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INDIA'S TRYST WITH TRIPS: THE PATENTS (AMENDMENT) ACT, 2005

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ABSTRACT

The Patents (Amendment) Act, 2005 introduces pharmaceutical product patents in India for the first time. This Act attempts to balance out competing interests of a variety of stakeholders, including domestic generic medicine producers, foreign multinational pharmaceutical companies and civil society groups concerned with access to medicines. Although this dexterous manoeuvring around competing interests deserves praise, the net result of such a compromise has been a lack of clarity in the law.

While highlighting the key aspects of the 2005 amendments and this lack of clarity, this article also focuses on the vexed issue of the likely impact of the new regime on access to medicines. It notes that the provisions as they stand now could be interpreted in a manner that would leave considerable scope for the continued production of some generics. Whether these provisions would be so interpreted remains to be seen.

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I. INTRODUCTION

The controversial Patents (Amendment) Act, 2005 (hereinafter “the 2005 Act”) was India’s last step towards achieving complete TRIPS compliance.¹ This Act has had a fairly long innings. It began as the Patents (Amendment Bill), 2003 (hereinafter “the Bill”) under the BJP (Bharatiya Janata Party) government. The Bill lapsed owing to a change in government at the Centre and the consequent dissolution of the Lok Sabha (India’s lower house of Parliament).

The new Congress-led coalition government endorsed the Bill - however, since they were unsure of whether it would go through Parliament in time to meet the TRIPS deadline of January 1, 2005, they had it passed as a Presidential Ordinance.² Owing to pressure from the Left

¹ In order to comply with TRIPS, the Patents Act, 1970 (India) had been amended twice earlier by the Patents (Amendment) Act, 1999 and the Patents (Amendment) Act, 2002.

² Patents (Amendment) Ordinance, 2004 [hereinafter “the Ordinance”].

parties,³ changes were made to the Ordinance and cleared by the Parliament in the third week of March as the Patents (Amendment) Bill, 2005. After receiving Presidential assent and being published in the official gazette, it finally came into force with retrospective effect from January 1, 2005.⁴

The introduction of product patents for pharmaceutical inventions and the consequent threat to an internationally renowned generic industry that has thus far ensured the supply of affordable drugs spurred widespread protests, both nationally and internationally, to an extent never before witnessed in the annals of intellectual property law making in India. The result is an Act that attempts to balance the competing interests of a variety of stakeholders, including domestic generic medicine producers, the domestic research and development community, foreign multinational pharmaceutical companies, civil society groups concerned with access to medicines and intellectual property lawyers.⁵ Although this delicate balancing deserves some applause, the unfortunate fall-out has been the hasty introduction of provisions that go against the grain of time tested patent law principles and are likely to provide excellent fodder for litigation.

II. HIGHLIGHTS OF THE 2005 AMENDMENTS

This note highlights some of the main changes brought about by the 2005 Act and reflects on some of their broader implications. In particular, the note focuses on the introduction of product patents for pharmaceutical inventions and the controversial issue of how this change is likely to impact access to medicines.

A. Product Patents for Pharmaceutical Inventions

The most prominent and controversial change has been the deletion of section 5 of the Patents Act, 1970, thereby paving the way for product patents

³ The Communist Party of India, the Communist Party of India (Marxist), the Revolutionary Socialist Party and the Forward Bloc are leftist parties supporting the ruling coalition government.

⁴ The Patents (Amendment) Act, 2005 was published as law in the Gazette of India on April 5, 2005.

⁵ See F.M. Abbott, *Beginning of a New Policy Chapter: A Hopeful Way Forward in Addressing Public Health Needs*, FIN. EXPRESS, Apr. 6, 2005, http://www.financialexpress.com/fe_full_story.php?content_id=87112 (last visited Oct. 15, 2005).

in the area of pharmaceutical and other chemical inventions. Section 5 of the Patents Act, 1970 (as it stood after the 2002 amendments) had provided that, in the case of inventions being claimed relating to food, medicine, drugs or chemical substances, only patents relating to the *methods or processes of manufacture* of such substances could be obtained.

This deliberate strategy of denying product patent protection to pharmaceutical inventions is traceable to the Ayyangar Committee Report, a report that formed the very basis of the Patents Act, 1970.⁶ The Committee found that foreigners held between eighty and ninety percent of Indian patents and that more than ninety percent of these patents were not even worked in India. The Committee concluded that the system was being exploited by multinationals to achieve monopolistic control over the market, especially in relation to vital industries such as food, chemicals and pharmaceuticals. Medicines were arguably unaffordable to the general public and the drug-price index was rising rapidly. The Committee therefore recommended that certain inventions such as pharmaceutical inventions, food and other chemical inventions be granted only process patent protection.⁷ India's well-developed generic industry today is testimony to the farsightedness of this report.⁸

Quite naturally, it is feared that with the introduction of product patents for pharmaceuticals, there will be a steep rise in drug prices and an adverse impact on access to important drugs.⁹ The multinational pharmaceutical

⁶ N.R. AYYANGAR, REPORT ON THE REVISION OF THE PATENTS LAW (1959) [hereinafter AYYANGAR REPORT].

⁷ Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 VAND. J. TRANSNAT'L L. 507, 518 (1996).

⁸ In 2003, the size of India's pharmaceutical market was estimated at US\$4.9 billion. This constitutes about 1% of global pharmaceutical sales and about 10% of the global generic market. Today, India is among the top five bulk drug manufacturers of the world and has the largest number of US FDA-approved manufacturing facilities outside the USA. India is also the fourteenth largest exporter of drugs in the world and exported drugs worth \$3.2 billion to more than 65 countries. See SUDIP CHOUDHURI, R & D FOR DEVELOPMENT OF NEW DRUGS FOR NEGLECTED DISEASES: HOW CAN INDIA CONTRIBUTE? 37-48 (2005) (discussing recent trends in spending on research and development of pharmaceutical products and noting the importance of public-private partnerships to address market failure in the development of drugs for neglected diseases).

⁹ See, e.g., SHUBHAM CHAUDHURI ET AL., ESTIMATING THE EFFECTS OF GLOBAL PATENT PROTECTION IN PHARMACEUTICALS: A CASE STUDY OF QUINOLONES IN INDIA 43 (2004). See also UNCTAD

industry, on the other hand, argues that such patents are essential to encourage innovation and help the transition of domestic pharmaceutical companies from copycat generics to innovative R&D companies.¹⁰ They argue that this will serve India's interests better in the long run and that there are adequate safeguards in the patent regime and other laws to curb a sharp rise in drug prices.

B. Software Patentability

Section 3(k) of the Patents Act, 1970 excluded "a computer programme per se" from the scope of patentability. This exclusion met with conflicting interpretations at the patent office, with some examiners granting patents to software combined with hardware or software with a demonstrable technical application of some sort.¹¹ The 2004 Ordinance therefore qualified this exclusion by stating that software with a "technical application" to industry or when "combined with hardware" would be patentable.¹² Owing to vigorous opposition from the free software movement,¹³ this provision was removed from the 2005 Act. The earlier position under the Patents Act, 1970 that a computer programme per se is not patentable now prevails.

India Programme, *Product Patents: Implications for Pharmaceutical Industry and Consumers*, at http://www.unctadindia.org/MeetingOnProductPatents-ImplicationsForPharmaceuticalIndustry-April04-2005_Presentation.pdf (last visited Oct. 24, 2005).

¹⁰ Patent protection for pharmaceutical products will provide India's scientists with incentives to discover and develop new life-saving drugs. See PhRMA, *PhRMA Welcomes Passage of Patent Bill in India*, at <http://www.phrma.org/mediaroom/press/releases/23.03.2005.1157.cfm> (last visited Oct. 22, 2005).

¹¹ "According to sources, over 150 patents on 'technical effects of software' had been granted in the country even prior to the December Ordinance. These patents were granted despite the legal ambiguity that had prevailed prior to issuance of the Ordinance." See *Software Patents under Ordinance Face Reversal*, FIN. EXPRESS, Mar. 29, 2005, http://www.financialexpress.com/fe_full_story.php?content_id=86454 (last visited Oct. 16, 2005).

