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Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India

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**Impact of the Trips Agreement on Specific Discipline
Patentable Invention**

***507** PROSPECTS AND LIMITS OF THE PATENT PROVISION IN THE TRIPS AGREEMENT: THE CASE OF INDIA

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Abstract

This Article analyzes the impact of TRIPS on the pharmaceutical industry in India, an industry that has traditionally taken a "free-ride" on the technological developments of other nations. The authors discuss the patent system in India prior to TRIPS and India's long-term refusal to join the Paris Convention regarding intellectual property. In the past, India had limited protection for technology. Some areas -- food, pharmaceuticals, and products made by processes -- received no patent protection at all. TRIPS changed this system and also changed the compulsory licensing and license of right provisions that limited patent protection in India. The authors argue that all people -- scientists in India and abroad, as well as Indian consumers -- will eventually benefit from the new system so long as India subsidizes drug costs for the very poorest consumers.

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I. Introduction

A few years ago, one of the authors wrote an article about the resurgence of patent law in the United States. [FN1] The article discussed how the creation of the Court of Appeals for the Federal Circuit exemplified the renewed interest in and even respect for the patent system in the United States. Essentially this resurgence is part of the resurgence of capitalism in the United States, for a strong patent system corrects a serious defect in the heart of free market systems: the ability of competitors in certain market structures to free-ride on the work of innovators. Patent systems correct this defect by providing for protection against free-riding in all kinds of market structures. [FN2]

This respect for capitalism and free markets reverses a trend in the U.S. regulatory climate. During the post-World-War-II period, as the United States moved away from free markets, antitrust assumed the stature of a civil religion. Antitrust was not only good, but more antitrust was better. Many believed that free markets were so inherently defective that there was a need for a steady increase in broad scale intervention under the banner ***509** known as antitrust. There certainly was no need to strengthen the patent system, a monopoly-granting system. Indeed, in perhaps the most detailed modern review of the literature relating to patent systems (authored by Professor Fritz Machlup of Johns Hopkins University in the late 1950s), [FN3] Professor Machlup summed up in an oft quoted statement:

If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it. [FN4]

The post-WWII period was not the first time that the patent system was under attack, [FN5] nor will it likely be the last. In the future, tides may sweep across the world both for and against free markets. It is clear, however, that economists contribute to anti-patent sentiment by arguing that patent systems are inefficient. They note that many industries have other incentives to encourage innovation and argue that this fact makes the patent system unnecessary. The existence of industry incentives is of course irrelevant to efficiency because a principal purpose of any patent system is to make industrial structure essentially irrelevant to the innovation process. Thus, industries can adopt efficient industrial structures without being affected to any considerable degree by the need to encourage innovation. Mathematicians would assert that incentives to innovate under an effective patent system are essentially invariant over differing industrial structures.

A second error often made by economists is the charge that patent systems encourage wasteful attempts to invent around patents. This argument overlooks the fact that if inventing around occurs that does not lead to a superior product, it is the result of a bargaining failure between the patentee and the second inventor. The patentee should have granted a license to the second inventor under those circumstances, a transaction that would have benefited both the patentee and the second inventor.

Bargaining failures, of course, occur in all property rights systems. They are not an appropriate basis for an attack on a ***510** particular property rights system unless that system is uniquely prone to such failures. While the foregoing is self-evident, these mistakes are nevertheless made repeatedly in the economics literature, even by economists of the caliber of Professor Machlup. [FN6] Such mistakes led in part to the incredible conclusion quoted above and form the basis of many attacks on patent systems.

During the life of any patent, products covered by a product patent will be more costly than they would have been in the absence of the patent. Otherwise, the patent would have no market effect. The monopoly profits generated by the patent benefit the patent owner, although in reality all of the economic value created by the patented technology cannot be captured by the patent owner while the patent is alive. Plainly, however, the patent system does not simply generate winners, it also generates losers: those who pay monopoly prices for products that for one reason or another would have been invented in the absence of a patent system. Yet, even these losers may also be winners, since they also benefit from products that are off-patent, but which may not have been developed in the absence of a patent system. Therefore, there may not be many losers; indeed, there may not be any losers at all. [FN7]

Of course, since patents are territorial, some countries may decide that they can win by free-riding on the patented technology developed elsewhere without substantially slowing the march of technological development. In this way, their societies are advantaged, although if everybody adopted this strategy, societies worldwide would lose out as technological advancement slowed. Moreover, this strategy is more likely to be followed in the more socialized areas of a country's economy. Thus, many countries have in the past adopted weak patent protection for pharmaceuticals, [FN8] an industry whose structure makes it particularly dependent on the existence of a patent system. They let the rest of the world, particularly the wealthy Western countries, pay the cost of the development of new drugs and hope that the failure to participate will not stunt so many drugs' development that the strategy backfires. One surprising former ***511** member of this club is Canada. [FN9] India is one of the most important current members. Indeed, India is a good example of what can happen when a large percentage of the world's population decides to go its own way, and part of its strategy is to place the cost of developing new drugs on others.

