No Pills for Poor People?
Understanding the Disembowelment of India's Patent Regime

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'No pills for poor people? Understanding the disembowelment of India's patent regime'[1]

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Abstract

The recent amendment to the Patent Act, 1970 brings India into full compliance with its obligations under the TRIPs Agreement, in particular allowing for product patents in the area of pharmaceuticals and agri-chemicals. This amendment, the third to the 1970 Act, was characterised by a relatively muted rhetoric and a remarkable level of shared consensus amongst campaigners and critics. Focusing largely on domestic compulsions, as opposed to the global, the paper explores whether the shared consensus sets too narrow an agenda for patent reform. The paper suggests that the limits to implementing TRIPs are equally on account of ambivalence within the government with respect to intellectual property and the changing self-interest of sections of Indian pharma. Thus, despite a favourable international climate in the area of intellectual property (read Seattle, Cancun and Doha), the patent reform in India has been doubly constrained by the narrow agenda and domestic factors.

Keywords: TRIPs Agreement, patent reform, India, pharmaceutical industry, globalisation.

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[1] The title is obviously inspired by Lanjouw and Cockburn (2001), though with apologies for the transconfiguration.

Introduction

Having availed of the additional transitional provisions in Article 65.4[2] of the Trade-related Intellectual Property Rights (TRIPs) Agreement, India was obliged to introduce product patent for these exempt technologies by 1 January, 2005. This obligation follows two earlier binding deadlines with respect to patents. The first, a consequence of availing the additional transitional period, was an obligation to put in place by 1 January, 1995 mechanisms for receiving product patent applications in these exempt technologies (i.e., the 'mail-box' requirement, Article 70.8) and allow for the grant of exclusive marketing rights (Article 70.9). The second was an obligation to come into compliance with TRIPs at the end of the five-year transitional period available for developing countries (Article 65.2), i.e. by 1 January, 2000. The first case brought under TRIPS was by the United States alleging that India had failed to implement its obligations with respect to Articles 70.8 and 70.9. Following an adverse ruling, India enacted the first amendment, *The Patents (Amendment) Act, 1999* (No. 17 of 1999), adding Chapter IVA titled 'exclusive marketing rights'. The second amendment, *Patents (Amendment) Act, 2002* (No. 38 of 2002) was enacted on 25 June, 2002. The final patent-related obligation, product patents in exempt technologies, was to be enacted through the *Patents (Amendment) Bill, 2003*, but this lapsed with the dissolution of Parliament. The new government, the Congress-led and Left-backed, United Progressive Alliance decided to introduce a marginally revised version of the same as the *Patents (Amendment) Ordinance, 2004* (Ord. No. 7 of 2004) (henceforth, the Ordinance) in light of the 1 January, 2005 deadline.

These demands on a (developing) nation to revise domestic intellectual property law can be analysed in terms of historical changes in the global architecture of intellectual property governance. However, it is the case that domestic factors influencing the law-making process enjoy a degree of autonomy. It is in this interplay between the domestic and the global that pertinent insights may be gained with respect to law-making in general and the third amendment, specifically. The latter, in contrast to earlier amendments, is characterised by a relatively muted rhetoric[3] and a shared consensus (amongst critical commentators)[4]. This should not suggest the absence of contrasting views. Rather, to the contrary, there was some predictable bipolarity. The *Wall Street Journal* praised the government for resisting pressure from civil society organisations for "passing a new law [i.e. the Ordinance] that will allow it to be a respected partner in drug development [...] by approving patent legislation that will finally put a stop to decades of simply copying someone else's pharmaceutical breakthrough" (Anon, 2005b). In contrast, the *New York Times*, in a series of editorials, remained critical of the Ordinance (Anon., 2005a, 2005c), observing that

[2] All references to articles are to the TRIPs Agreement, unless specified otherwise.

[3] Here, compare Anon. (1998), Murlidharan's (1998), and Ramachandran (1999) with Sridhar and Narrain's (2005) and Punj's (2005).

[4] By way of example, recall the difference of opinion concerning the choice between either coming into full compliance with product patents or opting for the additional period of transition and granting EMRs (see, Anon, 1998, Murlidharan, 1998, Rangnekar, 1998).

'[S]eldom has India's Parliament considered anything of such global import. If Parliament can preserve India's ability to provide generic versions of these medicines, it will make the difference between life and death for millions of people at home and abroad" (Anon., 2005a). No doubt, there was reason, as shall be seen, to revise the Ordinance and make better use of remaining TRIPs-flexibilities. However, by largely focussing on the implementation side of the issue, the *New York Times* was reprimanding the bullied while refraining from bringing to task the bully[5].

The focus of the article is on the shared consensus amongst critical commentators[6]. By way of example, the prescription in the *New York Times'* Editorial (Anon., 2005a) is highly consistent with Abbott et al. (2005). And not too dissimilar are the issues raised and amendments to the Ordinance proposed in Dhar and Rao (2005a) and Sengupta (2004)[7]. Noting this *consensus* across key commentators, the article does not seek to identify the 'fountainhead of ideas' or the processes through which this cognitive lock-in might have occurred. Rather, it explores whether this *consensus* sets too narrow an agenda for the third amendment. In doing so, the article suggests that the limits to amending the 1970 Act are equally on account of domestic factors like ambivalence within government and the changing self-interest of sections of Indian pharma industry.

