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Note

**The Effect of TRIPs on Indian Patent Law:
A Pharmaceutical Industry Perspective**

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I. INTRODUCTION

1. Like many developing countries, India currently maintains weak patent laws in order to provide inexpensive products to its citizens.¹ Such laws also benefit the development of India's national infrastructure by allowing Indian companies to compete on a more favorable basis with the local facilities of multinational corporations.² Nonetheless, in the interest of furthering patent harmonization, India signed the Trade Related Aspects of Intellectual Property Rights agreement ("TRIPs") of the General Agreement on Tariffs and Trade ("GATT") on April 15, 1994. Among other things, TRIPs requires minimum levels of patent protection. The objective of uniform patent protection under TRIPS is to promote international trade and investment in an increasingly interdependent global market.
2. This Note examines the impact of TRIPs on current Indian patent law as it relates to the pharmaceutical industry. Part II provides an overview of the current state of patent protection in India, the rationales behind Indian patent policy, and the effect of current law on the Indian pharmaceutical market. Part III discusses changes to Indian patent law required to comply with TRIPs. Part IV examines opposition to Indian patent reform. Part V analyzes legislation in India implementing TRIPs and raises issues likely to arise as reform efforts proceed. Part VI draws a comparison to the development of modern Japanese patent law and suggests that opposition to patent reform in India is unfounded. This Note concludes in Part VII that although there is some basis for the fears of its opponents, Indian patent reform will provide a net benefit by encouraging investment in Indian industries, especially the pharmaceutical industry, and by providing more pharmaceuticals to the Indian public.

II. STATUS QUO

A. *India's Patents Act of 1970*

3. The Patents Act of 1970 ("the Patents Act") governs current Indian patent law.³ In consideration for disclosing any new and useful (a) art, process, method, or manner of manufacture; (b) machine, apparatus or other article; or (c) substance of manufacture or an improvement thereon, the Patents Act provides exclusive rights for a limited period of time.⁴ These exclusive rights provide a cause of action for "the making, using or importation of any machine, apparatus or other article or by the using of any process or by the importation, use or distribution of any [patented] medicine or pharmaceutical."⁵

1. Statutory Subject Matter

4. Statutory subject matter under the Patents Act excludes the following:
 - (1) inventions that are frivolous;⁶
 - (2) inventions that are immoral or injurious to public health;⁷
 - (3) mere discoveries of scientific principles or formulations of abstract theory;⁸
 - (4) mere discoveries of new uses of known substances or processes;⁹
 - (5) mere admixtures;¹⁰
 - (6) mere arrangements of known devices, each device functioning independently in known ways;¹¹
 - (7) testing means applicable during manufacture;¹²
 - (8) methods of agriculture or horticulture;¹³
 - (9) inventions relating to atomic energy;¹⁴
 - (10) computer programs;¹⁵
 - (11) methods of teaching;¹⁶ or
 - (12) processes for treating humans, animals, or plants to cure them or increase their economic value or that of their products.¹⁷
5. In addition to these general exclusions, *product* patents are not available for inventions claiming alloys, optical glass, semiconductors, inter-metallic compounds, or — most importantly for this Note — food or medicine.¹⁸
6. In addition to qualifying as statutory subject matter, an invention must pass utility, novelty, and nonobviousness tests.¹⁹ Utility requires the “practical existence of a useful manufacturable item.”²⁰ For purposes of novelty and nonobviousness, prior art encompasses publicly available information in a particular industry at the time of the patent application,²¹ including prior patents in India, patents filed in India that claim an earlier foreign priority date,²² or any prior publication in any country.²³ The examiner must ascertain whether an invention lacks any of the above patentability requirements.
7. After determining patentability and accepting a complete specification for the invention, the examiner publishes the patent application in the Official Gazette.²⁴ The “date of the patent,” which is used to measure the length of the patent term, is defined as the date of publication.²⁵ Publication in the Official Gazette also marks

the beginning of the opposition period,²⁶ during which the public has four months to oppose a patent for failure to meet any statutory requirement. Statutory grounds for opposition include: (1) wrongfully obtained inventions;²⁷ (2) lack of novelty in light of prior publications²⁸ or prior patent claims;²⁹ (3) lack of novelty given prior public knowledge or public use in India;³⁰ (4) obviousness given the prior art or public use;³¹ (5) non-statutory subject matter;³² (6) inadequate enablement;³³ (7) failure to disclose information regarding foreign applications; or (8) time-barred convention applications.³⁴

2. Patent Term Duration

8. Upon expiration of the opposition period without successful opposition, the applicant may request a patent grant and issuance, known as a "sealing."³⁵ During the opposition period — between the date of publication and the date of issuance — the applicant enjoys the benefits of an issued patent.³⁶ As explained below, complaining parties may request a compulsory license beginning three years from the date of issuance.³⁷ The Patents Act provides special treatment for process patents on food or medicine. For food and medicine patents, the date of issuance is one of two possible dates on which the patent term may begin. The term of a process patent for food or medicine lasts five years from the patent seal's date or seven years from the date of the patent, whichever period ends earlier.³⁸ Process or product patents otherwise last for fourteen years from the date of the patent.³⁹

3. Compulsory Licenses

9. The Indian government grants patents to encourage inventions and relies on compulsory licensing to ensure that the patentee or a licensee works the invention in India. The patentee must work the invention, or have another work the invention, on a commercial scale and to the fullest extent reasonably practicable without undue delay.⁴⁰ Under the current Patents Act, mere importation does not justify a patentee's monopoly.⁴¹ The Patents Act limits working the invention to manufacturing in India on a commercial scale and excludes importing the invention as a means of satisfying the working requirement.⁴²
10. Each year, the patentee and any licensees must disclose the extent of working the invention to the Controller General of Patents, Designs, and Trademarks ("Controller").⁴³ If a patentee or licensee fails to meet the working requirement, a compulsory license or a license of right may result.⁴⁴ At any time after three years

from the date of issuance, any person may apply for a compulsory license.⁴⁵ A compulsory license forces the patentee to license the patented invention to a complaining party who can show that either the patented invention is not available to the public at a reasonable price or that the “reasonable requirements” of the public with respect to the patented invention have not been met.⁴⁶ Reasonable requirements may include: (1) not prejudicing existing or new trades or industries; (2) meeting the demand for the patented article in India at an adequate quantity and a reasonable price; (3) developing or supplying the export market for the patented invention; and (4) not prejudicing the establishment or development of commercial activities in India.⁴⁷ Alternatively, the Indian government may apply for a license of right by claiming the patentee’s failure to meet the reasonable requirements of the public or to sell the invention at a reasonable price.⁴⁸ In contrast to a compulsory license, a patent endorsed by the “license of right” label requires the patentee to license the patent to anyone who is interested in the invention at a mutually agreed upon royalty⁴⁹ or a royalty prescribed by the Controller.⁵⁰ Process patents for food, medicine, or the manufacture of chemical substances, including pharmaceutical patents, are automatically endorsed as licenses of right three years from the date of issuance.⁵¹ The Controller may cap patent royalties at four percent of the total wholesale cost of a shipment to the buyer.⁵² If the patentee still has not worked the invention after two years from the date of a compulsory license grant or “license of right” endorsement, any person or the Indian government may apply for revocation of the patent.⁵³

4. Burden of Proof: Infringement

11. Finally, the Patents Act places the burden of proof on the patentee to prove infringement.⁵⁴ For process patents, the patentee must ascertain that a particular product could only have been made through the patented process.⁵⁵ For pharmaceuticals, ascertaining the process used to make a product is exceedingly difficult unless the process itself leaves identifiable traces in the resulting product. If a manufacturer uses quality control to eliminate impurities — a common practice in the pharmaceutical industry — identifying an infringing process is even more difficult.⁵⁶ The patentee can only hope that poor quality will result in tell-tale substances, evidencing that the manufacturer used the patented process.