¹² Section 3(b) of the Ordinance excluded "a computer programme per se other than its technical application to industry or a combination with hardware".

¹³ See Free Software Foundation, *Representation Made by the Free Software Foundation of India to the Government of India to Immediately Withdraw the Patents (Amendment) Ordinance, 2004*, at <http://fsf.org.in/representation/representation.html> (last visited Oct. 18, 2005).

Interestingly enough, a draft of a recent manual of the Patent Office that attempts to lay down guidelines to interpret the Act arrives at a conclusion that is similar to what the Ordinance provision sought to achieve. It notes:

*The statute excludes from patentability the software per se. The inventions relating to the application of the computer program or software is [sic] held patentable under the Indian Patent Act, 1970 when claimed in combination of hardware and software components of a computer which provide a “technical advancement” over the prior art. It is necessary for the applicant to describe the “technical contribution” to the prior art when the invention involves software. The technical problem, which needs to be solved by the invention, should be sufficiently described as to how the hardware is controlled by the software to overcome the previously described problem. [sic] The “technical character” of the invention should be brought out clearly in the claims.*¹⁴

C. Problematic Definitions

An unfortunate fallout of a hasty legislative process has been the introduction of definitions that not only go against the grain of time-tested patent law concepts but also defy logic. The key ones are elucidated below:

1. ‘New Invention’

The Patents Act, 1970 defines the term ‘new invention’ as

*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 a 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.*¹⁵

It appears that the intent behind this provision is to define a ‘novelty’ standard - which, along with ‘non-obviousness’ (or ‘inventive step’) and ‘utility’ (‘industrial applicability’), are the three prerequisites for ‘patentability’.¹⁶

¹⁴ PATENT OFFICE, MANUAL OF PATENT PRACTICE AND PROCEDURE 156 (2005). The manual, however, cautions, “The contents of this manual including the guidelines are merely for the purpose of illustrations and not meant for legal purposes. In case of any conflict, legal provisions of the Patents Act will prevail.”

¹⁵ Patents Act, 1970, § 2(1)(i), amended by Patents (Amendment) Act, 2005.

¹⁶ Most patent regimes provide that in order to be patentable, an invention has to be new, non-obvious (to a person skilled in the art) and industrially applicable.

However, a term such as ‘new invention’ raises the question of what an ‘invention’ is in the first place. Section 2(j) defines an invention as “a new product or process involving an inventive step and capable of industrial application”.¹⁷ Since ‘new’ is already a part of the term ‘invention’, introducing a term such as ‘new invention’ to define a novelty standard is circular and makes for shoddy drafting. A clearer way of doing this would have been to define the term ‘new’ as found in the term ‘invention’.

The ‘new invention’ definition suffers from yet another infirmity. While it appears to endorse an ‘absolute’ novelty ground, the Act still retains a ‘relative’ novelty ground in section 25. Section 25 stipulates that a patent application can be opposed on the ground that the invention was “publicly known or publicly used in India before the priority date of that claim”. To this extent, the ground for opposition is based on ‘relative novelty’, i.e. the invention should be known or used in India, whether or not it is so known or used in any other part of the world. The new definition under the 2005 Act however provides for ‘absolute’ novelty - in order to qualify as a ‘new invention’, the said invention should not have “been anticipated by publication in any document or *used in the country or elsewhere in the world*”.¹⁸ (emphasis supplied).

Consider an application for invention X in India, where the said invention had already been used in China at some earlier point in time. It would appear that such application could be refused by the patent office on the ground that the invention had been used in China and is not therefore a ‘new invention’. However, at the stage of opposition, a third party cannot take up this ground under section 25, since the invention had never been publicly used in India before the priority date of the claim. This difference in standard seems odd, given that an interested third party is more likely to be aware of a foreign use of the invention in question than an Indian patent examiner.¹⁹

2. The ‘Inventive Step’ Test

The 2005 Act makes a critical change to the earlier ‘non-obviousness’ or ‘inventive step’ test. The definition now reads:

¹⁷ Patents Act, 1970, § 2(j).

¹⁸ Patents Act, 1970, § 25, as amended by Patents (Amendment) Act, 2005.

¹⁹ More often than not, a third party who opposes a patent application is a competitor of the applicant.

*‘inventive step’ means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to the person skilled in the art.*²⁰

As can be seen from this definition, while the fundamental yardstick for measuring an ‘inventive step’ remains that which is “not obvious to a person skilled in the art”,²¹ a requirement that the invention involve a ‘technical advance’ or have an ‘economic significance’ of some sort has been added.

This change in the standard seems odd, given that the very purpose of the ‘inventive step’ criterion is to determine whether an invention sufficiently advances the technical arts so as to warrant an exclusive right. This is no doubt achieved in an optimal manner by the simple test of whether the invention, though novel, is non-obvious to a person skilled in the art.²² By itself, the non-obviousness test is a difficult one to apply - additional criteria such as ‘technical advance’ and ‘economic significance’ only further the complexity. Contrary to suggestions by some commentators, the addition of ‘technical advance’ or ‘economic significance’ to the ‘non obviousness’ test does not dilute the ‘inventive step’ requirement - on the contrary, it is susceptible to being interpreted in a manner that renders it more onerous to satisfy.²³

Further, ‘economic significance’ seems to be more of a ‘utility’ or ‘industrial applicability’ standard. By including such a criterion within a ‘non-obviousness’ or ‘inventive step’ standard, the Act creates considerable uncertainty. As a commentator observes: “It interferes with the time-tested principles of patents

²⁰ Patents Act, 1970, § 2(1)(ja), as amended by Patents (Amendment) Act, 2005.

²¹ The earlier section 2(ja) defined ‘inventive step’ as “a feature that makes the invention not obvious to a person skilled in the art.”

²² In so far as the term ‘person skilled in the art’ is concerned, it may be worth noting that Lord Hoffman was critical of what he termed “anthropomorphic conceptions of justice” and “the varied cult of imaginary and sometimes improbable people invented by the law to embody concepts like ‘reasonableness’, ‘business efficacy’ and ‘lack of inventiveness’.” *Biogen Inc. v. Medeva plc*, [1997] RPC 1.

²³ See, e.g., K.M. Gopakumar & Tahir Amin, *Patents (Amendment) Bill 2005: A Critique*, 40(15) *ECON. & POL. WKLY.* 1503, 1504 (Apr. 9, 2005) (“Thus the definition dilutes the requirements of an inventive step and broadens the existing provision to the benefit of patent holders.”)

law, and in that process has created a new definition that can lead to loose interpretations.”²⁴

3. ‘Pharmaceutical Substances’

The term ‘pharmaceutical substances’ has been rather strangely defined in section 2(1) (ta) as “any new entity involving one or more inventive steps”. Defined in such a broad way, one is forced to query: would a mobile phone that deploys advanced technology be a pharmaceutical substance if it is shown that such entity is new and involves one or more inventive steps?

What is even more perplexing about this definition is the fact that the term ‘pharmaceutical substance’ does not find mention anywhere else in the Patents Act.²⁵ In the absence of such a term in the Act, one wonders why the legislature, in all its wisdom, did not see fit to clarify this concept.

4. The ‘New Use’ Exclusion

Section 3(d) of the Patents Act, 1970 excluded a “new use for a known substance” from the ambit of ‘invention’. The 2005 Act has expanded on this exception by providing that “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance” would not be patentable. It then states (via an explanation to the section) that salts, esters, ethers, polymorphs, metabolites, etc. shall be considered as the same substance unless they “differ significantly in properties with regard to efficacy”.

The introduction of a new definition for the term ‘substance’ through the explanation above would make for some nuanced interpretative battles. If, for example, X1 is a polymorphic²⁶ form of X, then would a showing of

²⁴ M. Pillai, *India's Patents Bill, 2005 - Is It TRIPS Compliant?*, MONDAQ NEWSL. (Mar 31, 2005), at http://www.mondaq.com/i_article.asp_Q_articleid_E_31717 (last visited Oct. 26, 2005).

²⁵ Section 92A, which deals with compulsory licences in the context of exports to countries with minimal manufacturing capabilities, uses the term ‘pharmaceutical products’. However this term is used in a different sense than ‘pharmaceutical substances’, as is made evident by the fact that it is defined in section 92A itself. The absurd definition in section 2(1) (ta) cannot therefore apply to ‘pharmaceutical products’ under section 92A.

