010).

²³ http://www.care.org/newsroom/articles/2007/06/20070613_novartis.asp

²⁴ Recent post-grant opposition decisions include; Novartis vs. Cipla (DULERA), Gendon vs. Cipla (IPILL), Roche vs. Cipla (VALCYTE), Roche vs. Wockhardt (PEGASYS).

case which is currently ongoing between the Swiss-based Roche and local (Indian) producer Cipla.²⁵ Roche introduced the drug “Erlontinib” under the trademark name of Tarceva in India in April 2006 and was granted patent rights in June 2007. Nearly six months following the patent’s issuance, local generics producer Cipla launched a generic version called of Erlocip. In response, Roche challenged Cipla’s right to generic production and requested an injunction which would prohibit its manufacture.

Cipla’s response reflected the view of many local producers and public health groups in India; according to Indian jurisprudence there is no presumption of the validity of patents, given the multiple stages at which a patent application may face objection and review. Cipla suggested that examination and opposition at India’s patent offices comprise a first stage of patent review: “The patent is subject to scrutiny at several higher levels, unlike the case of trademarks.” In addition to its procedural arguments against the issuance of an injunction, Cipla argued that patent had been granted without proving sufficiently innovative under Section 3 (d). Cipla pointed out that Erlontinib was merely a derivative from quinazolin compounds, which are widely known to inhibit growth and proliferation of mammalian cells.²⁶

Thus far, the importance of this case has not been in the debates over the application of Section 3 (d). In 2009, Delhi High Court Justice Ravindra Bhat dismissed the request by Roche for an injunction, on the grounds that the Cipla alternative was being offered at one third the price of the originator product. Prohibiting the product from entering the market, before a full evaluation of the patent’s validity, would be in conflict with public interest. Bhat’s order represented, for the first time in India, that public interest was brought into explicit consideration in the rejection or granting permission of an injunction. As a number of HIV/AIDS cases move forward, having established the “public interest” precedent is an important and positive development in the wake of the 2005 Act.

²⁵ The case has now evolved into a full-blown series of suits against Indian producers, including locally based Matrix. See posts by Shamand Basheer, at Indian IP blog, SPICY IP, for full legal coverage of this case.

²⁶ An important case on evergreening which is used as a reference in this case is the ruling of the Madras High Court in *Novartis vs. Union of India*, 2007 (4) MLJ 1153. Cipla also shows three European patents of similar compounds dating back to 1993.

c) Defensive Strategy: GSK and Abacavir

While a number of important cases are currently being fought out in Indian courts others are taking shape in the public ambit. One such interesting example has emerged through the multiple cases of multinational enterprises which have withdrawn patent applications, or issued voluntary licenses. Such is the case of GlaxoSmithKline (GSK) which withdrew its application for Abacavir Sulfate in India in 2007.²⁷ The Indian Network of Positive People (INP+) had filed an opposition against the GSK's application, arguing that it did not meet innovative standards set out in Section 3 (d). The INP+ noted that in an earlier published patent (1991, EP 0434450) the release of sulfuric acids make the addition of hemisulfate salt an obvious step and therefore the mere large scale manufacture of these combinations does not entail sufficient innovation. The INP+ was joined in its patent opposition by the local producer Cipla.

In response to the oppositions generated by the Abacavir application, GSK withdrew its claim, citing its concern for the "public interest." A number of local groups questioned if the motivations of the company were less than altruistic and merely represented a calculated defensive strategy: "We wonder whether GSK is truly acting in the public interest or is avoiding the build up of case law by the patent office that could serve to hinder other similar applications/granted patents in India and other countries."²⁸

Withdrawal of a patent application in the face of public scrutiny or a potentially damaging case law is one approach multinationals appear to be adopting.²⁹ Another strategy is that of issuing a voluntary license to a select number of generic companies, essentially granting them permission to produce the product and, thus, avoiding costly legal battles over patent rights. Gilead Sciences, the proprietor of the key ARV Tenofovir Disproxil Fumarate, known by the brand name Viread, followed this route when it

²⁷ Marketed as Ziagen, application no. 872/Cal/1998.

²⁸ I-MAK, "Initiative for Medicines, Access & Knowledge," <http://www.i-mak.org/i-mak-blog-updates/2007/12/9/gsk-withdraws-its-application-for-abacavir-in-india.html> (Accessed June 1, 2008.)