B. *Historical Rationale for the Patents Act of 1970*

12. During the three years preceding enactment of the Patents Act, patent applications by foreign nationals exceeded those of Indians by more than 340%.⁵⁷ Indian

companies controlled an estimated ten to twenty-five percent of the domestic pharmaceutical market, with the remainder controlled by multinational companies.⁵⁸ The Patents Act of 1970 sought to enhance domestic development at the expense of foreign corporations through the following protectionist provisions: (1) assisting the development of an independent Indian pharmaceutical industry; (2) making new pharmaceuticals cheaply available to the Indian public; (3) promoting import substitution by encouraging local process development followed by bulk pharmaceutical production; (4) reversing the negative pharmaceutical balance of payments by stimulating exports; and (5) encouraging original pharmaceutical research and development in India.⁵⁹

13. In January 1995, at a conference of Labor Ministers from developing countries held in New Delhi, Indian Prime Minister P.V. Narasimha Rao commented on India's earlier protectionist stance. He admitted that "[t]hese policies had a definite historical context which accounts for their acceptance and adoption in the early stages of our quest for development. They have given and established in our countries a sound economic infrastructure."⁶⁰
14. India was not the only protectionist nation in 1970, particularly with regards to pharmaceuticals. Until recently, many of the developed countries had equally restrictive intellectual property laws. For example, Canada refused to grant pharmaceutical product patents until 1987⁶¹ and maintained compulsory licensing of pharmaceutical patents until 1991.⁶² Similarly, Japan included pharmaceutical product patents only as of 1976 and still has compulsory licensing provisions.⁶³

C. The Pharmaceutical Industry's Perspective on the Patents Act of 1970

15. The Patents Act of 1970 effectively offers no protection for pharmaceuticals. Four factors contribute to this lack of protection in India. First, the duration of the Indian patent term is too short to protect pharmaceuticals because the length of the pharmaceutical development cycle often exceeds the duration of patent protection. Second, delays in examination and opposition procedure further reduce the available duration of patent protection for pharmaceuticals. Third, Indian patent law imposes an artificially low royalty ceiling on compulsory licenses. Fourth, product patents simply are not available for pharmaceuticals,⁶⁴ a situation that undercuts research and development incentives by encouraging a strong domestic "pirate" industry.

1. Patent Term Duration

16. Although Indian patent law grants process patent protection, process patents do not adequately protect pharmaceuticals because the pharmaceutical development cycle often exceeds the patent term duration for food and medicine patents. A typical pharmaceutical company will file a patent application only after synthesizing an active ingredient and screening it to determine its pharmacological profile.⁶⁵ On average, compound development and animal and toxicological testing cost between \$230,000,000⁶⁶ and \$300,000,000 and require at least seven years to complete.⁶⁷ Clinical trials and regulatory approval require at minimum an additional three years. As a result, the average pharmaceutical development cycle from laboratory to market can require ten years.⁶⁸ Because the Controller automatically orders the endorsement of a pharmaceutical process patent as a license of right three years from the date of issuance, the patent monopoly expires at least seven years before the pharmaceutical ever reaches the market.⁶⁹

2. Procedural Delays

17. The time required to examine and approve a process patent also contributes to the inadequate duration of food and medicine patents. Typically, patent examination requires a minimum of six years. An additional two to four years may be required to complete examination if an opposition is filed.⁷⁰ Because the term of a pharmaceutical patent is the earlier of seven years from the date of publication or five years from the date of issuance,⁷¹ if an opposition is filed, the patent expires before the completion of the opposition period. Because issuance occurs after the opposition period, seven years from the date of publication is earlier than five years from the date of issuance. As a result, patent protection for foods and medicine expires well before a typical pharmaceutical product ever reaches the market.

3. Compulsory Licenses

18. Another factor contributing to ineffective patent protection in India is the royalty ceiling on compulsory licenses, which is significantly lower than royalty ceilings in many industrialized countries. Assuming examination requires less than two years and that no opposition occurs, the four percent maximum royalty under a compulsory license or a license of right will begin in the last two years of the patent's term. If opposition does occur, the compulsory license issue is irrelevant

because, as discussed above, the patent expires before completion of the opposition period.

19. India's four percent royalty ceiling on licenses of right is much lower than that for compulsory licenses granted in the United Kingdom, which are capped at forty percent, and typical royalties in the United States, which have no maximum limit.⁷² Facing these unfavorable conditions, multinational pharmaceutical corporations including Pfizer, Merck, Searle, and Squibb have either cut back their operations in India or abdicated from the Indian pharmaceutical market altogether.⁷³

4. Lack of Product Patent Protection

20. The Patents Act fails to extend product patent protection to pharmaceuticals. As a result, Indian pirate companies may easily and quickly duplicate pharmaceuticals without paying royalties to the patentee.⁷⁴
21. In most industries, the high cost of reverse engineering a product justifies a policy allowing firms to invent around a process patent.⁷⁵ For pharmaceuticals, however, alternatives to a patented process usually are inexpensive to develop and may be developed in less than two years.⁷⁶ In contrast to the difficult and expensive patent-prosecution and regulatory approval process, pirate firms need only acquire regulatory health approval from the Director General of Health Services. To acquire regulatory health approval, pirate companies merely file an application with the health authority to show that a pirated and a patented pharmaceutical are bioequivalent and bioavailable.⁷⁷ Bioequivalence requires the two drugs to have the same active ingredient in the same amount. Pharmaceuticals are bioavailable despite different inactive ingredients if they are absorbed by the body's treatment site at the same rate and extent, given a set dosage of the active ingredient.⁷⁸
22. In India, currently, the bioavailability tests of patented pioneer pharmaceuticals are in the public domain.⁷⁹ By availing themselves of this information, pirate companies avoid costly clinical trials. After reproducing a pharmaceutical, such firms merely compare the rate and extent of absorption of the pirated pharmaceutical with public domain data for the patented pharmaceutical. If the patented pharmaceutical and the pirated pharmaceutical are bioequivalent, the Director General of Health Services automatically registers the pirated pharmaceutical as "generic."⁸⁰