²⁶ A polymorph is “a solid crystalline phase of a given compound resulting from the possibility of at least two crystalline arrangements of the molecules of that compound in the solid state.”

increased efficacy for X1 change it to a new substance (as suggested by the explanation to the section)?²⁷ In short, at what point would a showing of increased efficacy change a 'new form' of an existing substance to a new substance altogether?

In order to answer this question, one has to first address the issue of what exactly the term 'efficacy' means. Would this term be construed in a manner similar to how a drug approval agency would construe it?

It is interesting to note in this connection that this provision in the 2005 Act, which finds no parallel in any other patent legislation in the world, has been copied from a European Directive dealing with drug safety regulation. Article 10(2) (b) of Directive 2004/27/EC defines a 'generic medicinal product' as

*a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.*²⁸

2 W.C. MCCRONE, PHYSICS AND CHEMISTRY OF THE ORGANIC SOLID STATE 725 (David Fox et al. eds., 1965).

²⁷ Whether such a determination would make any practical difference is debatable, as both the new 'form' as well as the new 'substance' would merit patent protection as a product.

²⁸ Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, (2004) O.J. (L 136) 34.

As one can well appreciate, blindly transposing a provision that operates within the context of a drug regulatory regime to a patent regime can pose problems. For one, it makes it more likely that the term ‘efficacy’ would be construed in a drug-regulatory sense - consequently, the requirement would be a difficult one for most patent applicants to satisfy. Pharmaceutical companies generally file patent applications at the initial stage of discovery of a drug; it is only much later in the development process that clinical studies (phase III) are conducted to gather information pertaining to the therapeutic efficacy of the drug. The requirement of information on ‘efficacy’ at the stage of filing a patent application is therefore an onerous one.²⁹

If, on the other hand, the term ‘efficacy’ were to be construed in a liberal manner to include even a general hint of an added advantage in using the new form, it is possible that a good number of formulations would qualify as new substances upon the showing of an increased efficacy.

The amended section 3(d) appears to be limited to only new forms that demonstrate an increase in known efficacy. It does not, therefore, apply to a case where the new form is found to have a completely different use (and not just an increased efficacy vis-à-vis the known use). If the intention behind this provision is to heighten the obviousness standard and weed out frivolous and fairly obvious patents, this seems a rather illogical result, as a new use for a new form is certainly more inventive than a mere showing of an increase in known efficacy.

As with the problematic definition of ‘inventive step’ discussed above, this provision is likely to provide an excellent platform for “meticulous verbal analysis in which lawyers are too often tempted by their training to indulge”.³⁰

²⁹ “The task of proving efficacy is much more difficult, expensive, and time-consuming than the task of proving safety.” The Independent Institute, *History of FDA Regulation: 1902-Present*, at <http://www.fdareview.org/history.shtml>. Another commentator notes: “Thanks to a 1963 law, the FDA requires pharmaceutical and medical device manufacturers to prove that new drugs and devices are both safe and effective - but the agency has refused to give a clear definition of efficacy.” James Bovard, *Bureaucratic Tyrants*, 25(23) CONN. L. TRIB. 15 (June 7, 1999).

³⁰ This widely quoted sentiment of Lord Diplock was expressed in the context of patent claim construction and the laying down of what commonly came to be referred to as the doctrine of ‘purposive construction’. *Catnic Components Ltd. v. Hill & Smith Ltd.*, [1982] RPC 183, 243.

D. Pre-Grant/Post-Grant Opposition

The Patents Act, 1970 is endowed with a fairly robust pre-grant opposition mechanism. It provides for several grounds on which a patent could be opposed including the lack of novelty, inventive step or utility (the traditional patentability criteria) or that the claimed invention does not fall within eligible subject matter or that the specification does not disclose the source or geographical origin of biological material used for the invention.³¹

The 2005 Act has introduced a post-grant opposition mechanism for the first time. Within a year of the patent being granted, a 'person interested' can challenge the issued patent on grounds that are identical to the grounds available at the pre-grant opposition stage.³² The key difference between the pre-grant and the post-grant opposition mechanism appears to be that while 'any person' could challenge at the pre-grant stage, the challenger has to be a 'person interested' at the post-grant stage.

A competitor who fails to challenge a patent application at the pre-grant/post-grant stage has a further opportunity - he or she can seek revocation of the patent under section 64 of the Patents Act.³³ Here again, the grounds that could be cited for revocation (whether by a direct petition to the Controller or as a counter-claim during infringement proceedings) are broadly similar to that available at the pre-grant and post-grant stage. This combination of a pre-grant opposition mechanism, a post-grant opposition mechanism and a revocation mechanism makes the regime a very effective one for filtering out frivolous claims.³⁴

E. Compulsory Licensing Regime

This is one area where there have been major changes, both substantive and procedural.

1. Automatic Compulsory Licences for Mailbox Applications

The biggest substantive change has been the addition of a new ground for compulsory licensing. As is well known, India amended the Patents Act

³¹ Patents Act, 1970, ch. V (§ 25-28).

³² Patents Act, 1970, § 25(2), as amended by Patents (Amendment) Act, 2005.

³³ In much the same way as the post-grant opposition mechanism, it has to be a 'person interested' who initiates the challenge and not just any person.

³⁴ Patents Act, 1970, § 64.

in 1999 to provide that applications claiming pharmaceutical inventions would be accepted and put away in a mailbox, to be examined in 2005. These applications are commonly referred to as 'mailbox applications'. This amendment was in pursuance of a TRIPS obligation aimed at preserving the novelty of pharmaceutical inventions in those developing and least developed country (LDC) members that did not grant product patents for pharmaceutical inventions in 1995.³⁵ By virtue of this 'mailbox facility', applications would be judged for 'novelty' on the basis of the filing date and not with reference to 2005, the year in which product patents were first incorporated into the patent regime.

The Act provides that in the case of those mailbox applications that result in the grant of a patent, an automatic compulsory licence would issue to those generic companies that made a 'significant investment' and were 'producing and marketing' a drug covered by the mailbox application prior to 2005.³⁶ Such licence is subject to a payment of a 'reasonable royalty'. However, no specific yardstick is provided to determine 'reasonableness' and this term is likely to lead to disputes in coming years.³⁷ Perhaps one will have to go by the broad criteria in section 90 of the Act - that while computing the royalty

³⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Dec. 15, 1993, 33 I.L.M. 81 [hereinafter TRIPS Agreement]. In the WTO dispute filed by the United States against India for a failure to comply with this provision, the WTO appellate body held that India was obliged to provide a sound legal mechanism for an interim mailbox arrangement. See WTO Appellate Body, *India: Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (Dec. 19, 1997), available at http://docsonline.wto.org/GEN_highLightParent.asp?qu=&doc=D%3A%2FDDF DOCUMENTS%2FT%2FWT%2FDS%2F50ABR%2EWP%2EHTM. The Patents (Amendment) Act, 1999 was introduced as a response to this ruling, and was in fact given retrospective effect from 1995, the date on which India was supposed to have instituted the mailbox facility under TRIPS.

³⁶ Patents Act, 1970, § 11A, proviso, amended by Patents (Amendment) Act, 2005.

³⁷ It is pertinent to note that during the Parliamentary debates, a number of members suggested that a specific royalty rate or a ceiling on the royalty rate be fixed (see specifically comments by Mrs. Maneka Gandhi and Mr. Suresh Kurup). However, at the time of voting, the clause was adopted with the words 'reasonable royalty' and no specific percentage was fixed. See Lok Sabha Debate, Mar. 22, 2005, at <http://164.100.24.230/Webdata/datalshom001/dailydeb/22032005.htm>.

payable, one shall have regard to “the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors”.³⁸

It will be interesting to see how this new provision pans out in the years to come. It is reminiscent of the ‘licence of right’ provisions under the earlier patent regime. Inventions pertaining to food and medicine were subjected to an automatic endorsement (i.e. they were deemed to be so endorsed) with a ‘licence of right’ after a period of three years from the date of sealing of the patent.³⁹ In other words, any person interested in working the patented invention, endorsed with a ‘licence of right’ could have a licence as of right, without needing to establish any specific grounds for it.⁴⁰

2. *Compulsory Licences for Exports*

In order to incorporate what is commonly referred to as the *Paragraph 6 Decision*⁴¹, the Ordinance introduced section 92A, which provides for compulsory licences to enable exports of pharmaceutical products to those countries with no manufacturing capacity of their own. Unfortunately, this suffered from a handicap - the provision required that the exporter obtain a compulsory licence from the importing country as well. In the process, the provision failed to cater to those situations where there was no patent in such importing country and no requirement for obtaining a compulsory licence there.⁴² The 2005 Act therefore seeks to rectify this by adding that an exporter can resort to section 92A where the importing country “has by notification or

³⁸ Patents Act, 1970, § 90.