The paper begins with a discussion of India's Patent Act, 1970 (henceforth, IPA) where key provisions are discussed and presented in terms of the consequent transformation of the pharmaceutical sector. This is followed by an analysis of recent changes in and around the Doha Declaration that have changed the context of TRIPs-implementation. It is within these two frames that the third amendment is presented and analysed. A conclusion closes the paper by drawing attention to changing perceptions and governmental ambivalence with respect to intellectual property and noting how this might have constrained the opportunities to launch a radical challenge to the proposed amendments of IPA.

The 1970 Patent Act

Patents in India have their origin in the 1856 Act for Granting Exclusive Privileges to Inventors, which along with other Acts was consolidated into the Patents and Designs Act, 1911. A need to comprehensively review the Act was noted soon after independence and became the subject of analysis of

[5] Notable in absence is the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA has substantially influenced the US government at various key moments through the negotiations of TRIPs and subsequently in its process of implementation. This influence is exercised through, among others, the association's submissions to 'Special 301' Commission and its estimates of trade-loss to the National Trade Estimate Report. Recently, it "conservatively" estimated annual losses on account of India's weak patent laws amounted to US$1.7bn (PhRMA, 2002); thus, suggesting that over 25% of the Indian market is 'pirated'.

[6] This statement is based on the author's review of the following: Abbott et al. (2005), Anon. (2005a), Dhar and Rao (2005a, 2005b), Gopalkumar and Amin (2005), Punj (2005), Rajkumar et al. (2004), and Sengupta (2004, 2005).

[7] Without overemphasising the *consensus*, there are differences in the emphasis authors have placed on specific issues and these are accordingly noted. Equally, there have been differences in the reception to the final legislation. Thus, the special correspondent (Anon., 2005d) to this journal has deemed it a confused piece of legislation, while Sridhar and Narrain (2005) characterise it as a 'tempered patent regime'. Yet, the broad contours of the debate have been shared by all commentators.

two expert committees: the Tek Chand Patents Enquiry Committee (1948-50) and the Ayyangar Committee (1959). Despite a number of recommendations by the Tek Chand Committee, a single amendment to the 1911 Act was enacted in 1952 to allow compulsory license of patents in the field of food or medicine (cf. Act LXX of 1952, adding Sec. 23CC to the Patent and Designs Act, 1911)[8]. The Ayyangar Committee's *Report on the Revision of the Patent Law* (1959) set the stage for a deliberative, participatory and transparent process. A bill[9] based on the recommendations of the Expert Committees was referred to a Joint Committee of the Parliament which received oral and written testimonies from individuals, firms and groups from India and abroad. Hans Harms of the German Federation of Pharmaceutical Industry noted that it is "remarkable and an expression of exemplary fairness that you [i.e. the Joint Committee] have decided to study the opinion of organisations and experts of other countries concerning the provisions under consideration" (quoted in Vedaraman, 1972). Pertinent here is Justice Krishna Iyer's (2000) glowing tribute to the law and process of law-making: "A well debated, development-oriented and patriotically processed statute of 1970, with a progressive perspective ….passed after a thorough study [cf. the Ayyangar Report] proved [to be] a tremendous national triumph". This stands in marked contrast to the current disembowelment of the 1970 Act.

The IPA sought to 'make patents work for the nation'; thus, reversing regressive aspects of the colonial act. This point is corroborated by various pieces of evidence, such as the subsequent price of drugs in India in comparison to other developing countries, the emergence and growing competency of an indigenous pharmaceutical industry, and the export earnings of these firms. This is true. However, the IPA should be viewed in a broader framework that places it as a constituent element of two interrelated policies: reforming the drug system and building indigenous scientific and technological capacity.

At the time of independence, drug availability was substantially controlled by MNCs, operating a small number of plants, which formulated a limited range of medicines while importing the balance; hence the relatively high price of drugs[10]. Most MNCs set up formulation and bulk production facilities decades after being established in the country. Other problems related to the marketing practices of these companies, such as the mark ups on prices, excessive promotional efforts, creation of artificial scarcities and insufficient disclosure of information. An example is Parke Davis' promotion of choloramphenicol, an antibiotic commonly prescribed for typhoid, as a common cure for infections like coughs and common cold. Its wider use led to a build-up of resistance and drug ineffectiveness, which had a devastating impact during the typhoid epidemic in South India in the 1960s. To address these issues the government adopted

[8] As the procedures remained cumbersome, foreign patentees continued to delay the grant of CLs. Following this amendment and upto 1972, only five applications were made, of which only two were granted, one was refused the other two withdrawn (Chaudhuri, 2002).

[9] To be pedantic, a bill was initially introduced in 1965 and then again in 1966; both of which lapsed.

[10] This paragraph is based on Bidwai (1995).

a set of policies. One set of regulations were directed at information and pricing through the Drug (Display of Prices) Order, 1962 and the Drug (Price Control) Order, 1963. The other policy changes included establishing drug production facilities within the public sector (e.g. Hindustan Antibiotics Ltd. and Indian Drugs and Pharmaceuticals Ltd.)[11] and the introduction of a system for drug testing by state-level Food and Drug Administration. Reform of the patent act was part of this set of interventions in the drug system.