5. Market and Policy Considerations

23. Because India's intellectual property laws in general, and patent laws in particular, offer ineffective protection to research and development investments in technology, it is hardly surprising that a 1994 World Bank survey noted that India discourages foreign investment and technology transfer.⁸¹ The ease with which Indian firms manufacture pirate pharmaceuticals has helped convince eighty-one percent of major U.S. chemical and pharmaceutical firms that Indian patent protection is too weak for them to license their newest or most effective technology to either unrelated firms or even wholly owned subsidiaries in India.⁸² On the other hand, India has made considerable progress toward meeting four of the five objectives of the Patents Act, including developing an indigenous pharmaceutical industry, making inexpensive pharmaceuticals available, promoting import substitution, and reversing the trade balance for pharmaceuticals.⁸³ By September 1993, Indian companies dominated at least seventy percent of the domestic pharmaceutical market, in contrast to the worldwide trend of multinationals engulfing local markets.⁸⁴ The domestic sales of active ingredients increased from \$78,000,000 in 1980-81 to \$429,000,000 in 1993-94. Similarly, the production of formulations — the specific forms in which a pharmaceutical is delivered, such as a liquid or tablet — increased from \$390,000,000 in 1980-81 to more than \$2,200,000,000 in 1993-94.⁸⁵
24. The substitution of locally produced active ingredients for imported products patented in Europe, North America, and Japan has reached significant levels in India.⁸⁶ In 1990, India achieved a positive pharmaceutical trade balance for the first time.⁸⁷ Pharmaceutical prices in India are among the lowest anywhere in the world.⁸⁸ Indian pirate manufacturers market pharmaceuticals domestically, increase manufacturing capacity, and reduce their marginal manufacturing costs. As a result, pirate manufacturers are able to export cheap pharmaceuticals to countries that also have weak intellectual property laws. By the time a pharmaceutical's patent term expires in major markets, Indian companies often already possess the technical knowledge to manufacture the pharmaceutical more efficiently than the original inventor and can immediately offer cheap generic versions to worldwide consumers.⁸⁹

D. Modifications to the Drug Policy of 1986

25. Prior to 1986, oppressive domestic price controls limited profit margins in the Indian pharmaceutical industry, directly inhibiting one of the objectives of the

Patents Act, the development of the indigenous pharmaceutical industry. In response, the Indian parliament enacted the current regulatory scheme, the Drug Policy of 1986, for the purposes of: (a) ensuring abundant availability of essential, life-saving, and prophylactic medicines of good quality at reasonable prices; (b) strengthening quality control in drug production and promoting the rational use of drugs in the country; (c) creating an environment conducive to channeling new investment into the pharmaceutical industry and to encouraging cost-effective production and introduction of new technologies and new drugs; and (d) strengthening local drug production capabilities.⁹⁰

26. Issued in August 1987, the Drug Policy Control Order (“DPCO”) completed this policy. The DPCO covers 143 pharmaceuticals: twenty-one Category I pharmaceuticals, deemed necessary for national health programs, and 122 Category II pharmaceuticals, deemed Essential Drugs.⁹¹ The distinction between Category I and Category II pharmaceuticals creates separate price-markup ceilings for each category, termed Maximum Allowable Post Manufacturing Expenses (“MAPE”).⁹² These post-manufacturing expenses include advertising and distribution costs.⁹³ The markup ceiling is seventy-five percent over the previous pharmaceutical policy’s price-control regime for Category I pharmaceuticals and a one-hundred percent increase for Category II pharmaceuticals.⁹⁴ The DPCO’s policy, therefore, sets a maximum for a manufacturer’s sale price while still leaving a theoretical reasonable profit. Pre-tax profits from domestic sales during 1991-92, however, averaged a mere one percent.⁹⁵ As a result, the DPCO’s original MAPE still forces domestic companies to subsidize their national businesses with export and nonpharmaceutical sales.⁹⁶ To its credit, however, the DPCO did create a modicum of research and development incentives by exempting from price control for seven years active ingredient manufacturers who adopt processes developed through their own research and development efforts.⁹⁷
27. Modifications to the Drug Policy of 1986 (“the Modifications”) established a new price-control regime. The Modifications established the National Pharmaceutical Pricing Authority to review the list of pharmaceuticals under price control and to monitor the prices of decontrolled pharmaceuticals.⁹⁸ Although the new criterion for price-controlled pharmaceuticals is a minimum turnover of \$1,300,000, pharmaceuticals having sufficient market competition — at least five active ingredient producers and at least ten formulators and no more than forty percent of the market share — are exempt from price controls.⁹⁹ This exemption reduces the number of price-controlled pharmaceuticals to seventy-three. The new MAPE

applies to current Category I and II pharmaceuticals and places a one-hundred percent markup ceiling on the remaining price-controlled pharmaceuticals. The new MAPE also exempts from ten years of price control new pharmaceuticals produced by indigenous research and development, thereby expanding previous research and development incentives. With these new price-control measures, the Indian government has diminished the impact of radical pharmaceutical price increases. If, as expected, the capacity of the indigenous pharmaceutical industry to compete with multinationals becomes more robust, the government can phase out these price controls.

III. CHANGES TO THE PATENTS ACT OF 1970 TO COMPLY WITH TRIPS

28. The General Agreement on Tariffs and Trade seeks to “provide a framework of certainty and predictability about conditions in which traders conduct their transactions in the world market.”¹⁰⁰ Negotiations during the Uruguay Round of the GATT over Trade Related Aspects of Intellectual Property concluded with the signing of TRIPs by GATT-member countries on April 15, 1994, in Marrakesh, Morocco.¹⁰¹ Agreement on TRIPs represented a giant step toward harmonizing global intellectual property. Indeed, TRIPs seeks to promote “technological innovation and ... transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations” through the “protection and enforcement of intellectual property rights.”¹⁰² Developing countries that signed the agreement, including India, are required to enact legislation in accordance with TRIPs within ten years.¹⁰³ By signing TRIPs, the Indian parliament must amend India’s currently weak intellectual property laws to comply with the minimum requirements set forth in TRIPs.

A. *Product Patent Protection*

29. Article 28 of TRIPS requires member countries to provide both product and process patent protection to patent owners, including the exclusive rights to make, use, offer for sale, sell, or import a patented product or process.¹⁰⁴ TRIPs defines patentable subject matter as “any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”¹⁰⁵ Signatories may exclude inventions from patentability if they “[do not] protect public morality, ... human, animal, or plant life or health or to avoid serious prejudice to the environment.”¹⁰⁶ More

importantly for this Note, Article 27 authorizes member countries to “exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans and animals, and (b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than nonbiological and microbiological processes.”¹⁰⁷ Because Article 27 does not authorize member countries to exclude pharmaceuticals from product patent protection, the Indian parliament must extend product patent protection to pharmaceuticals to comply with Article 28 of TRIPs.