³⁹ Patents Act, 1970, § 87, *omitted by* Patents (Amendment) Act, 2002. Since the 1970 regime provided only ‘process patents’ in the case of pharmaceutical inventions, it was not too surprising that this compulsory licensing provision was hardly ever invoked by generic manufacturers.

⁴⁰ See generally SHANTI KUMAR, *DIFFERENCE BETWEEN COMPULSORY LICENCE AND LICENCE OF RIGHT* (1975).

⁴¹ WTO General Council, *The Implementation of Paragraph 6 of the Doha Declaration the TRIPS Agreement and Public Health*, WT/L/540 (Aug. 30, 2003), available at <http://docsonline.wto.org/DDFDocuments/t/WT/L/540.doc>.

⁴² In fact, most of the countries that have little or no manufacturing capacity are LDC (Least-Developed Country) members that have time till 2016 to introduce product patents for pharmaceuticals. It is therefore absurd to expect any existing patents on pharmaceutical inventions in these countries in the interim.

otherwise allowed importation of the patented pharmaceutical products from India".⁴³

3. Procedural Changes

The general compulsory licensing procedure under Chapter XVI states that in most cases, a compulsory licensing application can be entertained only if negotiations towards a voluntary licence have not borne fruit within a reasonable time period. In order to prevent patentees from dragging on voluntary negotiations to the detriment of applicants, the Act caps a 'reasonable' period of negotiations at six months.

F. Government Use

Most patent regimes provide that, under certain circumstances, the government is entitled to use an existing patent (commonly referred to as 'government use' provisions). The 2005 Act expands the scope of 'government use' provisions in some respects and reduces it in others. Thus, sub-clause (iv) has been added to section 2(h) of the old act to include any 'institution wholly or substantially financed by the Government' within the ambit of a 'government undertaking' that can avail itself of a patent under the 'government use' provisions spelt out in Chapter XVII. However, the Council for Scientific and Industrial Research (CSIR), a premier science research institution, has now been excluded from the ambit of the term 'government undertaking'. This, perhaps, is in recognition of the fact that CSIR has been patenting extensively and is a private player in several respects.⁴⁴

G. The Bolar Exception

The Indian patent regime encapsulates what is commonly referred to as the Bolar exception⁴⁵ - an exception that allows generic manufacturers to start

⁴³ Patents Act, 1970, § 92A.

⁴⁴ CSIR filed 184 patents with the Paris Convention Treaty (PCT) countries in 2002 alone, tying for the number one spot in this field with Samsung. *Samsung Finds its Match in CSIR*, HINDU BUS. LINE, Jul. 27, 2003, <http://www.blonnet.com/2003/07/27/stories/2003072701380100.htm> (last visited Oct. 11, 2005).

⁴⁵ This exception was named after a US case, *Roche Products Inc. v. Bolar Pharm. Co. Inc.*, 733 F.2d 858 (Fed. Cir. 1984), in which it was held that the 'experimental use' exception under US law was not broad enough to permit Bolar to develop and submit a generic product for regulatory approval before the expiry of Roche's patent. The Hatch-Waxman Act in the US, which introduced such an exemption favouring generic companies, was a response to this ruling.

producing a patented drug in limited quantities during the period of the patent in order to collect data to be submitted to a drug approval authority. This exception therefore enables generics to enter the market soon after a patent expires.

Section 107A of the Patents Act (as amended up to 2002) excluded from infringement “the act of making, using or selling a patented invention” for the purpose of obtaining information to be submitted to a regulatory authority. The 2005 Act expands this provision to bring even the act of ‘importing’ within its ambit. 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.

H. Parallel Imports

The earlier section 107A(b) provided that it was not an infringement to import a patented product provided such import was from an exporter who was “duly authorised by the patentee to sell or distribute the product”. The 2005 Act now makes such import easier by dispensing with the authorisation required from the patentee - it only requires that the exporter of such patented product be “duly authorised under the law to produce and sell or distribute the product”.

Under this amended provision, it would appear that an Indian pharmaceutical company could set up base in Bangladesh to manufacture and export medicines to India.⁴⁶ In the absence of a patent in Bangladesh and/or any other law barring manufacture/exports, such company would presumably be ‘duly authorised’ under the laws of Bangladesh to ‘sell or distribute the product’.

The provision therefore is extremely broad in scope and may contravene TRIPS. Article 6 of TRIPS states, in pertinent part, that “...nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights”.

⁴⁶ As per paragraph 7 of the Doha Declaration, a least developed country (LDC) member such as Bangladesh has time till January 1, 2016 to introduce product patents for pharmaceutical inventions. See WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001), available at <http://docsonline.wto.org/DDFDocuments/t/WT/min01/DEC2.doc> [hereinafter Doha Declaration].

The meaning of Article 6 is made clear by Article 5(d) of the Doha Declaration which states: “The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge ...”

However, the above hypothetical example of an Indian company setting up base in Bangladesh does not involve an ‘exhaustion’.⁴⁷ There is no first sale of the patented drug by the patentee - rather the drug is manufactured and then exported by a third party. In short, the very essence of an exclusive right to import mandated under Article 28 of TRIPS is affected.

III. SOME BROAD IMPLICATIONS OF THE 2005 ACT

A. Access to Medicines

Although the 2005 Act has made wide-ranging changes to India’s patent regime, the most controversial provision is the one introducing product patents for pharmaceutical inventions. Civil society proponents are concerned that this would cause a steep rise in drug prices and adversely impact access to important drugs. They argue that the available TRIPS flexibilities have not been exploited appropriately and that adequate safeguards have not been built in to ensure an affordable supply of medicines.⁴⁸

The 2005 Act has a number of important safeguards built in to ensure that the production of existing generic versions of drugs is not jeopardised. It also has provisions to ensure affordable access to new drugs. Whether such provisions would in fact be interpreted in a manner conducive to public health needs remains to be seen. Some of the key provisions in the 2005 Act and other related laws are discussed below.

⁴⁷ “Exhaustion means that once a patent holder has sold a patented invention, the patent holder has no further right to exclude others from subsequent use, including offering to sell or distribute the patented invention. In essence, exhaustion presupposes that the patent owner, unless there is an agreement to the contrary, implicitly licenses the subsequent use and resale of a patented product upon first sale.” James Thuo Gathii, *The Doha Declaration on TRIPS and Public Health under the Vienna Convention of the Law of Treaties*, 15 HARV. J. L. & TECH. 292, 308 (2002).

⁴⁸ According to Health GAP (Global Access Project), a US-based NGO that advocates the cause of AIDS patients, human rights and fair trade, the 2005 Act fails “to utilise fully the

1. *Compulsory Licensing*

As mentioned earlier, the provision of two new grounds for compulsory licensing (one in respect of exports to countries that lack manufacturing capabilities and the other in respect of the manufacture of drugs that are the subject matter of mailbox applications⁴⁹) would go a long way towards ensuring that local industry can continue to manufacture at a cost lower than the innovative drug company.