The free-riding strategy has another flaw. To the extent that a particular country has special needs that are not as acutely felt in the wealthy West, technological development that affects such needs will not take place. Thus, that country will pay a stiff price for the absence of an effective patent system. This is plainly the case with respect to pharmaceuticals for certain diseases such as malaria and leprosy, which are a far greater problem in countries like India than in the West.

II. The TRIPS Era Begins

As everyone in the intellectual property field is aware, over 100 countries have now agreed, through the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), not to free-ride on the inventive efforts of others. The importance of TRIPS cannot be easily overemphasized. [FN10] With respect to patents, TRIPS requires that all signatory countries put in place an effective patent system for essentially all branches of technology. [FN11] It also requires that patents must live for at least ***512** twenty years from the filing date. [FN12] Patent rights are clearly defined, [FN13] and remedies for infringement include the availability ***513** of damages [FN14] and injunctive relief. [FN15] A shifting of the burden of proof also makes process patents more readily enforced than under a regime that follows the ordinary rules on burden of proof. [FN16] Moreover, TRIPS requires each signatory country to put ***514** in place a reasonably effective enforcement mechanism for patents [FN17] and to comply with Articles 1-12 and 19 of the Paris Convention. [FN18]

Important issues raised by TRIPS, including restrictions on the patentee's exclusive rights, limitations on compulsory licensing, and questions relating to biotechnology and computer programs will not be discussed in detail here. [FN19] However, given the strong patent system required by the TRIPS provisions, it is important to study the ability of a signatory country to install a compulsory licensing system that effectively eliminates or gravely weakens its patent system. For example, a system could be envisioned that allows for drug patents, but that also provides that any third-party can obtain a license for a royalty rate of four percent, effectively destroying the value of the patent granted in compliance with the other TRIPS-inspired provisions.

There is a modest limit on the use or abuse of such a system in the Paris Convention. Article 5(A) of the Paris Convention reads in part as follows:

(2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise ***515** of the exclusive rights conferred by the patent, for example, failure to work. . . . . (4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his [or

her] inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license. [FN20] This provision of the Paris Convention provides that effective patent protection cannot be removed by a compulsory licensing system until at least three years from the grant [FN21] -- a very short period of effective protection for a patentee.

Article 31, entitled "Other Use Without Authorization of the Right Holder," goes considerably further in controlling abuses of compulsory licensing. [FN22] While this provision would allow a ***516** country determined to weaken its patent system to attempt to do so through the mechanism of compulsory licensing, TRIPS makes such deliberate weakening more difficult than it is under the Paris Convention. Indeed, the requirements of Article 31 are sufficiently onerous that its effect may well be to sharply curtail the abuse of compulsory licensing in the world today. Note also ***517** that Article 27 [FN23] precludes the claim that satisfying the market demand through imports can be used as a basis for compulsory licensing where satisfying it in the same way through domestic manufacture would not be.

TRIPS also does not have a provision regarding infringement. There is little to prevent a country from deliberately weakening its patent system by providing that claims are to be limited by the use of the specification, as Japan has done for many years. [FN24] Moreover, TRIPS permits a member nation to have a pre-grant opposition procedure, which presents the potential for abuse in that it can unreasonably delay the issuance of a patent. Finally, TRIPS did not tackle the question of patent exhaustion. [FN25] Nevertheless, there can be no doubt that any patent system that fairly complies with TRIPS will be an effective patent system applicable throughout a wide area of technology.

In the short run, of course, TRIPS will result in the enrichment of the innovating community, because that community is structured to make money in an environment where many free-ride on their efforts. In the long run, the world community will benefit, because there will be more inventive activity leading to more innovation than there would have been in the absence of TRIPS. An interesting, but probably unanswerable, question is the extent to which TRIPS is a result of the worldwide resurgence of capitalism (and, therefore, a symptom rather than a root cause of the strengthening of the world's patent systems). It may well be that the function of TRIPS is to provide political cover for politicians to do what they know is right for their countries, but it is subject to demagoguery by opposition politicians. It may also be that TRIPS resulted from the pressure that those who have suffered serious free-riding placed on their governments. Then again, TRIPS may be the result of all of these disparate forces. In any event, the dramatic effect of TRIPS, or whatever forces are behind it, may be shown by studying one important patent system that will be revolutionized by **compliance** with TRIPS, the patent system of **India,** and the effect of TRIPS on the pharmaceutical industry in particular. However, in order to ***518** properly understand the extent of the revolution, it is helpful to review the major provisions of the current patent law in India. [FN26]