B. Patent Term Duration

30. Article 33 of TRIPs requires patent terms for all patents to last twenty years from the date of filing.¹⁰⁸ To comply with Article 33, the Indian parliament must enact legislation increasing the patent term for patents on foods and medicine from five years from the date of issuance or seven years from the date of publication to twenty years from the date of filing, and for all other patents from fourteen to twenty years from the date of filing. In doing so, legislation to comply with Article 33 must also eliminate the current provision basing the patent term for food and medicine patents on the earlier of the date of issuance or the filing date.¹⁰⁹

C. Compulsory Licenses

31. Article 30 of TRIPs allows member states to enact limited compulsory licenses “provided that such [licenses] do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.”¹¹⁰ Article 31 of TRIPs imposes certain conditions on compulsory license grants.¹¹¹ These conditions include: (1) the third party must accept the license on reasonable commercial terms; (2) the license is nonexclusive; (3) the license is nonassignable; (4) the license is authorized predominantly to supply the domestic market; (5) the license is limited to authorized uses; (6) the license may terminate if reason for the grant ceases to exist; (7) adequate remuneration is required and is subject to judicial review; (8) the issuance of a compulsory license is itself subject to judicial review.¹¹²
32. Under Article 31, permissible compulsory licenses include a license to practice a dependent patent from the holder of the dominant patent.¹¹³ The dependent patent must “involve an important technical advance of considerable economic significance in relation” to the first patent. The first patentee is entitled to cross-

license the second patentee's invention on reasonable terms. Upon licensing the use of the first patent, the second patentee may not assign the right to use the first patent to another party.¹¹⁴

33. The generality of Article 30 fails to mandate clearly changes to the Patents Act with respect to compulsory licenses. The TRIPs drafters neglected to define key terms in Article 30 such as "unreasonably conflicting," "normal exploitation," and "legitimate interests." Legislation reforming the Patents Act may, as a result, retain the current compulsory licensing structure or remove it altogether.

D. The Working Requirement

34. Article 1 of TRIPs provides that adequately working a patent includes importation.¹¹⁵ This provision runs counter to the Patents Act's specific rejection of importation as a method of working a patent. By permitting importation of a patented product, multinational companies will be able to avoid the significant fixed costs of constructing manufacturing facilities in India. Importation will drive down the cost of pharmaceuticals, alleviating fears that patent reformation will send prices of products skyrocketing. Compliance with Article 1 will require amending the Patents Act to include importation as a permissible method of working a patent.¹¹⁶

E. Burden of Proof: Infringement

35. Article 34 of TRIPs alters the burden of proof in process patent infringement suits. In contrast to current law, which requires the plaintiff to prove infringement,¹¹⁷ under TRIPs the defendant has the burden of proving noninfringement when "the product obtained by the patented process is new"¹¹⁸ or "there is substantial likelihood that the identical product was made by the process."¹¹⁹

IV. OPPOSITION TO THE PATENT REFORM REQUIRED BY TRIPS

36. The Indian public is concerned that massive price increases following patent reform to comply with TRIPs will preempt widespread access to valuable pharmaceuticals. Patented pharmaceuticals account for approximately ten percent of pharmaceuticals sold in India.¹²⁰ Because the Indian government provides free health care to the poor,¹²¹ higher pharmaceutical prices raise fears that price increases will bankrupt the health care system. Critics of amending the patent statute cite studies conducted in other developing countries showing that brand-name pharmaceuticals cost more than the equivalent pirated version.¹²²

37. Another popular concern is that multinationals will swallow the domestic pharmaceutical market.¹²³ Even with a transition period of up to ten years, Indian firms fear that they will be unable to develop the applied research facilities and the telecommunications and transportation infrastructure necessary to compete effectively with multinational pharmaceutical companies.¹²⁴ Moreover, Indian industry may face a delayed foreign-investment “dilemma.” Because Indian industry requires foreign investment to develop the facilities and infrastructure necessary for further development, a transition period to effect this transformation would be meaningless if foreign investment is delayed until the transition period has lapsed.

V. THE PATENT ORDINANCE OF 1994

38. At the conference of Labor Ministers of non-aligned and other developing countries in January 1995, Prime Minister Rao urged the represented countries to “modify our policies to ensure that we make the best use of our resources and the opportunities offered by the growing volumes of international trade and investment.”¹²⁵ On December 31, 1994, Indian President Shankar Dayal Sharma issued a presidential decree that amends the current patent law and serves as a foundation for the patent reform Prime Minister Rao encouraged at the conference of Labor Ministers.¹²⁶ The Patents (Amendment) Ordinance of 1994 (“Ordinance”)¹²⁷ effectuates Articles 70(8) and (9) of TRIPs, creating a transition period before the parliament enacts actual patent reform to comply with the major requirements of TRIPs.¹²⁸

A. Overview

39. Articles 70(8) and (9) ease the transition period for would-be patentees in two important ways. First, under Article 70(8), as soon as a signatory country ratifies TRIPs, companies may file immediately for patents in that country.¹²⁹ When the signatory country’s legislature enacts a patent statute conforming to TRIPs, the country’s examiners will then process the prefiled patents.¹³⁰ When and if the patent issues under the reformed law, its duration will be twenty years from the filing date.¹³¹ Second, Article 70(9) of TRIPs provides proprietary rights in bioavailability data resulting from clinical trials, in that it grants nonpatent market exclusivity for five years to the patentee of the pharmaceutical associated with the data.¹³² Market exclusivity of bioavailability data prevents pirate companies from circumventing expensive clinical trials. Because a pirate firm is unable to free-ride

on the patentee's work, a pirate firm must either wait for the market exclusivity period to expire or expend resources to conduct its own clinical trials to obtain approval from the health authorities.¹³³

B. Interim Marketing Rights for Product Patents

40. In accordance with Article 70(8) of TRIPs, the Ordinance provides a means for accepting product patent applications for medicine or pharmaceuticals.¹³⁴ Examinations of such applications, however, will not occur until December 31, 2004.¹³⁵ In the interim, in accordance with section 70(9) of TRIPs, a pharmaceutical corporation that has filed a product patent application for a pharmaceutical in India may receive exclusive marketing rights to the invention from the Indian Government.¹³⁶ The exclusive marketing rights last five years or until the issuance or rejection of a patent.¹³⁷ To obtain these rights, a multinational pharmaceutical company must demonstrate that it obtained a patent in a foreign country for an application filed after January 1, 1995, that it received regulatory approval from the health authority of that country, and that it received regulatory approval from India's health authority.¹³⁸
41. At first glance, it may appear that Article 70(9) will create up to a ten-year loss of patent protection between filing and examination. Even under the present system, however, the time between patent filing and regulatory approval typically lasts ten years. Consequently, from a practical perspective, no patent protection is lost during the transition period. In the unusual case where a company develops a pharmaceutical and obtains regulatory approval in India, the company has the opportunity to apply for the exclusive marketing rights until an examiner reviews its application.¹³⁹