However, despite these new grounds, the new regime has done little to ease the administrative and procedural bottlenecks that constrained the invocation of compulsory licensing provisions under the old regime.⁵⁰ Indeed, a rather stark example of the procedural delays inherent in compulsory applications is provided by a case under the old regime, where the compulsory licensing application was dragged on all the way to the Calcutta High Court, by which time the patent had almost expired.⁵¹

The 2005 Act has streamlined one such procedural hurdle by providing that 'voluntary negotiations' with a patentee should be concluded within six months.⁵² It could therefore well be the case that extensive provisions on paper may not translate easily into practice. Further, contentious terms such as 'reasonable royalty rates' (used in the context of the newly added compulsory licensing ground to permit generic companies to continue manufacturing drugs that are the subject matter of mailbox applications) could significantly slow down the compulsory licensing process.

public health safeguards available to WTO member states under TRIPS, which were reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health." Health Global Access Project, *The Impact of India's Amended Patents Act to Access to Affordable HIV Treatment*, at http://www.healthgap.org/press_releases/05/020105_hgap_fs_india_ipr.pdf (last visited Nov. 1, 2005).

⁴⁹ There are reportedly 8,926 applications in the mailbox. K.G. Narendranath, *Patent Mailbox Opens: Pfizer is Top Applicant*, FIN. EXPRESS, Mar. 21, 2005, http://www.financialexpress.com/fe_full_story.php?content_id=85782 (last visited Nov. 1, 2005).

⁵⁰ For an analysis of some of these procedural drawbacks, see Sudip Chaudhuri, *TRIPS Agreement and the Amendment of Patents Act in India*, 37(32) ECON. & POL. WKLY 8 (Aug. 10, 2002).

⁵¹ *Imperial Chemical Industries Ltd. v. Controller General of Patents, Designs and Trade Marks*, A.I.R. 1978 Cal. 77.

⁵² A new explanation has been added to section 84(6) in this regard.

It is nevertheless important to appreciate that possibly another reason for the non-optimal use of the compulsory licensing regime under the old regime was the absence of a well-developed local industry. Needless to say, in the context of pharmaceutical inventions, this is not an issue, as India has a well-developed local industry with extensive expertise and a readiness to exploit compulsory licensing provisions.⁵³ In the years to come, India is likely to provide a fertile ground for the emergence of sophisticated compulsory licensing jurisprudence, at least with respect to pharmaceutical inventions.

2. Retrospective Damages

The newly added proviso to section 11A of the Patents Act considerably dilutes the monopoly granted to pharmaceutical patents that flow from mailbox applications.

Section 11A(7) provides that patentees are entitled to claim damages retrospectively from the date of publication of their patent applications, which means that the moment a patent application is published (as opposed to a patent being granted), a third party runs the risk of damages in case of infringement. The Act, however, provides that such retrospective rights under section 11A do not apply to pharmaceutical mailbox applications. This result, coupled with the fact that the twenty-year patent monopoly term runs from the date of the mailbox application and not from the date of grant, will reduce the strength of drug patents that fructify from mailbox applications, a consequence likely to benefit the continued production of generics at low prices.⁵⁴

Therefore, the failure to grant retrospective remedies to mailbox applications, coupled with making them automatically susceptible to

⁵³ It has to be borne in mind that prior to the 2005 Act, only process patents were available for pharmaceutical inventions. Generic companies were able to work around such processes with ease, without resorting to any form of licensing, whether compulsory or voluntary. Also, very few processes were actually patented, since the term of protection was a mere seven years and such processes could anyway be designed around with ease. See Shondeep Banerji, *Who Controls Domestic Law-Making? The TRIPS Agreement and the Indian Intellectual Property Regime*, Address at the Political Studies Association UK 50th Annual Conference, London, UK (Apr. 10-13, 2000), available at <http://www.psa.ac.uk/cps/2000/Banerji%20Shondeep.pdf> (last visited Oct. 28, 2005).

⁵⁴ For a more detailed treatment of this issue, see Shamnad Basheer, *Of Generics, Pharmaceutical Patents and the Countdown to 2005: A Note To Policy Makers*, *ECON. TIMES*, Sep. 26, 2004, <http://www.patentmatics.org/pub2004/pub11a.doc> (last visited Oct. 11, 2005).

compulsory licensing provisions, will ensure that the supply of existing generic drugs at affordable prices is not unduly hampered. To a limited extent, generic manufacturers could also avail of the research exemption⁵⁵ and the wide Bolar provision in section 107A.⁵⁶

3. *The Patentability Threshold*

The question of whether the new regime will have an impact on access to new drugs is more vexed. This will depend significantly upon the scope of patentability of pharmaceutical inventions. Notwithstanding calls by civil society to restrict the patentability of pharmaceutical inventions to only new chemical entities (NCEs),⁵⁷ no such express limitations were introduced.⁵⁸ However, this does not automatically mean that all such substances (including new chemical entities, formulations, new drug delivery systems etc) will merit patent protection. Rather, the more rigorous requirements for 'inventive step' introduced by the 2005 Act and the expansive 'new use' exclusion could help in curbing new grants.⁵⁹ Indeed, as argued earlier, a very strict reading of the term 'efficacy' could result in very few patents for incremental pharmaceutical innovations that rely on new forms of existing substances.⁶⁰

⁵⁵ Section 47(3) encapsulates the 'experimental use' exception in the Indian context and provides that a patent may be used by any person 'for the purpose merely of experiment or research including the imparting of instructions to pupils'. This exception appears to be fairly wide, but its ambit is yet to be tested in a court of law.

⁵⁶ See discussion *supra* Part IIG.

⁵⁷ See B.K. KEAYLA, NATIONAL WORKING GROUP ON PATENT LAWS, PATENTS AMENDMENT ORDINANCE 2004: A CRITIQUE 1 (2005) ("Pharmaceutical patentability should be restricted only to new chemical and medical molecules/entities. This will help exclusion of frivolous claims").

⁵⁸ However, the government has constituted a technical committee to determine whether restricting the grant of patents for pharmaceutical substance to only new chemical entities (NCEs) would be in compliance with TRIPS. *Technical Panel to Look into IPR Issues*, FIN. EXPRESS, Apr. 5, 2005, http://www.financialexpress.com/fe_full_story.php?content_id=87046 (last visited Oct. 23, 2005).

⁵⁹ See discussion *supra* Part IIC.

⁶⁰ It is pertinent to note that a member of Parliament, Mr. Kharabela Swain, had, during the Parliamentary debates, opined that patents should be given for 'incremental innovations' as Indian scientists do not have the know-how or capital to come up with new chemical entities but do have the know-how to make improvements. Lok Sabha Debate, *supra* note 37. The term 'pharmaceutical substances' may also have been defined with the intent of curbing the

Apart from the ‘new use’ exclusion, the Patents Act has several patent eligibility or subject matter exclusions⁶¹ such as the ‘method of medical treatment’ exception⁶² and the ‘product of nature’ exclusion.⁶³ These could be effectively used to limit the scope of protection to pharmaceutical inventions.

In this regard, it bears noting that the Patent Office has a well-entrenched history of adopting a conservative approach towards patentability.⁶⁴ Relying on the Ayyangar Report and the mantra that fewer patents are conducive to a more robust indigenous industry, the Patent Office has, in the past, demonstrated a ‘policy style’ approach to the issue of patentability and denied protection to several inventions that merited patents in other parts of the world. Indeed this trend was discernible in as late as 2001, when the patent office refused an application by Dimminaco AG (a Swiss biotechnology company) claiming a method of producing a live vaccine on the ground that the term ‘manufacture’ did not include a process that had a living substance as its end product.⁶⁵

Therefore, it is likely that patentability criteria and subject matter exclusions will be interpreted by the patent office in a rigorous manner so as to filter out inventions that do not represent a genuine therapeutic advance. The patent office could draw from the experience of developed countries that

scope of patents granted to pharmaceutical substances. However, in the absence of a mention of the term in the text of the legislation, the purpose of such a definition remains obscure.

⁶¹ The principle of ‘patent eligibility’ broadly refers to the requirement that a subject matter for which a patent is sought be inherently suitable for patent protection, in the sense of falling within the scope of subject matter that patent law prima facie exists to protect. The term ‘patentability’, on the other hand, refer to those set of principles that inform the requirements that must be satisfied for a patent eligible subject matter (i.e., an invention) to be granted a valid patent. Principally they are the requirements of novelty, inventiveness (non-obviousness), utility (industrial applicability) and sufficient description. See Justine Pila, *Bound Futures: Patent Law and Modern Biotechnology*, 9 B.U. J. SCI. & TECH. L. 326, 341-356 (2003).