These changes were consistent with *new ideas* on decolonisation and development that were in currency in this period (cf. Escobar, 1995; Sell, 1998) and the accumulating evidence concerning the functioning of the international patent system (Bagchi et al., 1984; Patel, 1974; Penrose, 1973; UN, 1964). New nation-states were coming into existence after the rules governing the global economy had largely been designed, debated and deployed. Increasingly frustrated with the liberal rhetoric of "trickle-down" and "rising tide lifts all boats", many 'developing' states made a call for a *New International Economic Order*, sought import-substitution policies, and also considered delinking national economies from global channels of trade and commerce (e.g. Amin, 1990). India in 1970, along with Brazil in 1971, the Andean Pact in 1974, and Mexico in 1976 revised national IP legislation, codifying their dissatisfaction with prevailing international principles governing technology transfer (Sell, 1998). Exploring space that existed for the autonomous determination of the domestic architecture of IP law, these countries sought to use IP law to foster indigenous technological development. Some of the key changes are the following:

- Patentable subject matter: Section 2(j) sets out the definition of 'invention', whilst Section 3 lists subject matter that is deemed non-patentable. This includes exceptions such as frivolous inventions, inventions that are contrary to morality or injurious to public health, mere discoveries, admixtures, trivial re-arrangements, etc. In addition, inventions related to atomic energy are not patentable (Section 4).
- Patentability in the area of Chemicals, Food and Drugs: Chapter II, Section 5 sets out that inventions in this technological area will be limited to claims concerning methods or processes of manufacture; thus, prohibiting claims to the substance (i.e. product patents)[12].
- Term of protection: Chapter VIII, Section 53 provides a general period of protection of 14 years from the date of filing. In the case of inventions in chemicals, food and drugs, the term is seven years from the date of filing or five years from the date of sealing the patent.

[11] Gehl Sampath (2005) makes an important observation on the role of public sector companies in fostering technological absorption and spin-offs on account of the entrepreneurial activities of ex-employees. Notable here is Dr Reddy's Laboratories, one of the top three indigenous pharma companies that were set up by a former employee of Indian Drug and Pharmaceuticals Laboratories.

[12] The rationality of this provision is captured through a quote from Justice Ayyangar's Report (1950, p36): "I have considered the matter with the utmost care and have reached the conclusion that the chemical and pharmaceutical industry of this country would be advanced and the tempo of research in that field would be promoted if the German system of permitting only process claims were adopted."

- Compulsory licensing and royalties: Detailed provisions exist for the issuing of licenses, aimed as they are at deterring the abuse of economic power of a patent (e.g. particularly Chapter XVI). For instance, compulsory license can be applied for only after three years from the date of grant (Section 84). In addition, in sectors of vital public interest (e.g. food, drugs, chemicals, etc.), 'licenses of rights' exist (automatically)[13] at the end of three years from patent grant, which allow any interested person to seek a license, subject, of course, to payment of royalties (Sections 87, 88). Section 95 sets out the mechanisms for setting the terms and conditions for compulsory license, in particular considerations regarding the royalty rate. A ceiling rate of 4% of net factory sale price in bulk is set. In sectors of vital public interest, where licenses of right have been granted, a ceiling rate exists (Section 88(5)).
- Working of a patent: Chapter XIV is guided by the principle that patents are granted to promote the domestic working of a patent (section 83(a)) and not to engender import monopolies (section 83(b)). Section 89 provides the broad contours for revocation of a patent for non-working, which is largely premised on the non-satisfaction of the 'reasonable requirement of the public', which includes, inter alia, domestic demand not being met by manufacture in India (90(a)(ii)), development of domestic industry is prejudiced (90(a)(iii)), insufficient working of the invention (90(c)), and domestic working of the invention is hampered by importation (90(e)).

These changes to national patent law lie at the heart of building indigenous technological and scientific competency. Improved technological capability is reflected in the increased share of patents granted by the US patents office from 0.02 per cent in 1977-87 period to 0.06 per cent during 1996-2000 (Kumar, 2002: table 2). Although marginal, India fares well in comparison to other developing countries – ranking seventh in 1998[14]. Another indicator of this competency is the relatively short time lag between international launch and domestic introduction of new medicines. Importantly, domestic introduction was largely by indigenous firms who discover new processes to produce known chemical entities (Bidwai, 1995)[15]. This competency should not be belittled. Lanjouw (1998, p26) reports of Ranbaxy's three-year and US$20Mn effort to get around the 56 patented processes to produce Eli Lilly's drug cefaclor. Equally, there has been a remarkable transformation in the pharmaceutical industry with the emergence of domestic firms. By 1991, domestic firms accounted for 70 per cent of the bulk drugs production and 80 per cent of formulations were produced in the country (Lanjouw 1998). While in 1970, amongst the top ten firms in terms of retail sales only two were indigenous (Lanjouw, 1998), by 1996 this rose to six and

[13] Despite an 'obvious' similarity between IPA and the UK Patents Act (1949), the former provides for 'licenses of rights' in sectors of 'vital public interest' (Vedaraman, 1972). 'Licenses of rights' were introduced to pre-empt the delaying tactics of patentees who sought judicial review, provisions for which continue to exist in the Act.
[14] In chemicals and biotechnology, the country ranks fourth.
[15] At times, indigenous firms had to overcome MNC's resistance to share knowledge even upon patent expiry. For example, in the late 1960s, Pfizer refused to share knowledge concerning Teramycin upon patent expiry so as to prevent post-patent price competition; thus, Dr Sarabhai Laboratories engaged in extensive reverse engineering (Gehl Sampath, 2005, p21).

by 2001 it was eight (Gehl Sampath, 2005, p22). This industrial restructuring has been accompanied by rapid growth of the pharmaceutical industry, reportedly crossing 15% per annum (1990-95) (Katrak, 2004). A substantial part of this growth has been absorbed by exports, with pharmaceuticals now ranked as the second largest export industry in the country (Gehl Sampath, 2005, p15). Even while the country's share of world merchandise exports stagnates at 0.6% (1970-98), its share of world pharmaceutical exports increased 2.5 times (Kumar, 2002). The country now ranks second after China amongst developing country pharma exporters.