C. Compulsory Licensing

42. The Ordinance also addresses the working requirement for compulsory licensing. Compulsory licensing provisions apply to pharmaceutical product patent applications.¹⁴⁰ Assuming a pharmaceutical company obtains exclusive marketing rights to a pharmaceutical, the Controller may grant a compulsory license after two years if the company fails to adequately work the invention.¹⁴¹ In contrast to the Patents Act of 1970, the Ordinance permits importation as the principal means for satisfying the working requirement.¹⁴²

D. *The Need for "Pipeline" Protection*

43. Legislation in India immediately implementing TRIPs does not protect products under patent in foreign countries. Lack of protection for inventions under foreign patents allows pirates to copy these products. In response, the pharmaceutical industry advocates "pipeline" protection in developing countries such as India to extend domestic patent protection in the developing country to pharmaceutical and agrochemical products already patented in other nations for the remainder of their foreign patent terms.¹⁴³
44. To illustrate, if a company with a U.S. patent that expires in five years files a patent application in India, pipeline protection would give the company five years of Indian patent protection. If India exercises its transitional right to take ten years to comply with TRIPs, however, pharmaceutical companies will not be able to file patent applications until 2005. Because clinical trials and regulatory approval often take more than ten years, this means a new pharmaceutical may not reach the market until after 2015.¹⁴⁴
45. TRIPs, however, does not provide pipeline protection for patents.¹⁴⁵ The issue primarily concerns the pharmaceutical industry and other industries with high research and development costs.¹⁴⁶ The rationale behind the lack of a pipeline protection requirement as part of TRIPs is that "subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain" should not be eligible for protection.¹⁴⁷
46. In pursuing patent reform, India should not institute pipeline protection for two reasons. First, proposed legislation including pipeline protection would face far greater opposition than would patent reform legislation to comply with TRIPs itself, due to popular concerns that multinational corporations will engulf the Indian market. Second, India would be better off using the ten-year transition period that TRIPs affords developing countries, to permit Indian industry to prepare for international competition.

VI. RESPONSES TO PATENT REFORM CONCERNS

A. *Pharmaceutical Prices*

47. Despite the arguments of its opponents, patent reform enacted to comply with TRIPs will have no practical effect on pharmaceutical prices, for three reasons. First, the

limited purchasing power of the Indian public provides an important check on potential pharmaceutical price increases. In 1991, per capita purchasing power in India was 5.2% of that in the United States.¹⁴⁸ Because seventy-eight percent of all Indian health care costs are paid for privately,¹⁴⁹ the majority of the Indian public would not be able to afford higher pharmaceutical prices. Limited purchasing power should function as a self-regulating mechanism to prevent price increases by forcing pharmaceutical manufacturers to choose either a low sales volume and a high unit cost or a high sales volume and a low unit cost. In the latter scenario, arbitrage concerns — companies buying cheaply in the local Indian market and selling competitively in a foreign market, such as the United States or Europe — may force multinational corporations to place export restrictions in contracts with Indian firms.

48. Second, because of the Indian public's limited purchasing power, the cost effectiveness of pharmaceuticals will become increasingly important. All things being equal, for a given illness, a doctor will rarely prescribe pharmaceuticals with different active ingredients since each pharmaceutical affects the body differently. When cost is an issue, however, cheaper generic pharmaceuticals with different active ingredients will be prescribed over high-priced patented alternatives.¹⁵⁰
49. Third, the Modifications to the Drug Policy of 1986 will control any abnormally large price increases. The Indian government pays twenty-two percent of total health care costs to maintain the supply of Essential Drugs to the poor.¹⁵¹ However, because the more extensive list of Category I and II pharmaceuticals under the Drug Policy of 1986 include only one patented pharmaceutical,¹⁵² the impact even on Essential Drug prices will be limited.

B. Japan's Experience with Development and Patent Reform

50. In the early 1970s, Japan experienced many of the same technological and economic issues that India is currently facing. Regulations and protective economic measures, including interest-rate controls and concentrated investment in priority industries, enabled Japan to experience its phenomenal post war economic growth. By the 1970s, however, regulation in Japan became an obstacle to further growth. As a result, Japan instituted a repeal program to increase market efficiency.¹⁵³
51. Although not a perfect corollary to India today, the Japanese experience can help India predict how patent reform will affect its own pharmaceutical industry. The

Japanese patent laws of the 1950s governed the first twenty-year period in Japan following World War II. In the pharmaceutical industry, patent law protected only processes for making pharmaceuticals, not the pharmaceuticals themselves.¹⁵⁴ The rationale employed by the Japanese Diet in the 1950s paralleled that of current Indian patent law, in that the Japanese parliament deemed pharmaceuticals, foods, and beverages indispensable to the daily life of the people.¹⁵⁵ The parliament also determined that certain industries, including the chemical industry, were weak in technical development capabilities and required protection from foreign competition.¹⁵⁶ The patent regime enacted to meet the needs of the public and industry enabled the Japanese pharmaceutical industry to create highly competitive development and manufacturing capabilities. This strategy, however, led to Japan's dependence on technology licensed from Europe and the United States. Japan's research capabilities languished as a result.¹⁵⁷

52. Passed in 1975, Japan's Law of Adoption of a Patent System for Substances provides product patents for pharmaceuticals and mandates that all preclinical and clinical studies be conducted in Japan.¹⁵⁸ The availability of product patents has led to increased research expenditures. According to a recent study by the World Bank of fifteen leading Japanese pharmaceutical companies, research and development expenditures rose from six percent of sales in 1975 to 10.8% in 1990.¹⁵⁹ While the Japanese pharmaceutical industry developed 4.5 major global pharmaceuticals from 1960 to 1979, the Japanese pharmaceutical industry developed 25.5 such pharmaceuticals from 1980 to 1992.¹⁶⁰ The 1994 World Bank survey reflects the fact that confidence in the reformed patent act had a positive effect on foreign investment in Japan. None of the U.S. chemical firms surveyed felt that Japanese protection was too weak to permit licensing of their newest or most effective technology to wholly owned subsidiaries.¹⁶¹ Only twelve percent felt protection was too weak with respect to unrelated firms.¹⁶²
53. The Japanese model reflects the likely future for the Indian pharmaceutical industry. To obtain a similar level of foreign investment in India while simultaneously fostering local research, the Indian government must act quickly to effectuate TRIPs.

VII. CONCLUSION

54. With respect to the pharmaceutical industry, patent reform to comply with TRIPs affects current Indian patent law in five major ways. First, product patent protection must be extended to pharmaceuticals. Second, the current patent term must be

extended to twenty years from the date of filing. Third, the imprecision of compliance requirements under Article 30 of TRIPs necessitates an examination, beyond the scope of this Note, of how India's objectives may best be served by revising its current compulsory licensing system for patents. Fourth, the current definition of working a patent must be extended to include importation. Fifth, the default burden of proof in process patent infringement suits must be shifted from the plaintiff to the defendant.