⁶² Section 3(i) excludes “any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings” from patentability.

⁶³ Section 3(c) excludes the “discovery of any living thing or non-living substances occurring in nature” from patentability.

⁶⁴ See generally Shamnad Basheer, ‘Policy Style’ Reasoning at the Indian Patent Office, 3 INTELL. PROP. Q. 309 (2005).

⁶⁵ *Dimminaco AG v. Controller of Patents and Designs*, (2002) I.P.L.R. 255 (Cal). See also *id.*

have strictly applied patentability criteria in some cases to prevent 'evergreening'. For example, SmithKline's secondary patent on a polymorph of cimetidine, granted approximately five years after the original patent, was invalidated in the UK and other countries on the grounds that such a polymorph could not be considered 'novel' - i.e. it was inevitably obtained by applying the process already claimed in the original patent.⁶⁶

It is pertinent to note in this context that Article 27 of TRIPS stipulates that "patents shall be available for any inventions... provided that they are new, involve an inventive step and are capable of industrial application."⁶⁷ This leaves some flexibility in the hands of member states to define these patentability criteria in a manner that suits their specific national interests.⁶⁸ Member states have, in fact, refined patentability criteria in the context of specific fields of technology, taking into account the unique concerns posed by such technologies.⁶⁹ For example, in 2001, the revised utility guidelines formulated by the United States Patent and Trademark Office (USPTO) were

⁶⁶ *SmithKline and French Laboratories Ltd v. Evans Medical Ltd* [1989] FSR 561. *But see* TREVOR COOK ET AL., PHARMACEUTICALS, BIOTECHNOLOGY AND THE LAW 86, 89 (1991). *See also* Dow Chemicals Application (unreported - SRIS O/179/83) and Shell International's Application (unreported - SRIS O/187/83) (rejecting claims to optically active isomers as obvious because the improved properties were not unexpected and there was either an expectation or it was predictable that this would be so).

⁶⁷ A footnote states: "[F]or the purposes of this Article, the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non-obvious' and 'useful' respectively."

⁶⁸ In the opinion of the Commission on Intellectual Property Rights (CIPR), "[T]here is ample scope for developing countries to determine for themselves how strictly the common standards under TRIPS should be applied and how the evidential burden should be allocated." The CIPR recommends the application of strict standards of novelty, inventive step and industrial application or utility and asks developing countries to consider higher standards than those currently applied in developed countries. COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 114, 123 (2002), available at http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf (last visited Nov. 1, 2005) [hereinafter *CIPR Report*].

⁶⁹ This is normally done through 'examination guidelines' to be followed by the patent offices of member states. In the context of pharmaceutical inventions, see Patent Office, *Examination Guidelines for Patent Applications relating to Medical Inventions in the UK Patent Office* (March 2004), available at <http://www.patent.gov.uk/patent/reference/medguidlines/claims.htm> (last visited Nov. 1, 2005).

targeted towards biotechnology inventions.⁷⁰ It is also pertinent to note that a provision has been enacted in Germany to ensure that the patent monopoly on a gene sequence is limited to the specific function disclosed and not to all functions.⁷¹

4. *Opposition Mechanism*

Apart from this, the robust opposition mechanism (pre-grant and post-grant) could be leveraged to filter out frivolous patents. Some mailbox applications have already been challenged under the pre-grant opposition procedure. Thus, for example, Natco Pharma Ltd, an Indian pharmaceutical company, has opposed an application by Novartis India Ltd pertaining to the anti-cancer drug imatinib mesylate on the ground that it lacks novelty. According to Natco, the Indian patent application merely claims a crystal form (beta) version of a drug that was already known in 1993.⁷² This challenge

⁷⁰ See Utility Examination Guidelines, 66(4) Fed. Reg. 1092 (Jan. 5, 2001), available at <http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf>. These guidelines require that an applicant assert a specific, substantial and credible utility for the claimed invention. These guidelines owe themselves to the difficulty in determining whether certain biotechnology-related inventions, such as those covering genes or proteins, really have any industrial application. Often any such application is not evident from the invention itself. Such a requirement is now to some extent also being applied by the EPO. See, e.g., EPO Opposition Decision revoking EP0630405 (*ICOS Corporation*) (Jun. 20, 2001) (unreported), cited from CIPR Report, *supra* note 68, at 117. In relation to these guidelines, the CIPR Report notes:

It is to be hoped that this new standard will prevent patents being granted on inventions for which only a speculative application is disclosed, but it may be that it does not go far enough and the impact of the new Guidelines will therefore need to be closely monitored. Developing countries providing patent protection for biotechnological inventions should assess whether they are effectively susceptible to industrial application, taking account of the USPTO guidelines as appropriate.

CIPR Report, *supra* note 68, at 117.

⁷¹ An amendment approved by the German Parliament in 2004 limits patent protection on human gene sequences to 'disclosed functions' at the time of the patent application, i.e. a patent on a human DNA sequence used for a specific function would not cover a second function discovered later by another researcher using the same DNA sequence. Ned Stafford, *German Biopatent Law Passed*, SCIENTIST, Dec. 10, 2004, available at <http://www.the-scientist.com/news/20041209/01/> (last visited Oct. 28, 2005).

⁷² Other grounds for opposition include the fact that the application falls within the subject matter exclusion under section 3(d), as it claims a new form that does not show increased efficacy and also that the claimed invention does not involve an 'inventive step'. Press Trust of India, *Natco Opposes Novartis' Patent Claim*, at <http://inhome.rediff.com/money/2005/jun/20natco.htm> (last visited Oct. 28, 2005).

is bound to create considerable interest, as Novartis already owns an exclusive marketing right⁷³ over this drug (which it sells under the name Glivec) and has injuncted several generics on the basis of this exclusive marketing right.⁷⁴

5. Price Control/Competition Regime

Fears that the price of patented pharmaceutical inventions may spiral also fail to take into account price control mechanisms and the newly instituted competition regime in India.

When India passed its Patent Act in 1970, it also instituted a Drug Price Control Order (DPCO) under the Essential Commodities Act of 1955 to control the price of drugs and ensure access to the general public.⁷⁵ Under this order, prices of bulk drugs and their formulations were fixed by the government as per a specified formula that allowed a 100% margin on ex factory cost. Price changes of the remaining drugs were also to be monitored.

However, over a period of time, as a result of sustained lobbying by the Indian pharmaceutical industry, the number of drugs listed in the DPCO fell from 347 in 1979 to 76 in 1995.⁷⁶ A new pharmaceutical policy in 2002 that sought to relax controls even further was challenged on the ground that, under the policy, certain life-saving drugs had the potential of being excluded from

⁷³ In accordance with Article 70.9 of TRIPS, Chapter IVA of India's Patent Act (which has now been deleted by the 2005 Act) provided that till such time as a product patent regime for pharmaceutical inventions was established, limited rights known as 'exclusive marketing rights' would be granted to inventions that met certain criteria - the applicant had to have a patent issued in a foreign country and have procured marketing approval from the relevant authority in that country as well as from the relevant authority in India. As the name itself suggests, the crux of this concept is a limited right to exclusively market the drug or medicine in question. The exclusive marketing right lasts five years or until the issuance or rejection of a patent (§ 24B, Patents Act, 1970). Out of 17 applications filed for the grant of an EMR during the period in which the mailbox system was functional, only four were granted. See Archa Saran, *A Changing Regime: India's Tryst with January 1, 2005*, 38 I.P.B.A. J. 17, 21 (2005).

⁷⁴ See SUDIP CHAUDHURI, *TRIPS AND CHANGES IN PHARMACEUTICAL PATENT REGIME IN INDIA* 7 (Indian Institute of Management, Calcutta, Working Paper No. 535, Jan. 2005).

⁷⁵ See R. Gupta, *TRIPS Compliance: Dealing with the Consequences of Drug Patents in India*, 26 HOUSTON J. INT'L L. 599, 608 (2004).