These trends are concretised in the widely quoted evidence of the relatively low price of drugs in India – and by extension the loss of consumer welfare that might occur with full TRIPs compliance. In this matter, Hamied (1993) recalls that the Kefauver Committee in the US noted that (in 1961) 'India ranks amongst the highest priced nations of the world [with respect to drugs]'. It is against this background that the fall in prices following the 1970 Patent Act is noted. Lower prices in comparison to developed countries might be explained in terms of 'what the market can bear'; however, a price difference with countries with similar per capita incomes makes the point. A number of estimates have been made of the potential consumer surplus loss from price increases following the introduction of product patents. An exercise by Watal (2000) estimates price increases in the range of 26% (for linear demand curves) to 242% (for a constant elasticity demand curve).

The global context: Chipping away at constrained sovereignty

The above transformation occurred at a particular historical juncture. In terms of the evolving architecture of intellectual property governance, three phases have been identified: national, international and global (Drahos, 1997). The national phase corresponds to a period when nations used intellectual property law to positively discriminate in favour of domestics. In the US, patents were initially restricted to nationals and when foreigners could seek patents they were discriminated against: in 1836, patent fees for foreigners were 10 times the rate for US citizens and only in 1861 were foreigners treated in an almost non-discriminatory manner. The 'international phase' is marked by the establishment of the two pillars of multilateral IP agreements: the Paris Convention for the Protection of Industrial Property (1883) and the Berne Convention for the Protection of Literary and Artistic Works (1886). Largely promoted by technology-exporting countries, these Conventions primarily sought adherence to the principle of national treatment so as to ensure that contracting states treat foreigners on par with nationals. Thus, space was saved for the sovereign determination by contracting states of the protection to be granted within national territory. Consequently, difference between contracting states in the domestic contours of intellectual property protection: the subject matter protected, the rights conferred and the exceptions to those rights.

The global phase is heralded by the completion of the Uruguay Round Agreement and characterised by the strong limits to sovereign space for autonomous determination of the domestic architecture of IPRs. To reiterate well rehearsed statements, the TRIPs Agreement is unique in not only consolidating pre-existing IP Conventions – notably Paris (cf. Article 2.1) and Berne (cf. Article 9.1) – in a single agreement, but also in its comprehensive coverage of different instruments of IPRs within a single agreement. It goes beyond these Conventions by establishing (high) universal minimum standards across all fields of technology, supported by detailed and substantive rules with time-lined implementation. Additionally, there is the WTO's dispute settlement system in which these obligations are enforced through mandatory and time-bound adjudication backed up by cross-sectoral retaliatory sanctions upon non-compliance.

TRIPs has been constantly resisted and challenged from within and outside[16]. This resistance is partly mapped by the time lag in completing the Uruguay Round or currently in terms of the persistent difficulty to start a new round (read Seattle and Cancun). For that matter, holding a WTO ministerial remains problematic as testified by the choice of post-Cancun sites for Ministerial meetings, like Doha and Hong Kong, where popular participation and protest is constrained. Equally, a variety of civil society organisations have mobilised themselves to 'resist' TRIPs. Thus, in India during the Uruguay Round, the National Working Group on Patent Law provided a crucial base for informed resistance. More recently, an international coalition of 189 NGOs, the 'TRIPs Action Network', called for "a fundamental re-thinking of TRIPS in the WTO … urging WTO members to initiate a process of reviewing and reforming TRIPs" (Anon., 2001c)

Equally, policy makers and consultative bodies have questioned TRIPs. For instance, the UK government's Commission on IPRs (CIPR, 2002) questioned the 'one size fits all' approach of TRIPs and recommended revisions to the standards to take into account the needs of developing country governments and their nationals. More trenchant is UNDP's suggestion that the "relevance of TRIPs is highly questionable for large parts of the developing world," and recommendation for an epistemic revolution with developing countries "begin[ning] dialogues to replace TRIPs . . . with alternate intellectual property paradigms" (UNDP, 2003, pp 221-22). Symptomatic of this challenge is the post-TRIPs proliferation of inter-governmental agencies and forums dealing with and deliberating on IP. These include the World Health Organisation[17], the Food and Agriculture Organisation[18], the Conference of

[16] Opposition to TRIPs often occurs in the context of popular protest against the WTO.

[17] Most recently crystallised in the work of the Commission on Intellectual Property, Innovation and Public Health, set up in 2003 (see http://www.who.int/intellectualproperty/en/).

[18] The International Treaty on Plant Genetic Resources for Food and Agriculture has a number of articles with IP provisions, notably article 12.3(d) requiring that recipients "shall not claim any intellectual property or other rights that limit the facilitated access" to plant genetic resources, or their "genetic parts or components", in the form received from the Multilateral System.