55. In light of Japan's experience with technological development and patent reform, India must consider limiting government control over the pharmaceutical industry. Market economics, and not government regulation, will cap prices and ensure a steady supply of new drugs and medicines to consumers.
56. From the Indian government's perspective, patent reform to comply with TRIPs appears inopportune because India still lacks strong research capabilities, particularly in the pharmaceutical industry. Reforming the patent laws to comply with TRIPs and phasing out drug price-controls, however, would provide an incentive structure necessary to encourage Indian pharmaceutical corporations to increase their research and development expenditures. The reformed patent laws and relaxed drug regulations would give Indian companies the opportunity to recoup their investment during the twenty-year patent term. Increased incentives would also encourage multinational firms to reenter the Indian market, further increasing the number of pharmaceuticals available to the Indian public. The delayed foreign-investment "dilemma," described above, may seem to undercut the usefulness of a ten-year grace period for implementing laws to comply with TRIPs. The grace period, however, provides the Indian government with the opportunity to implement supplemental corporate incentives such as tax breaks on research and development expenditures to enable Indian pharmaceutical companies to compete effectively in the international pharmaceutical market.

ENDNOTES

¹ Alan S. Gutterman, *The North-South Debate Regarding the Protection of Intellectual Property Rights*, 28 *WAKE FOREST L. REV.* 89, 121 (1993).

² *Id.*

³ *Patents Act, 1970*, 27 *INDIA A.I.R. MANUAL* 450 (1979) [hereinafter *Patents Act*].

⁴ *Id.* § 2(1)(i)-(iii) (1979).

- ⁵ Id. § 107(2).
- ⁶ Id. § 3(a).
- ⁷ Id. § 3(b). Cf. *Bedford v. Hunt*, 3 F. Cas. 37, 37 (C.C.D. Mass 1817) (Story J.). These first two types of inventions would fail patentability for lack of utility. Id.
- ⁸ Patents Act, *supra* note 3, § 3(c). Cf. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (holding that formulas in the abstract and laws of nature are not patentable subject matter).
- ⁹ Patents Act, *supra* note 3, § 3(d). Cf. Robert P. Merges, PATENT LAW & POLICY 153-54 (explaining that although a product patent covers all applications of an invention, a process patent may be obtained for a new use of an existing invention).
- ¹⁰ Patents Act, *supra* note 3, § 3(e). Cf. PETER D. ROSENBERG, PATENT LAW BASICS 6-21 (1994) (noting that a composition of matter, consisting of a mixture lacking a “set of properties distinct from those possessed by the separated constituents,” is not patentable).
- ¹¹ Patents Act, *supra* note 3, § 3(f). Cf. *In re Worrest*, 201 F.2d 930, 934 (C.C.P.A. 1953) (holding that “a device having two or more unrelated independent units or elements, each of which performs its function separately, uninfluenced by and indifferent to the action of the other units” is not patentable).
- ¹² Patents Act, *supra* note 3, § 3(g).
- ¹³ Id. § 3(h).
- ¹⁴ Patents Act, *supra* note 3, § 4. Cf. Atomic Energy Act, 42 U.S.C. § 2181(a) (1988) (denying patentability to military uses of atomic energy).
- ¹⁵ D. Moitra & S. Ravirdran, INDIA: Patent Law & Practice, in DIGEST OF INTELLECTUAL PROPERTY LAWS OF THE WORLD, 1, 4 (Lester Nelson ed., 1994). Cf. *In re Freeman*, 573 F.2d 1237 (C.C.P.A. 1978) (holding that computer programs are patentable to the extent that they do not preempt the use of an algorithm).
- ¹⁶ Moitra & Ravirdran, *supra* note 15.
- ¹⁷ Id. § 3(i). Cf. 35 U.S.C. §§ 101 et seq. [hereinafter U.S. Patent Act]. Patentable statutory subject matter is defined in inclusive terms, requiring that the invention be a process, a machine, manufacture, a composition of matter. Id. § 101.
- ¹⁸ Patents Act, *supra* note 3, § 5(a)-(b). However, claims for methods or process of manufacture are patentable.
- ¹⁹ Id. § 12(1).
- ²⁰ Unlike U.S. Patent Act § 102, the Patents Act does not explicitly define prior art. See generally MOITRA & RAVIRDHAN, *supra* note 15, at 3, for an Indian practitioner’s definition of prior art. Cf. ROBERT P. MERGES, PATENT LAW AND POLICY 147-59 (explaining that in U.S. patent law, the utility requirement has two elements: specific and beneficial utility; specific utility requires that the invention do what the application claims it can do; beneficial utility requires at least one non-harmful use for the invention).

- ²¹ See sources cited supra note 20.
- ²² Patents Act, supra note 3, § 135. India is not a signatory to the Paris Convention. However, under § 135 of the Patents Act, India recognizes the priority date of the matter disclosed in the application prosecuted originally in a convention country. Section 135 also requires that the patentee file an application in India within twelve months of a PCT application.
- ²³ Id. §§ 13(1)-(2).
- ²⁴ Id. § 23.
- ²⁵ Id. § 24.
- ²⁶ Id. §§ 12(1), 23.
- ²⁷ Id. § 25(1)(a). Cf. U.S. Patent Act, supra note 17, § 102(f) (denying patentability to inventions derived from someone other than the patent applicant).
- ²⁸ Patents Act, supra note 3, § 25(1)(b). Cf. U.S. Patent Act, supra note 17, § 102(a) (denying patentability to inventions “described in a printed publication in [the United States] or a foreign country, before the invention thereof by the applicant for patent”).
- ²⁹ Patents Act, supra note 3, § 25(1)(c). Cf. U.S. Patent Act, supra note 17, § 102(a) (denying patentability to inventions “patented ... in [the United States] or a foreign country, before the invention thereof by the applicant for patent”).
- ³⁰ Patents Act, supra note 3, § 25(1)(d). Cf. U.S. Patent Act, supra note 17, § 102(a) (denying patentability to inventions “known or used by others in [the United States] ... before the invention thereof by the applicant for patent”).
- ³¹ Patents Act, supra note 3, § 25(1)(e). Cf. U.S. Patent Act, supra note 17, § 103 (denying patentability to inventions for which “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time of the invention was made to a person having ordinary skill in the art to which said subject matter pertains”).
- ³² Patents Act, supra note 3, § 25(1)(f). Cf. U.S. Patent Act, supra note 17, § 101 (denying patentability to inventions that are not processes, machines, articles of manufacture, compositions of matter, or improvements thereof).
- ³³ Patents Act, supra note 3, § 25(1)(g). Cf. U.S. Patent Act, supra note 17, § 112(1) (stating that the specification in a patent application requires a full, clear, concise, and exact description of the invention and the manner and process of making and using it).
- ³⁴ Patents Act, supra note 3, § 25(1)(i). Cf. U.S. Patent Act, supra note 17, § 102(b) (denying patentability to inventions “patented or described in a printed publication in [the United States] or a foreign country or in public use or on sale in [the United States], more than one year prior to the date of the application for patent in the United States”).
- ³⁵ Patents Act, supra note 3, § 43(1).