III. Indian Patent Act of 1970

India enacted its first act relating to patent rights in India in 1856. It granted exclusive privileges to inventors of new products for a period of fourteen years. [FN27] It was renewed in 1859 with revisions founded on the British Patent Act of 1852. [FN28] Subsequently, the Indian Patents and Design Act of 1911 [FN29] replaced all previous legislation. This act was the governing legislation when India gained independence in 1947. After independence, the Indian government felt that the Indian laws, framed under British rule, required basic changes to bring them in line with the aspirations of an independent country with a rapidly transforming, dynamic, industrial economy. The Indian Government appointed two committees (the Tek Chand Committee in 1948 and the Ayyangar Committee in 1957) to review the Indian patent system with a view toward ensuring that the system comported with national interests.

The committees found that between eighty and ninety percent of the Indian patents were held by foreigners and more than ninety percent of them were not worked in India. [FN30] The committees asserted that the system was being exploited by foreigners to achieve monopolistic control over the market. In regard to vital industries like food, chemicals, and pharmaceuticals, the data for patents was similar for the period 1947 through 1957. Medicines were arguably unaffordable to the general populace, and the drug-price index was rising.

These reports led to an extensive debate in the Indian Parliament that finally resulted in the 1970 enactment of the Patents Act (the Act). [FN31] It is, with some important exceptions, a ***519** copy of the English Patent Act of 1949. [FN32] However, the modifications were critical to creating a system that was far weaker than the corresponding English patent law of the era.

Any appraisal of Indian patent law should begin with the principal objectives it attempts to achieve, as articulated in Section 83:

(a) The patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay; and

(b) That they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article. [FN33] The considerations that are said to be the quid pro quo for the grant of a patent monopoly are:

(i) Working of the invention within the country so as to result in the establishment of new industry and employment of labor and capital in the country.

(ii) Disclosure to the public of the invention so that on the expiry of the life of the patent, the public is enabled to work the invention. [FN34] The public interest is given priority over the private interest of the inventor by providing:

(1) Government the right to use a patented invention in particular circumstances.

(2) Remedies for abuse of patent rights (e.g., compulsory licenses, licenses of right, and revocation of patents). [FN35] This language suggests that India not only sought to encourage innovation but also to encourage the working of patents in India. However, the policy of encouraging local working does not explain why India chose to severely weaken its patent system.

The question of patentable subject matter was handled in a conventional manner. Accordingly, a patent may be obtained only for an invention that is new and capable of industrial application. [FN36] It must relate to a machine, article, substance produced by manufacture, or process of the manufacture of an article. [FN37] One may also obtain a patent for an improvement of an ***520** article or of a process of manufacture. [FN38] However, the discovery of a scientific abstract theory, [FN39] or the discovery of a new property or use for a known substance or machine, cannot be patented, unless it results in a new reactant. [FN40] In addition, inventions that are contrary to law and morality, injurious to public health, [FN41] or those related to methods of agriculture or horticulture [FN42] cannot be patented. Any process for the treatment of human beings or animals falls outside the ambit of patentable subject-matter. [FN43] Similarly, inventions related to atomic energy are not patentable. [FN44] While not unusual in 1970, the Indian law does not protect food, medicines, drugs, or any substance produced by a chemical process. However, process claims covering methods of their manufacture are patentable. [FN45]

IV. Indian Patent Practice

The procedure for filing a patent application and obtaining a patent is fairly simple but involves lengthy delays. The average time span for a patent application examination is between two and five years. There are a total of four patent offices in India, with roughly forty-five examiners. The average annual number of applications is 3000, out of which about 1000 are domestic filings. [FN46]

India, which is not a member of the Paris Convention, is a "first-to-file" country. India, however, does have a system of domestic priority. To be property filed, an application for a patent should be filed in the patent office in the prescribed form, along with the prescribed fee. [FN47] The application should consist of a provisional or complete specification. [FN48] If a provisional specification is filed, the complete specification should be submitted within twelve to fifteen months from the date of filing the first application. [FN49] The provisional and complete specification ***521** practice found in Indian law mirrored the practice of England at the time and for many years previously.

Each application should contain claims to a single invention. [FN50] The examination begins with the question of whether the claimed invention falls within the ambit of patentable subject-matter and is new and useful. The examiner looks for prior art by searching in publications available in the Patent Office and specifications of previous applications and patents. [FN51] Such searches are not exhaustive or final.

The complete specification is the basis of the Indian patent system. Its claims define the boundaries of the patentee's property rights. The complete specification should fully describe the invention and the method by which it is to be carried out [FN52] and disclose the best mode of performing the invention known to the applicant. [FN53] Specifications should be accompanied by drawings whenever necessary. [FN54] Claims should be based on the matter disclosed in the specification.