Parties of the Convention on Biological Diversity[19], and the UN Commission on Human Rights[20]. Within this setting of forum-shifting and shopping, the Doha Declaration (WTO, 2001b) deserves special mention. Not only is it the consequence of an initiative of the *coalition of the weakest*; but it is an indicator of the success of the transnational NGO network in foisting an alternative frame on TRIPs where stringent IP obligations are seen as working against public health objectives (Sell and Prakash, 2004). Not surprisingly, Helfer (2004, p5) wonders if this is the harbinger to "revise, reinterpret, or supplement intellectual property protection standards adopted in the WTO and in WIPO"?

A series of developments prior to and subsequently after Doha are pertinent. For instance, the anthrax cases in North America in October/November 2001 brought into focus measures to promote access to medicine, with the US and Canadian governments considering measures that included federal appropriation of Bayer's patent in ciprofloxin and issuing compulsory licenses. There was also news of seeking generic supply from India (Joseph, 2001). Another key event was the challenge[21] of the South Africa's Medicines and Related Substances Control Amendment Act (1997) launched in 1998 by 38 pharmaceutical companies[22]. This amendment sought to help the government to respond to the looming HIV/AIDS crisis by, among other things, authorising parallel imports from third countries where the drug was being manufactured (cf. Section 15C). Eventually, in April 2001, on the back of a campaign by the transnational NGO network, the companies withdrew their challenge (Bond, 1999).

Equally significant, was the aborted US-Brazil WTO-dispute (WTO, 2000b, 2001a). The US was aggrieved by compulsory licensing provisions in Brazil's *Industrial Property Law No. 9279* (of 1996) and in the Presidential Decree on Compulsory Licensing (Decree No 3201 of 6 October, 1999). Controversial, as suggested by the US submission, was the presumption that 'local working' of a patent can only be satisfied by the local production and not importation (WTO, 2000b). Even while the US withdrew its request for a panel a few months later in June 2001, it strongly expressed its views on the subject: "The United States continues to view local manufacturing requirements as being inimical to the principles of free trade and inconsistent with various WTO rules, including the TRIPs Agreement. The US government will aggressively engage other countries that impose or maintain such requirements and, if appropriate, pursue WTO dispute settlement" (Anon., 2001b).

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[19] The Convention's principles, among others, is the fair and equitable sharing of benefits arising from the use of genetic resources. Thus, it has a number of articles with IP-provisions that deal with technology transfer, access to and use of genetic resources and traditional knowledge, and informed consent.

[20] Resolution 2001/33 passed at the 57th session of the Commission recognises access to medicine, particularly in pandemic situations, as a human right.

[21] An indication of future confrontation was the removal, in 1998, of South Africa from the Generalised System of Preferences, a preferential regime for accessing the US market. The following year, the country found itself on the S301 watch list.

[22] The Pharmaceutical Manufacturers' Association of South Africa et al vs The President of the Republic of South Africa et al, Notice of Motion, High Court of South Africa (Transvaal Provincial Division), 18 February, 1998.

These events are important milestones in a journey the end of which is not yet known. The specific contours of TRIPs compliance remain unanswered till a dispute actually goes through the WTO process. In the present climate this seems unlikely, despite the grand posturing by the US. Rather, forum shifting and shopping by developing countries and their allies are "challenging established legal prescriptions and generating new principles, norms, and rules of intellectual property protection for states and private parties to follow" (Helfer, 2004, p6). It is in terms of these developments that have chipped away some of the constraints facing developing countries that amendments to IPA should be examined. At issue is whether new space carved out in the global translates into the domestic IP law-making.

The third amendment: A consensus to concede?

The Joint Action Committee Against Amendment of the Indian Patent Act recognised the developments noted above and advocated a full exploitation of the flexibilities that remain in the TRIPs Agreement (JAC, 2004). In assessing the third amendment, it is also useful to keep in mind the industrial transformation achieved following the 1970 Act. Thus, at issue is whether there were opportunities that policy activists did not raise and/or policy makers did not take. Reviewing the third amendment debate, the following policy themes are evident:

- The criterion of patentability: conditions for grant of protection, pre- and post-grant opposition, exclusions from patentability.
- Access to medicine: export of generic medicine, provisions related to compulsory license, the opening up of mailbox applications.

The first set of issues related to well-documented practices in the pharmaceutical industry of pursuing patent thickets by seeking and securing multiple patents around a single invention[23]. A variety of economic problems are associated with patent thickets, for instance, transaction costs rise substantially where innovation depends on having access to existing patents held by many different owners. Thickets arise when trivial modifications like changes in size, colour, dosage, delivery mechanism, and composition, around a known and patented molecule are either simultaneously or subsequently protected. In addition, new formulations and combinations of existing active ingredients are also protected by patents. Between 1989 and 2000, of the 1035 new drug applications approved by the US Food and Drug Administration, 361 (or, 35%) were for new chemical entities and the balance, 65%, were incrementally modified drugs (NIHCM, 2002). Another consequence is that these practices render non-existent the finite time-limit of patent terms as new patents continue to keep the molecule under patent protection; hence the

[23] For a recent treatment see the US Federal Trade Commission (2003).

term of 'evergreening patents' (NIHCM, ibid.)[24]. This is not new; the US Senate Committee headed by Kefauver (1959) noted that many molecules were 'manipulated' and therapeutically similar to existing molecules (see Comanor, 1986). While it has been noted that "innovation constitutes one of the key sources of competitiveness in this industry and it is a major determinant of market structure" (Gambardella et al., 2000, p36), it is also the case that innovation occurs in the form of 'me-too' drug development – an activity predicated on the dual prongs of incremental product modifications and obsolescence: the six statins in the market (Mevacor, Lipitor, Zocor, Pravachol, Lescol and Crestor) are all variants of the first (Angell, 2004). Zantac is a classic example: the US regulatory body, the Food and Drug Administration, classified it as providing "little or no contribution to existing drug therapies", viz. Tagamet; yet, aggressive pricing strategies and intensive marketing led to its dominant position (Sutton, 1999). Commentators drew attention to the 8,000 plus applications for product patents in the 'mail-box' during a period (1995-2003) when the US Federal Drug Administration is said to have approved only 274 new chemical entities. The suggestion being that a substantial number of applications are either 'me-too' drugs or incremental modifications.