⁷⁶ Siddarth Narrain, *A Life Saving Order*, FRONTLINE, Jul. 17-30, 2004, <http://www.frontlineonnet.com/fl2115/stories/20040730004110300.htm> (last visited Oct. 21, 2005).

the DPCO. The challenge made its way to the Supreme Court and is yet to be resolved.⁷⁷

Going by this history, one is prone to be a little sceptical of the role of price control in India. However, there are indications that, in view of the 2005 Act and its expected impact on prices, the government is considering strengthening the price control regime to increase competition and ensure affordable medicines to the general public. To this end, a new Drug Pricing (Regulation & Management) Act is being considered.⁷⁸ The proposed Act would, while retaining the DPCO within its ambit, have additional provisions such as end-to-end price monitoring and negotiated settlement of prices of new/patented drugs. It would also lay emphasis on cutting promotional expenses that contribute substantially to the price of the drug.

The Competition Act, 2002 was brought in to replace the earlier Monopolies and Restrictive trade Practices (MRTP) Act, 1969.⁷⁹ Modelled on the lines of the EC competition regime,⁸⁰ it is possible that case law under the EC regime that places a check on abusive practices by intellectual property owners could be transposed to India as well. In particular, section 4 of the Act, which prohibits an enterprise from abusing its dominant position, mirrors the prohibition in Article 82 (ex Article 86) of the EC Treaty.⁸¹ It provides

⁷⁷ Union of India v. K.S. Gopinath, S.L.P.(C) No. 3668 of 2003. This is an appeal from a lower court ruling that had stayed the operation of the new policy. Although the Supreme Court granted leave in the matter, it is still to render any decision or pass any orders. The net result is that the stay on the policy granted by the lower courts continues to be operational. See *SC Concern Over Non-Inclusion of Essential Drugs*, HINDU, Aug. 2, 2003, <http://www.hinduonnet.com/thehindu/2003/08/02/stories/2003080204201300.htm> (last visited Oct. 28, 2005).

⁷⁸ K.G. Narendranath, *DPCO May be Retained in New Drug Pricing Act*, FIN. EXPRESS, Aug. 1, 2005, http://www.financialexpress.com/fe_full_story.php?content_id=98022 (last visited Oct. 29, 2005).

⁷⁹ Only some of the provisions of this Act have been brought into force (sections 1, 2, 7-17, 22, 23, 36 and 49-65 have come into force by virtue of Notifications Nos. S.O. 340(E) and S.O. 715(E) dated March 31, 2003 and June 19, 2003 respectively).

⁸⁰ See generally A. Viswanathan, *From Commanding Heights to Competition: A Comparative Analysis of India's Competition Act 2002 with UK/EC Law*, 14(7) INT'L. COMPANY & COM. L. REV. 229 (2003) (comparing the Indian and EU regimes).

⁸¹ Treaty Establishing the European Economic Community, 25 Mar. 1957, 298 U.N.T.S. 3 (Treaty of Rome).

examples of conduct that amount to an abuse of a dominant position and includes “[t]he imposition of an unfair or discriminatory condition or price in the purchase or sale of goods or services, including predatory prices except where adopted to meet competition”. A similar provision in the EC has been interpreted as proscribing high monopolistic prices.⁸²

B. Spurring an Innovation Culture in India

The multinational pharmaceutical industry argues that a product patent regime is essential for encouraging R&D in new drugs and catapulting the domestic industry into the innovative drug sphere. It needs to be noted however that basic reverse engineering skills (organic chemistry skills) are different from the skills required to arrive at new drugs (medicinal chemistry skills).⁸³ Besides, the costs of researching upon and introducing a new drug into the market are colossal.⁸⁴ It therefore remains to be seen whether incentives through a patent regime will achieve the desired results and whether Indian companies will be able to compete with global multinational companies on this turf. A commentator rightly notes that till recently, the emphasis has been “mainly on building a system of production and not on a system of innovation”.⁸⁵

⁸² This possibility was first acknowledged by the European Court of Justice (ECJ) in *Sirena v. Eda*, [1971] C.M.L.R. 260. Later cases include *United Brands Co. v. Commission*, [1978] E.C.R. 207, and *British Leyland plc v. Commission*, [1986] E.C.R. 3263.

⁸³ See S. Subramaniam, *Pharmaceutical R&D in India: Addressing the Emerging Model of Drug Innovation*, Address at Chatham House Conference, London, UK (Feb. 1, 2005), available at <http://www.chathamhouse.org.uk/pdf/conferences/proceedings/subr0105.ppt> (last visited Oct. 29, 2005).

⁸⁴ The current average capitalised cost of developing a new drug is estimated to be US\$ 870 million. See generally J.A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003). This estimate has been criticised as not representing “...what companies actually spend to discover and develop new molecular entities. It includes the expense of using money for drug research rather than other investments (known as the ‘opportunity cost of capital’).” Public Citizen, *Critique of the DiMasi/Tufts Methodology and Other Key Prescription Drug R&D Issues*, at http://www.citizen.org/congress/reform/drug_industry/articles.cfm?ID=6532 (last visited Nov. 1, 2005).

⁸⁵ PADMASHREE GEHL SAMPATH, *ECONOMIC ASPECTS OF ACCESS TO MEDICINES AFTER 2005: PRODUCT PATENT PROTECTION AND EMERGING FIRM STRATEGIES IN THE INDIAN PHARMACEUTICAL INDUSTRY* 30, available at <http://www.who.int/intellectualproperty/studies/PadmashreeGehlSampath.Final.pdf> (last visited Nov. 1, 2005).

However, over the last couple of years, Indian firms have been engaging in incremental modifications of pharmaceutical products developed in foreign (mainly Western) countries.⁸⁶ Such modifications or incremental innovations that cater specifically to the public health needs of India (such as new drug delivery systems and formulations that are created to withstand tropical temperatures) are of immense value.⁸⁷ An excellent example of such incremental innovation is that of Wockhardt Ltd., which developed humidity-resistant salt forms and isomers of known anti-microbial substances. The original compounds had been patented by the Otsuka Pharmaceutical Company as potential antimicrobial agents against bacteria that were resistant to conventional antibiotics such as penicillin, ampicillin and streptomycin. The patented salts have better solubility characteristics and greater stability in the presence of high humidity climates than the original patented active substance.⁸⁸ It is likely that the new regime will, at the very least, incentivise these kinds of incremental innovations - the extent to which it will do so will, of course, depend on how the patent eligibility and patentability requirements are interpreted by the Patent Office and courts.

⁸⁶ See CARSTEN FINK, HOW STRONGER PATENT PROTECTION IN INDIA MIGHT AFFECT THE BEHAVIOR OR TRANSNATIONAL PHARMACEUTICAL INDUSTRIES 9 (The World Bank, Washington DC, USA, Working Paper No. 2352, 2000) 9. A recent news item points out that “[d]omestic pharma majors fear that the new negative list on patenting substances will discourage indigenous research and development (R&D). Since they are far from launching a new chemical entity of their own, some of India’s largest pharmaceutical companies are focusing on novel drug delivery systems (NDDS) for the time being.” K.G. Narendranath & Ravi Krishnan, *Long Negative List of Patentability Discouraging Research and Development*, FIN. EXPRESS, Sept. 12 2005, http://www.financialexpress.com/fe_full_story.php?content_id=98948 (last visited Nov. 1, 2005). On the basis of all these reasons, it is often claimed that the Indian industry is not invention-based, aiming at the production of new chemical entities, but rather innovation-based, aiming at producing incremental modifications of existing drugs.

⁸⁷ The example of Ranbaxy is noteworthy in this regard - it came up with an innovative drug delivery system for ciprofloxacin. The invention, sold as Cipro-OD, enabled a patient to take the medicine just once a day (OD) and was successfully licensed to Bayer AG. See SAMPATH, *supra* note 85, at 43.

⁸⁸ The new salt innovations have been patented: arginine salt forms (6,514, 986; 6,753,333); specific isomers of arginine salts referred to as L-arginine salts (6,664,276) and optically pure carboxylic acid salt forms (6,750,224; 6,608,078). World Intellectual Property Organization Secretariat, *Follow-on Innovation and Intellectual Property* 13-14 (20 May 2005) (Submission to the WHO’s CIPIH), at <http://www.who.int/entity/intellectualproperty/submissions/Innovation%20&%20Intellectual%20Property%20WIPO.pdf> (last visited Oct. 29, 2005).