²⁹ In another case, GSK withdrew its patent application in India for the ARV combination known as Combivir. Facing a similar controversy in Thailand, GSK adopted a similar strategy for Abacavir.

permitted 11 Indian generic manufacturers to produce the drug at a much lower price. Voluntary licensing, like the withdrawal of patent applications does not present a sustainable solution for public health groups because it depends on the interests of private firms. What these double-pronged strategies reflect in India is how firms are adapting to local challenges; with some products not worth the legal investment and others used as tools to create alliances with local industry.

4. Ensuring Generic Market Entry: Challenges to the Bolar Exception

The intellectual property standards established under the TRIPS agreement mandated the introduction of patent ownership for pharmaceutical products for all WTO members.³⁰ As discussed earlier, in a number of developing countries, India among them, pharmaceutical products were previously not considered patentable goods.³¹ Despite the push toward a universal, homogenous standard system of patenting processes, the TRIPS agreement did provide a number of flexibilities allowing for national governments to tailor international standards to local demands (Grosse Ruse-Khan, 2009). These flexibilities have been largely underutilized by developing countries, and have been the frequent target of bilateral trade agreements.³²

One specific area of flexibility is the so-called Bolar exception. The Bolar exception stipulates that generic manufacturers have the right to manufacture a patented drug in limited quantities during a period in which patent rights are valid. The exception allows generic manufacturers to produce a patented drug with the intent of collecting data to submit to drug approval regulatory

³⁰ See Part II, Article 5 of the TRIPS Agreement (http://www.wto.org/english/docs_e/legal_e/27-trips.pdf).

³¹ Brazil, for example, was another country which did not consider pharmaceutical goods patentable due to public interest. A number of developed countries also shirked patent systems for pharmaceutical products; as late as 1976, Switzerland did not have pharmaceutical patents (Chang, 2002).

³² A number of studies have identified a pattern in bilateral trade agreements between northern and southern partners, in which countries such as the United States make tighter patent restrictions a requirement of preferential trade status. See, Roffe (2004), Rathod (2010) and Morin (2006).

authorities. Regulatory systems in developed and developing countries alike may take as many as 1-5 years to grant approval for the entry of a pharmaceutical product into the market. In short, the Bolar exception allows generics firms to prepare products for market entry so that with the expiration of the patent period, generic alternatives are readily available.³³ Without the Bolar exception, generic firms would have to wait until a patent period had fully expired before initiating regulatory approval processes, thereby granting patent-holding firms a *de facto* extension of their product's market monopoly.

The rejection of Bolar rights is frequently referred to as “linkage” of the regulatory approval system with the patent granting processes, as restricting Bolar rights would mandate regulatory agencies to review only those market access applications which have patent rights. Linkage of patenting and regulation processes is currently opposed in a number of developing and developed countries, including the European Community and United States.³⁴

In India, the 2005 Amendment included the Bolar exception.³⁵ Generic firms in India may seek regulatory approval of drugs for which patents are valid; if firms go beyond the purview of activities related to seeking regulatory permission, and bring drugs to market without patent approval, they may be held legally responsible.³⁶ Yet, the ensured existence of the

³³ The name Bolar exception is derived from US case law more than a quarter of a century ago through the case Roche Products Inc. vs. Bolar Pharm. Co. Inc. 733 F: 2d 858 which ruled against the right of generic producers. This ruling was overturned by the US Congress' enactment of the Hatch-Waxman Act, which established the right to pre-term patent production for generic firms.

³⁴ See, Section 271 (e) (1) of the Drug Price Competition and Patent Term Restoration Act. For a discussion of recent rulings related to the Bolar exception in the United States, see Adelman, (2009).

³⁵ As ensured in Section 107A of the Patents Act (2002 version). The 2005 Act updated and expanded Bolar exception rights to include the act of “importing.” According to Indian legal scholar Shamand Basheer, this will “no doubt aid the efforts of generic manufacturers, who are exploring all possible means to help mitigate the adverse consequences of a pharmaceutical patent regime” (Basheer, 2005).

³⁶ An example is the case of cancer drug Tarceva, in which Cipla was granted the approval to market, although the drug was patented by the Swiss drug maker F Hoffmann-La Roche. Cipla went ahead with the production of Tarceva and a lawsuit proceeded.