It is to practices like these that amendments to the Ordinance were proposed, recommending, *inter alia*, clearer language to raise the goal-posts for patentable subject matter and clarify exclusions from patentability. Other proposals concerned reinstating and strengthening provisions for pre-grant opposition measures; the hope being that this would wean out frivolous patent applications at an early stage. In response to these criticisms the following amendments were enacted:

- Definition of 'inventive step' amended though the addition of the following italicised text: *an invention that involves technical advance as compared to existing knowledge or having economic significance or both* and that makes the invention not obvious to a person skilled in the art (Section 2[ja]).
- Definition for 'new invention' inserted: 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 (Section 2(1)(l)).
- Definition for 'pharmaceutical substance' inserted: any new entity involving one or more inventive step.
- Exceptions to patentability (Section 3(d)), re-drafted to read as follows: the mere discovery 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

[24] A recent example would be the anti-histamine, Fexofenadine, that Aventis initially patented in 1979 (US Patent No. 4,254,129). Prior to the expiry of this patent, in 1996, Aventis was granted a patent claiming "a substantially pure compound" (Gehl-Sampath, 2005).

known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

- Reinstating pre-grant opposition: A new chapter V (headed, *Representation and Opposition Proceedings*) is introduced that reinstates provisions for pre-grant opposition[25].

These amendments have been deemed as confusing (Anon., 2005d) while others have criticised them for remaining ambiguous and allowing wide and differing interpretation (e.g. Gopalkumar and Amin, 2005). Some ambiguity (or, rather flexibility) in law is not in itself a problem as this allows response to a changing policy landscape. It is through context and practice that the architecture of law, i.e. principles and doctrines that give specific meaning to provisions, gets articulated. Others recognise an insidious element. Dhar and Rao (2005b) suggest that applicants will exploit the 'economic significance' element in the definition of inventive step by exaggerating claims. This is reminiscent of the 1889 Congo Red patent dispute in German courts (Belt and Rip, 1987 for a discussion).

The second set of issues relate to access to medicine. As Abbott (2002) notes, pertinent here was the opening-up of the patent applications lying in the 'mail-box'[26] and the loss of previously existing flexibilities related to compulsory licenses. It is probably here that developments around Doha, as noted above, have deep significance. Unfortunately, the Ordinance did not exploit these opportunities. For instance, even while India was an active participant in the deliberations leading to the August 2003 Decision (WTO, 2003)[27], the Ordinance did not incorporate this provision in that Section 92A(1) required eligible importing country to issue a compulsory license.

Responding to this lacuna, section 92A(1) was amended with the addition of the following text: 'or such country has by notification or otherwise allowed importation of the patented pharmaceutical products from India'. Further, section 90(1)(vii) was redrafted and a new sub-section introduced which states that, under certain conditions, exports are permitted when production occurs under a compulsory license. No doubt, the efficacy of these provisions is critically dependent on measures governing compulsory licenses. Compulsory licenses are framed by Article 31[28], are designed to act as a restraint on the rights conferred by patents[29]. Echoing the CIPR's (2002, p44) recommendation that "developing countries should

[25] Despite restoring pre-grant opposition, neither representation making the pre-grant opposition be party to the proceedings (Section 25(2)) nor is there a right of appeal.

[26] The eventual grant of a patent to a mail-box application raises the perplexing question concerning the future of existing generic production where it currently exists.

[27] The key breakthrough meeting to secure an agreement on the Decision convened by Chair of the TRIPs Council, Vanu Gopala Menon of Singapore, comprised the Brazil, India, Kenya, South Africa and US. The draft produced by this group formed the essential solution that became the agreed text of 30 August 2003.

[28] Article 31 provides a very detailed structure to the provisions for compulsory licenses: 'case-by-case' review [Art. 31(a)], prior request for voluntary license [Art. 31(b)], specified scope and duration [Art. 31(c)], non-exclusive [Art. 31(d)], non-assignable [Art. 31(e)], use predominantly for supply of domestic market [Art. 31(f)], remuneration of patent holder [Art. 31(h)], provisions for review by patentee [Art. 31(i) and (j)].

establish workable laws and procedures to give effect to compulsory licensing and provide appropriate provisions for government use", commentators proposed amendments to quicken and streamline the process. The other criticism of the Ordinance related to royalty rates, with commentators proposing an upper limit on rates set at 4-5% of the sales turnover at ex-factory prices. The only recommendation introduced has procedural significance: an explanation to Section 84(6)(iv)) now states that 'the reasonable period under this clause shall not ordinarily exceed six months'.