- ³⁶ Patents Act, *supra* note 3, § 24; see also *id.* § 107(2) (stating that patent rights include a cause of action against the unlicensed making, using, or importation of the patented invention).
- ³⁷ Patents Act, *supra* note 3, § 84(1); see generally Le-Nhung McLeland & J. Herbert O'Toole, Patent Systems in Less Developed Countries: The Cases of India and the Andean Pact Countries, 2 J.L. & TECH. 229, 234 (1987).
- ³⁸ *Id.* § 53(1)(a).
- ³⁹ *Id.* § 53(1)(b); see also McLeland & O'Toole, *supra* note 37, at 235.
- ⁴⁰ Patents Act, *supra* note 3, § 83(a).
- ⁴¹ *Id.* § 83(b).
- ⁴² *Id.* § 90(d)-(e).
- ⁴³ Patents Act, *supra* note 3, § 146(2); see generally Gianna Julian-Arnold, International Compulsory Licensing: The Rationales and the Reality, 33 IDEA 349 (1993).
- ⁴⁴ Patents Act, *supra* note 3, §§ 84, 86.
- ⁴⁵ *Id.* § 84(1).
- ⁴⁶ *Id.* § 84(1), (5).
- ⁴⁷ *Id.* § 90(a)(i)-(iv).
- ⁴⁸ *Id.* § 86(1).
- ⁴⁹ *Id.* § 99(1).
- ⁵⁰ *Id.* § 88(2).
- ⁵¹ *Id.* § 87(1)(a).
- ⁵² HEINZ REDWOOD, NEW HORIZONS IN INDIA: THE CONSEQUENCES OF PHARMACEUTICAL PATENT PROTECTION 17 (1994).
- ⁵³ Patents Act, *supra* note 3, § 89(1).
- ⁵⁴ *Id.* § 106(2).
- ⁵⁵ REDWOOD, *supra* note 52, at 21.
- ⁵⁶ *Id.*
- ⁵⁷ McLeland & O'Toole, *supra* note 37, at 237 (citing Kunz-Hallstein, The Revision of the International System of Patent Protection in the Interest of Developing Countries, 10 INT'L REV. INDUS. PROP. & COPYRIGHT (I.I.C.) 649, 660 n.42 (1979)).
- ⁵⁸ REDWOOD, *supra* note 52, at 24.

- ⁵⁹ *Id.* at 22.
- ⁶⁰ India Urges Developing Nations to Ease Protection, REUTER ASIA-PAC. BUS. REP., Jan. 19, 1995.
- ⁶¹ Gerald J. Mossinghoff, Research-based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide, 2 J.L. & TECH 307, 321 (1987).
- ⁶² REDWOOD, *supra* note 52, at 16.
- ⁶³ Robert H. Hammer III, An Overview of Foreign Patent Practice, C909 ALI-ABA 129 (May 5, 1994).
- ⁶⁴ Patents Act, *supra* note 3, § 5(a)-(b).
- ⁶⁵ D. BARTLING & H. HADAMIK, DEVELOPMENT OF A DRUG — IT'S A LONG WAY FROM LABORATORY TO PATENT 1-14 (1990).
- ⁶⁶ For ease of comparison, all monetary amounts in this Note are approximated in United States dollars at a rate of Rs.29 to \$1.
- ⁶⁷ Telephone Interview with International Patent Counsel of a multinational pharmaceutical company (Sept. 5, 1994) [hereinafter International Patent Counsel Interview].
- ⁶⁸ *Id.*
- ⁶⁹ *Id.*
- ⁷⁰ REDWOOD, *supra* note 52, at 21 (quoting R.A. Shah, Speech at the World Symposium of Intellectual Property Rights (Feb. 1993)).
- ⁷¹ See Patents Act, *supra* note 3, § 53(1)(a).
- ⁷² REDWOOD, *supra* note 52, at 17.
- ⁷³ International Patent Counsel Interview, *supra* note 67.
- ⁷⁴ Telephone Interview with Dr. Peter C. Richardson, Patent Counsel, Pfizer, Inc. (Oct. 25, 1994) (hereinafter Richardson Interview I).
- ⁷⁵ *Id.*
- ⁷⁶ *Id.*
- ⁷⁷ International Patent Counsel Interview, *supra* note 67; see also James J. Wheaton, Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984, 35 CATH. U. L. REV. 433, 441 (1986) (discussing the process in the United States).
- ⁷⁸ See Kevin J. McGough, Preserving the Compromise: The Plain Meaning of Waxman-Hatch Market Exclusivity, 45 FOOD DRUG COSM. L.J. 487, 492 (1990) (discussing the U.S. interpretation of bioavailability).
- ⁷⁹ Richardson Interview I, *supra* note 74.

80 *Id.*

81 EDWIN MANSFIELD, INTELLECTUAL PROPERTY PROTECTION, FOREIGN DIRECT INVESTMENT, AND TECHNOLOGY TRANSFER, DISCUSSION PAPER NUMBER 10, INTERNATIONAL FINANCE CORPORATION, THE WORLD BANK, tpls. 3, 4 (1994).

82 *Id.*

83 The fifth objective, encouraging domestic research and development, requires the same strong intellectual property rights as multinational research and development divisions in order to justify the risk and cost of industrial research.

84 MANSFIELD, *supra* note 81, at 24-25.

85 Modifications to the Drug Policy of 1986, 2 (1994), (India) (hereinafter Modifications).

86 REDWOOD, *supra* note 52, at 22-23.

87 *Id.*

88 *Id.*

89 Indian Drug Makers; Brand X Is Better, *ECONOMIST*, July 1, 1989, at 58.

90 Modifications, *supra* note 85, at 1.

91 Bhupesh Mangla, India: Proposed New Drug Policy, 341 *LANCET* 682, 84 (1993). The World Health Organization lists essential drugs for primary care. From this list, developing countries select pharmaceuticals to meet their own economic and traditional needs.

92 *Id.*

93 *Id.*

94 Modifications, *supra* note 85, at 5.

95 Mangla, *supra* note 91.

96 *Id.*

97 India's New Drug Policy Shows Positive Stance Toward Private Industry, *XIX BUSINESS ASIA* 373, at 74 (1987).

98 Modifications, *supra* note 85, at 15.

99 *Id.* at 14.

100 Marshall A. Leaffer, Protecting United States Intellectual Property Abroad: Toward a New Multilateralism, 76 *IOWA L. REV.* 273, 298 (1991).

101 PAUL GOLDSTEIN, EDMUND W. KITCH, & HARVEY S. PERLMAN, *SELECTED STATUTES AND INTERNATIONAL AGREEMENTS ON UNFAIR COMPETITION, TRADEMARK, COPYRIGHT AND PATENT* 406 (1994).