It is also likely that a product patent regime will encourage global multinationals to outsource some of their drug manufacturing and clinical trials to India and enter into appropriate partnerships with Indian companies.⁸⁹

C. TRIPS Implications

Despite the fact that the 2005 Act is purportedly India's final step towards TRIPS compliance, the TRIPS compatibility of some of its provisions may be in dispute.

Article 27 of TRIPS states, in the pertinent part, that "... patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." The non-grant of retrospective rights to mailbox applications, coupled with making them automatically susceptible to compulsory licensing provisions, may violate Article 27 - mailbox applicants could argue that, when compared with other fields of technology, they have been discriminated against.

The WTO panel in the *Canada - Patent Protection of Pharmaceutical Products* case⁹⁰ ruled that the term 'discrimination' was a "normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment". Whether the above disadvantageous treatment of mailbox applicants is an 'unjustified imposition' will depend upon an assessment of public health concerns and affordable access to medicines in India and the causal link between such concerns and the provisions that are allegedly in contravention of TRIPS. It must be borne in mind that Article 27.1 is to be interpreted in the context of the Doha Declaration, paragraph 4 of which reads as follows:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the

⁸⁹ Manojit Saha, *Drug Patent: A Viagra for Indian Pharmaceutical Industry*, DECCAN HERALD, Apr. 4, 2005, available at <http://www.deccanherald.com/deccanherald/apr42005/93626200543.asp> (last visited Oct. 29, 2005).

⁹⁰ WTO Panel on Canada - Patent Protection of Pharmaceutical Products, Report of the Panel on Canada-Patent Protection of Pharmaceutical Products, WT/DS114/R at ¶ 7.94 (Mar. 17, 2000), available at <http://docsonline.wto.org/DDFDocuments/t/WT/DS/114R.DOC>.

Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

Secondly, section 84(1)(c) of the Act, which provides for a compulsory licence if the invention is not worked in India ('local working' provision), could also arguably fall foul of Article 27 which, as mentioned above, prohibits any discriminatory treatment based on whether products are imported or locally produced. This issue is yet to be resolved by a WTO panel - an opportunity was lost when the US voluntarily withdrew its complaint against Brazil, which had a provision similar to the Indian one.⁹¹

While the TRIPS compatibility of the above provisions are not entirely clear, the argument that the amended section 107A(b) dealing with parallel imports contravenes Article 28 of TRIPS is a strong one.⁹² Since this section is not limited to pharmaceutical inventions, any potential justification for differential treatment in the context of pharmaceutical inventions will not apply here.

D. A Stitch in Haste Leads to Provisions in Bad Taste

As is evident from the above discussion, some of the provisions introduced by the 2005 Act could have done with more careful deliberation. Defining a term ('pharmaceutical substance') that is not mentioned thereafter in the Act cannot, even with an ample dose of charity, be attributed to anything other than shoddy drafting. Definitions of 'new invention' and 'inventive step' introduced by the Act not only go against the grain of time-tested principles, but lead to inconsistencies with other provisions in the Act.

These mistakes are not too surprising, given that most of the problematic provisions were deliberated upon and introduced in less than three months - between December 2004 (when the Ordinance was passed) and March 2005 (when a Bill was placed before Parliament). To a large extent, changes to the Ordinance were made to appease the Left Parties. A case in point is the

⁹¹ See WTO Panel on Brazil - Measures Affecting Patent Protection, Report of the Panel on Brazil - Measures Affecting Patent Protection, Request for the Establishment of a Panel by the United States, WT/DS199/3 (Jan. 9, 2001), available at <http://docsonline.wto.org/DDFDocuments/t/WT/DS/199-3.doc> (last visited Oct. 29, 2005).

⁹² See discussion *supra* Part IIIH.

'inventive step' clause, which was copied verbatim from the list of recommendations by the Communist Party of India (Marxist) (CPI(M)),⁹³ which in turn appears to be based on a report by a prominent peoples' commission.⁹⁴

A slower and more elaborate deliberation would have yielded better provisions. At a time when the word 'patent' meant patent leather shoes to most in India, the legislative effort was informed by a brilliant report from a Committee that circumnavigated the laws of the world and took a call on what they thought would best suit the needs of India.⁹⁵ The success of the generic industry today is testimony, albeit in some small way, to the brilliance of their foresight. This report has in fact acquired an almost canonical status in the patent office, which still relies heavily on it whilst determining patentability.⁹⁶

Contrast this with the present Act: legislative efforts began towards the end of 2002 and did not even so much as merit a Parliamentary Committee Report.⁹⁷ Rather, while debating provisions pertaining to the 2005 amendments, the government took repeated refuge in the fact that the issues had already been discussed by a JPC (Joint Parliamentary Committee) constituted for the purposes of the 2002 Amendments.⁹⁸ As the CPI(M) rightly puts it:

⁹³ Communist Party of India (Marxist), *Left Parties on Amendments to the Indian Patent Act*, at http://www.cpim.org/upa/2004_patents.pdf (last visited Nov. 1, 2005).

⁹⁴ Peoples' Commission on Patent Laws for India, *Report of the Fourth People's Commission on Review of Legislations Amending Patents Act 1970*, at <http://www.who.int/entity/intellectualproperty/documents/Report4thCommission.pdf> (last visited Nov. 2, 2005).

⁹⁵ AYYANGAR REPORT, *supra* note 6.

⁹⁶ See *generally* Basheer, *supra* note 64.

⁹⁷ Contentious legislations (or issues therein) in India are, more often than not, referred to select Parliamentary Committees.

⁹⁸ As stated in n.1 above, India's Patents Act, 1970 had been amended twice earlier to comply with TRIPS: first in 1999 and then in 2002. Most of the changes in the 2002 amendments were based on recommendations made by a Joint Parliamentary Committee constituted for this purpose by the then government. RAJYA SABHA SECRETARIAT, REPORT OF THE JOINT COMMITTEE ON PATENTS (SECOND) AMENDMENT BILL 1999 (2001).

*We fail to understand how the deliberations of the JPC constituted to consider the Second Amendment can now be cited as if it had the last word on all matters relating to the Patent Amendments under consideration at present. That JPC is now functus officio.*⁹⁹

The stakes being higher in 2005, one would have expected detailed deliberation on the patent regime and a far more elaborate legislative exercise. Indeed, as a *New York Times* editorial profoundly noted: "Seldom has India's Parliament considered anything of such global import."¹⁰⁰

The debates around the Bill were also characterised by a rather one-sided focus on pharmaceuticals. It was largely forgotten that the removal of section 5 not only introduced product patents for pharmaceutical substances, but also for other chemical substances including agrochemicals.

IV. CONCLUSION: WHITHER NATIONAL INTEREST?

The Patents Act in its final form is the result of extensive politicking, lobbying and of course, compromise. With competing pressures from multinationals, civil society, a communist coalition partner and an opposition party that performed the most stunning volte face (objecting to a bill that it had drawn up itself), the government performed the finest tightrope walk ever witnessed in the annals of Indian intellectual property law making. To top it all, it had to perform this delicate stunt within the contours of the TRIPS/WTO framework.

This dexterous manoeuvring around competing interests certainly deserves praise. However the net result of such a compromise and a hasty legislative process is a lack of clarity in the law. The price for these deficiencies will, no doubt, manifest itself in the years to come - in sharp contrast to the way that a carefully deliberated policy in 1970 resulted years later in a generic industry that became the pride of the nation.

As for the vexed question of the likely impact of the new regime on access to medicines, it bears noting that the provisions, as they stand now, leave sufficient scope for the continued production of some generics. Insofar

⁹⁹ See Communist Party of India (Marxist), *supra* note 93, at 1.

¹⁰⁰ *AIDS Drugs Threatened*, N.Y. TIMES, Mar. 5, 2005, <http://www.nytimes.com/2005/03/05/opinion/05sat3.html> (last visited Nov. 2, 2005).

as new drugs are concerned, the costs are likely to increase and in the absence of a nationwide healthcare insurance system, the common man may have to bear the brunt of the new regime. However, there are provisions in the patent regime and other related regimes that could be interpreted in a manner as to help keep the costs down. Whether these provisions would be so interpreted to further public health concerns remains to be seen.