Finally, the opening up of the mail-box throws up a perplexing situation concerning the status of on-going generic production. Surprisingly, the Ordinance, despite introducing provisions for opening-up the mail-box (cf. 11A(7)), did not take notice of this complicated situation nor make allowances for existing production. The status of generic producers has important bearings on access to medicine, a point borne out by the Glivec case. Glivec, a blood cancer drug, was the first EMR granted in India (Narrain, 2005). The applicant, Novartis, began using the courts to 'enforce' its EMR by seeking injunctions[30] against companies that manufactured, distributed or sold the drug (e.g. Cipla, Ranbaxy and Sun)[31]. Despite an appeal, Natco Laboratories is now the only Indian company permitted to manufacture a generic version of Glivec, which sells for Rs. 10,800 (for a box of 100) compared to Novartis' US$3,600 (for a box of 100). In response to the criticism, the government took the following remedial measures in revising the Ordinance:

- Generic production can continue on cumulatively meeting the following conditions: substantial investment has been incurred, production and marketing has commenced prior to and continues subsequent to 1 January 2005, and a reasonable royalty rate is paid to the patentee.
- Patentees cannot institute infringement proceedings against these said producers.

For some the campaign to revise the Ordinance was successful, particularly in achieving a 'tempered' patent regime (Sridhar and Narrain, 2005). As this overview suggests, many of the amendments proposed by commentators did get incorporated. While not diminishing this achievement, it is useful to explore whether sights were not set high enough: did the consensus amongst commentators set too narrow an agenda for reform?

Two particular areas that relate to the second amendment warrant attention, particularly given the Doha-related and accompanying developments referred to earlier: license of rights and local working. The

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[29] Other measures include provisions under Article 7 (and also Article 66.2) to contribute to technology transfer, Article 8 that allows measures to safeguard public health and nutrition and promote public interest in vital sectors, and Article 30 which allows for general (though 'limited') exceptions to the rights conferred.

[30] Rangnekar (1998), commenting on the first amendment to the 1970 Act that introduced the 'mail-box' and EMRs, had suggested that compulsory licensing safeguards are not consistent with EMRs. In particular, quoting the WTO dispute panel's report, it was argued that 'exclusive' is construed to mean 'excluding all others from the rights conferred'.

[31] P. Chidambaran, the current finance minister, represented Novartis (Narrain, 2005), which is a clear sign of the ambivalence within government on IPRs.

second amendment removed all references to the automatic licenses of rights in IPA (e.g. sections 86, 87, 88) on the presumption that Article 27.1's obligation for non-discrimination as regards fields of technology is absolute and that Article 31 prohibits such provisions. It being felt that TRIPs eliminates the space for sovereign action that existed under the Paris Convention; no doubt, supported by the general verdict that this is "one of the most goal and achievement" of TRIPs (see Watal, 2001, p109). This view prevailed during the second amendment despite several dissenting views, which suggested variations in the 20-year patent term in the instance of health-related inventions (Anon., 2001d). It is here that the WTO panel's ruling in EC-Canada (WTO, 2000a) has implications. In its complaint, the European Commission contended that under Canadian law, patent rights were not enjoyable without discrimination as to the field of technology, suggesting that exceptions were selectively applied. In its decision, the Panel did not seek to define the term 'discrimination'; however it spelt out an important distinction between 'discrimination' and 'differentiation'. While the former is inconsistent with TRIPs, the latter is permitted. In particular, different rules may be designed for particular product areas or locations of production, provided these are for bona fide purposes, such as compelling public interests (UNCTAD & ICTSD, 2005). Pertinent in this regard is the Doha Declaration where in paragraphs 6 and 7 rule for a particular product category (pharmaceutical products) and location (production in countries with limited manufacturing capacity) are to be considered.

The changes with respect to IPA's provisions on compulsory licensing are more telling. Section 90 (of IPA) dealing with 'reasonable requirement of the public', the central basis for granting compulsory licenses, was amended by removing the phrase 'manufacture in India'. Thus, while non-working continues as one of the basis for revocation (section 89(1), 2nd amendment), it is no more the case that domestic demand needs to be met to "adequate extent or on reasonable terms from manufacture in India" (section 90(a)(ii), IPA). The TRIPs-obligation regarding non-discrimination "whether products are imported or locally produced" (cf. Article 27.1) has been interpreted as denying possibilities of local working (e.g. Fink, 2000, Ragavan, 2001) is misconceived according to Shanker (2002). It is suggested that with Paris Convention's Article 5A – in particular paragraph 2 – incorporated into TRIPs, and independent from various TRIPs provisions, continues to allow Members of the Union (and WTO) to prevent abuses of patent (e.g. non-working, insufficient working, etc.) (Shanker, ibid.). Interestingly, a review of TRIPs' negotiating history clarifies that, as Members strongly disagreed, efforts to have a direct prohibition were rejected; instead the obligation is for patent rights to be enjoyable without "discrimination" as to whether goods are locally produced or imported (UNCTAD/ICTSD, 2005). It is here that the US's aborted challenge to Brazil's patent laws has relevance. At issue were provisions that equated 'failure to work' with 'failure to manufacture or incomplete manufacture of the product', or 'failure to make full use of the patented process'. The withdrawal of the request for a panel has been

explained in terms of the weakness of the claim (see Reichman, 2000, Shanker, 2002). No doubt, the political context, as note earlier, made the challenge an unlikely route for seeking a particular mode of TRIPs-compliance. It is this understanding of the obligation of TRIPs and the changing context of TRIPs-implementation that questions whether changes to IPA introduced through the second amendment could have been revisited and revised. At the WTO, India filed third party interests to the US-Brazil dispute; however at home it seemed to tread a more cautious line.