¹⁰² Agreement On Trade-Related Aspects of Intellectual Property Rights, Including Trade In Counterfeit Goods, Final Act Embodying The Results Of The Uruguay Round Of Multilateral Trade Negotiations, 33 I.L.M. 83-111 (Apr. 15, 1994) [hereinafter TRIPs].

¹⁰³ *Id.* arts. 65(1), 65(2), 65(4), 66(1).

¹⁰⁴ TRIPs, *supra* note 102, art. 28(1)(a).

¹⁰⁵ *Id.* art. 27(1). “Inventive step” means nonobvious and “capable of industrial application” means useful.

¹⁰⁶ *Id.* art. 27(2).

¹⁰⁷ *Id.* art. 27(3).

¹⁰⁸ *Id.* art. 33. U.S. pharmaceutical companies fear a patent term based on the filing date, which is typical of first to file patent systems. Often the examination period for pharmaceutical patents is so long that it significantly cuts into the twenty year patent period. Cf. James P. Chandler, *The Loss of New Technology to Foreign Competitors: U.S. Companies Must Search for Protective Solutions*, 27 *GEO. WASH. J. INT’L L. & ECON.* 305, 316 (1995). In the United States, pharmaceutical companies are guaranteed a seventeen year patent term, irrespective of the length of the examination. *Id.* This system encourages gaming by the patentee with respect to the length of the prosecution. *Id.* That is, an inventor may keep an application in prosecution until another of its inventions, which would compete with the invention under application, has expended its commercial value. *Id.*

¹⁰⁹ See discussion *supra* section II.A.

¹¹⁰ TRIPs, *supra* note 102, art. 30.

¹¹¹ *Id.* art. 31.

¹¹² *Id.* art. 31(a)-(l).

¹¹³ Harold C. Wegner, *Patent Harmonization*, C554 ALI-ABA 171, 223 (1990), available in WESTLAW, ALI-ABA Database.

¹¹⁴ J.H. Reichman, *The TRIPs Component of the GATT’s Uruguay Round: Competitive Prospects for Intellectual Property Owners in an Integrated World Market*, 4 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 171 (1993); TRIPs, *supra* note 102, art. 31(a)-(l).

¹¹⁵ TRIPs, *supra* note 102, art. 1.

¹¹⁶ As discussed *infra* in section V and note 126, Indian President Shankar Dayal Sharma issued a presidential decree that, among other things, expanded the definition of “working” to include importation.

¹¹⁷ Patents Act, *supra* note 3, § 89 (1).

¹¹⁸ *Id.* art. 34(1)(a).

¹¹⁹ *Id.* art. 34(1)(b).

- 120 India Criticizes GATT's Dunkel Text, 5 No. 4 J. PROPRIETARY RTS. 37 (1993).
- 121 "The poor (by official definition one-fifth of the urban and one-third of the rural population) are eligible for free pharmaceuticals at public sector hospitals." REDWOOD, *supra* note 52, at 4.
- 122 Gutterman, *supra* note 1, at 134 n.328 (citing Pharmaceutical Firms, PMA Jab Over Patent Protection in Argentina, 5 WORLD INTELL. PROP. REP. (BNA) 3 (Jan. 1991)). One study has shown that a brand-name anti-arthritis pharmaceutical costs \$169.84 in the U.S. compared to \$35.08 for its pirated equivalent in Argentina. *Id.*
- 123 See REDWOOD, *supra* note 52, at 24.
- 124 Gutterman, *supra* note 1, at 132.
- 125 India Urges Developing Nations to Ease Protection, *supra* note 60.
- 126 When the parliament is not in session, such decrees may be promulgated. Nevertheless, the parliament must endorse them. Narayaman Madharan, India Keeps Date to Join WTO, Fulfills Legal Needs, THE REUTER EUR. BUS. REP., Dec. 31, 1994. Telephone Interview with L.D. Ralte, India's First Secretary of Commerce (Apr. 21, 1995). Following the issuance of the presidential decree, the Parliament had six weeks to adopt the ordinance. *Id.* It did not do so, and the presidential decree expired. *Id.* The patent office, however, continues to accept patent applications pursuant to the ordinance. *Id.* Apparently, expiration of the ordinance has had no practical effect on patent application filings. *Id.*
- 127 The Patents (Amendment) Ordinance, 1994, The Gazette of India, No. 81 (Dec. 31, 1994) [hereinafter Ordinance].
- 128 Telephone Interview with Dr. Peter C. Richardson, Patent Counsel, Pfizer, Inc. (Jan. 13, 1995) [hereinafter Richardson Interview II].
- 129 TRIPs, *supra* note 102, art. 70(8); Richardson Interview I, *supra* note 74.
- 130 Richardson Interview I, *supra* note 74.
- 131 *Id.*
- 132 TRIPs, *supra* note 102, art. 70(9).
- 133 Richardson Interview I, *supra* note 74.
- 134 Ordinance, *supra* note 127, § 2 (amending § 5(2) of Patents Act).
- 135 *Id.* § 24A(1).
- 136 See Ordinance, *supra* note 127, § 24B(1); Richardson Interview II, *supra* note 128.
- 137 Richardson Interview II, *supra* note 128.
- 138 *Id.*
- 139 *Id.*

- 140 Ordinance, *supra* note 127, § 24C(b).
- 141 *Id.*
- 142 *Id.* § 24C(a).
- 143 Michael L. Doane, TRIPs and International Intellectual Property Protection in an Age of Advancing Technology, 9 *AM. U. J. INT'L L. & POL'Y* 465, 478-79 (1994) (footnote omitted).
- 144 See *supra* text accompanying notes 69-71.
- 145 TRIPs, *supra* note 102, § 5.
- 146 Richardson Interview I, *supra* note 74.
- 147 TRIPs, *supra* note 102, art. 70(1).
- 148 REDWOOD, *supra* note 52, at 63 (citing WORLD BANK, *WORLD DEVELOPMENT REPORT 1993 — INVESTING IN HEALTH* (Oxford Univ. Press 1993)).
- 149 *Id.* at 62.
- 150 *Id.* at 71-72.
- 151 *Id.* at 67.
- 152 *Id.* at 69.
- 153 *Id.*
- 154 Drug Discovery in Japan, *MARKETLETTER*, Jan. 6, 1992, at 1.
- 155 REDWOOD, *supra* note 52, at 91 (quoting KOSAKU YOSHIFUJI, *COMMENTARY ON PATENT LAW* (9th ed. 1991) (translated extracts)).
- 156 *Id.*
- 157 Drug Discovery in Japan, *supra* note 154, at 1.
- 158 *Id.*; see also REDWOOD, *supra* note 52, at 91.
- 159 REDWOOD, *supra* note 52, at 93.
- 160 *Id.* Joint or simultaneous discoveries by Japanese and foreign companies are designated as "0.5" pharmaceuticals. *Id.*
- 161 MANSFIELD, *supra* note 81, tbls. 3, 4.
- 162 *Id.*