Bolar exception in India has been repeatedly challenged by political and legal pressures to link patent and product approval systems. In 2007, the Drug Controller General of India (DCGI, the organization which regulates the market entry of pharmaceutical products) announced that he intended to reject applications for regulatory approval of patented generics from non-patented holders. Soon thereafter, facing an uproar in the public health community, this proposal was withdrawn. Nevertheless, in subsequent years, a number of legal suits levelled by the international pharmaceutical community have challenged the Bolar exception in India, arguing that the courts should restrict the ability of generics firms to seek regulatory approval for a product for which they do not enjoy patent ownership.

Two recent cases highlight the attempts of multinationals to challenge the Bolar exception in India. In January 2009, Bristol Myers Squibb (BMS) filed a suit against local generics producer Hetero Drugs. BMS argued that Hetero should be prevented from manufacturing, selling, or offering to sell “dastinib”. Dastinib is used by patients with leukemia. Hetero had not yet been granted regulatory permission for the drug at the time of the suit, nor had it brought the product to market. The Delhi High Court granted a restraining order in favor of BMS, ruling that permissions to seek regulatory approval amounted to patent infringement. Yet, in another ruling, in August 2009, the Delhi High Court rejected a suit brought by Bayer Corporation against Cipla Ltd. and the Union of India, arguing that the DCGI should consider the patent status for its cancer drug sofefenib tosylate. After initially granting an injunction on production of Bayer’s drug in October 2008, the Court’s final dismissal of the case included the “vexatious and luxury litigation which should be discouraged” (Lawyers’ Collective, 2009)³⁷. Bayer has now appealed the High Court’s ruling and the case is currently before India’s Supreme Court.

Legal attacks on the Bolar exception in India, and their continued evaluation in India’s highest courts illustrate that nearly half a decade following the passage of the Patent Amendment, fundamental issues regarding the

³⁷ The ruling can be found at, “High Court of Delhi at New Delhi,” LPA/443/2009. <http://lobis.nic.in/dhc/SMD/judgement/09-02-2010/SMD09022010LPA4432009.pdf>.

implementation of India's patent system are still under definition. India's DCGI is not qualified to evaluate the validity of patents granted, nor does it enjoy reliable data regarding which patents are granted (Shrivastava, 2008). In addition to these issues of institutional capacity, the policy implications of product-patent approval linkage would create a significant barrier to national and international access of generic drugs. The potential linkage of India's patent and regulatory approval systems would present a great challenge for local generic producers. A committee appointed by India's Ministry of Chemicals and Fertilizers (the Satwant Reddy Committee) was convened in 2007 to examine patent linkage and determined that it was not in India's interest, but the "implementation game" (Deere-Birbeck, 2009) regarding how national laws will apply international patent laws remains in full play.

5. Concluding Observations

This chapter has reviewed the importance of Indian generic products for global ART access, provided an overview of the major changes in Indian patent law through its 2005 Amendment, and introduced some of the most recent debates which would affect the implementation of patent law in India. The shape of institutions regulating the insertion of products in the Indian market, and the systems by which patents are granted, will have direct impact on the drugs which are brought to market by Indian firms and the strategies of these firms.

In the past, Indian firms have been at the frontline, not only in providing cheap, quality medicine to global health and public national programmes, but also in leading the way for a number of delivery system improvements and improved combination formulae, for which Indian firms have a history of developing. How do Indian producers react to the legal challenges they are facing in Indian courts and in other courts abroad will have a significant impact on the types of drugs they choose to produce. The cost of litigation, for example, can serve as a barrier for generic firms hoping to access developing markets.³⁸ Trends in the generic sector will lead, likely, toward local Indian firms adopting strategies for survival in the new competitive

³⁸ Managing director of Dr. Reddy's, Satish Reddy, reported that the firm spent US \$ 12 million on legal costs in 2005, equivalent to above 25 per cent of its R&D allocations. *The Economist*, "A Survey of Pharmaceuticals," p.17.

framework. We can expect for Indian firms to increasingly focus their resources on developing R&D for drugs intended for export where high-value revenue is anticipated. The battlefield of current litigation in India, much of it pending, will be critical in determining how the 2005 Act is interpreted and applied. The strategies of multinationals in relationship to their Indian competitors and the future of the Bolar exception will all be important issues in determining the future of low-cost ARV medicine production in India.

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