Conclusion: Changing perceptions about IPRs

Much ire has been directed at the WTO, in general, and the TRIPs Agreement, in particular. While not deflecting this focus, perceptions about IPRs in India have been changing. These changes occurred in concert with, and possibly as a consequence of, wider modifications to economic policy in the mid-80s. For instance, in 1986 when joining the Paris Convention was debated, the lobby group representing trade and industry interests, the Associated Chambers of Commerce and Industry (ASSOCHAM), came out in support of membership. Opposing this position were representatives of the (small) domestic generic drug firms, the Indian Drug Manufacturers Association (IDMA), and the primary organ of Indian industry, the Federation of Indian Chambers of Commerce and Industry (FICCI). Within government itself there were other signs of ambivalence despite the consistent opposition to the inclusion of IPRs in the Uruguay Round. Notable in this respect were regulatory changes with respect to the seed industry: beginning with the release of publicly bred varieties to the private sector (1983) and followed by relaxation of industrial licensing laws (1987), the Government considered introducing plant breeder rights in 1990 (Rangnekar, 2002). More telling is the manner in which industry and government have come together to embrace and develop copyright law (Chakravarti, 1998).

The transformations can be identified in the changing allegiances within the pharma industry, in particular the movement of firms between different lobby groups. Firms in the industry were initially distributed between two lobby groups: the mainly domestic grouping of generic firms under IDMA and the MNC-affiliated grouping of the OPPI[32]. However, in 1999 a new configuration of pharmaceutical firms was established, the Indian Pharmaceutical Alliance (henceforth, the Alliance), consisting of firms like Cipla, Dr Reddy's Laboratories, Lupin Labs and Ranbaxy that collectively account for 30% of domestic production and 33% of Indian exports (Anon, 2001a). To complete this story, the 'successes' on account of the 1970 Act laid the foundation for Indian pharma's deeper integration within global supply chains of production and innovation. It is this transformation that the government highlighted whilst presenting the third amendment: "The pharma industry and the IT industry are the two sunrise sectors for India. The

[32] It is also the case that these two groups share common cause in terms of relaxing price regulations under the DPCO (Bidwai, 1995). Even generic drug companies have come under the scrutiny of the National Pharmaceutical Pricing Authority for alleged mark-up pricing (Sardana, 2004).

Ordinance amending the Patent Act provides for an enabling environment for both of these. Among the sectors that have experienced the greatest transformation in India, the pharmaceutical industry is perhaps the most significant. …the transformed Indian pharma industry is itself looking for patent protection ….[…] Apart from the manufacture of drugs, the pharma industry offers huge scope for outsourcing of clinical research" (Nath, 2004).

A recent study on Indian pharma finds a group of indigenous (and some MNC-affiliated) firms adopting a mix of cooperative and competitive strategies to deal with the challenges and opportunities arising from the 'disembowelment' of IPA (Gehl Sampath, 2005). Beyond being keen on owning IP, these firms have adopted the following: exploring non-infringing processes, research on new chemical entities and generics, focussing on new drug delivery systems and biopharmaceutical research (ibid.). Thus, on the one hand, some firms see their future in exploiting their comparative advantages in process innovations; thus, seizing the generic drug route. However, for these firms the domestic market presents a constraint on account of relatively low per capita income, limited access to medicine and negligible insurance coverage. Even while the Indian market accounts for 8% of global volume its share of value is only 1% (Gehl Sampath, 2005). Consequently, these firms are looking at exports as a key element for future growth. Indian companies have sought approval for generic production of some 150 drugs in the US, of which approval for nearly 90 has been granted. The US market itself accounts for sizeable revenues of leading Indian firms: 32% in the case of Dr. Reddy's and 42% for Ranbaxy. On the other hand, some IPA members have achieved success in developing new molecules and are interested in seeking domestic and overseas protection. This competency has sparked off strategic alliances between domestic and foreign firms that go beyond one-off technology transfers of a previous era and enter areas of shared research, overseas production and global marketing (Sandhya and Visalakshi, 2000). Interestingly, the Alliance is composed of both sets of firms: "the IPA [i.e. the Alliance]….is perhaps a little schizophrenic about where its members' interests lie. On the one hand many of them, such as Ranbaxy, wish to develop as research based companies and see the value of strong patent protection to achieve that. On the other hand, the overwhelming majority of their revenues remain derived from generic production, and accordingly they share many of the concerns of IDMA" (CIPR, 2001). CIPR's comment may be too harsh and misses the wider trend of pharma firms combining an R&D focus with a generic production unit (e.g. Merck's entry into the generic sector); however, it captures the underlying contradiction.

This brief analysis suggests that patent reform campaigners have to confront ambivalence in the government and changing industrial interests' that patent-reform campaigners. The latter group presents a deeper problem for future strategies. Indian pharma, in one guise or another, has been the 'poster boy' of the global access to medicine campaign through its willing production of cheap anti-retrovirals. This has been a substantial public relations coup for industry and government. However, emergent innovation and

production patterns clearly indicate that this is not where the firms (or the government) see the future. Despite a changed and favourable international climate (read Seattle, Cancun, Doha) and increasing forum-shifting by developing countries and non-state actors in the area of intellectual property – the agenda at home has been doubly constrained by the narrow agenda and domestic factors. It is in the move from Geneva to New Delhi that problems concerning the making of IP-law present new challenges for scholars and campaigners.

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