Lack of novelty is a ground for the refusal of an application. An application can also be refused if the claimed invention has been published, claimed by any other person, or publicly used or known in India. [FN55] There is no grace period and no provision for examination as to obviousness. However, obviousness is a basis for opposing an application.

All patent applications are examined for compliance with the procedural requirements of the Act, [FN56] and whether there is any lawful ground of objection to the grant. [FN57] After the examination, the patent examiner makes a report to the Controller of Patents (Controller) of the objections, if any, to the grant. [FN58] These objections might relate to the drafting of the specification and claims or anticipation of any claims against such specification. [FN59] These objections may be communicated to the applicant, giving the applicant an opportunity to amend its specification. [FN60] If they are not satisfactorily removed, or if it appears to the Controller ***522** that the claimed invention is not patentable [FN61] or is contrary to the law, [FN62] the Controller may refuse the application. If the applicant satisfactorily removes the objections, the Controller may accept the complete specification and publish it in the Official Gazette. [FN63] Thereafter, any person may give notice of opposition within four months from the date of publication. [FN64] The grounds for opposition, as set forth in Section 25, are unremarkable. [FN65]

If there is an opposition, the Controller notifies the applicant, who then must reply to the notice of opposition within one month. Thereafter, the parties may file their evidence, and the matter will be heard and decided. [FN66] Where the application is accepted, either without the resolution of an opposition or after opposition, a patent will be granted if the applicant requests sealing. [FN67]

Infringement of a patent is governed by the claims in accordance with English precedent. [FN68] The defenses in infringement suits are similar to those listed as the grounds for opposition. The burden of proof for establishing infringement is on the plaintiff. [FN69] In cases where the patentee's rights are infringed, the patentee is entitled to an injunction and, at the patentee's option, either damages or an accounting of the infringer's profits. [FN70]

India is not a signatory to the Paris Convention, [FN71] apparently because India's basic philosophy (the working of the patent) is not ***523** in harmony with the Convention's principles. [FN72] In addition, Indian citizens have to obtain prior permission from the Controller to apply for patents outside India. [FN73] Under the principle of reciprocity, only those countries that give Indian citizens similar rights or privileges as are granted to its own citizens with respect to the grant of patents and protection of patent rights are declared "Convention countries" by the government of India. [FN74] If a person who has made a basic application for a patent in a Convention country makes an application for the same patent in India within twelve months, the applicant will be entitled to the priority date for claims in India. [FN75]

Up to this point, other than India's refusal to join the Paris Convention, its law is unremarkable. As of 1970, India's basic period of patent life, fourteen years from the filing of the complete specification, was two years shorter than that provided by English patent law and six years shorter than the current international standard. [FN76] However, not all inventions enjoy the usual period of protection. The term for inventions involving the method or process of the manufacture of a substance to be used as a food, medicine, or drug is five years from the date of sealing [FN77] or seven years from the filing date of the complete specification, whichever is shorter. [FN78] Thus, it is possible that a patent which is opposed will expire before the opposition is concluded. Hence, for processes that come within this special definition, patent protection is plainly minimal. Other aspects of India's patent law, however, are even weaker.

***524** V. India's Compulsory License and License of Right Regimes

The Patents Act mandates the local working of Indian patents. [FN79] The Controller grants compulsory licenses of patents when the patent rights have not been commercially exploited by the patentee or available to the public in India at a reasonable price. [FN80] The object of compulsory licensing is to ensure that the inventions are worked in India on a commercial scale for the benefit of the public. However, the requirement of a reasonable price puts the value of all patents in the hands of the Controller, even those worked in India. An application to the Controller for the grant of a compulsory license can be made by any person three years after sealing. [FN81]

A patent may be endorsed with the words "License of right" after three years from sealing if the reasonable public requirements with respect to the patented invention have not been satisfied or if the invention is not available to the public at a reasonable cost. [FN82] All patents on processes for making food and medicine are endorsed with these words three years

from sealing. [FN83] Under this provision, the Controller has capped the royalties at four percent of the total wholesale cost of a shipment. [FN84]

Even worse, Indian law provides that if the reasonable requirements of the public with respect to the patented invention remain unsatisfied, the patent may be revoked by the Controller on non-working grounds. [FN85] These provisions have been applied ten to fifteen times in the past two decades. Thus, even in those areas of technology where India allows patenting, the patents are only effective for a period of three years from sealing.

VI. Patent Protection for Pharmaceuticals

While technology generally receives some protection under the Indian patent system, such protection is limited primarily by compulsory licensing and licenses of right. Food, medicines, ***525** drugs, as well as products made by processes, do not receive any patent protection. For example, there currently is no system for protecting pharmaceuticals in India. The question then is: what is the state of the pharmaceutical industry in India, under a regime where the government has excluded it from the country's patent system and has attempted to protect it by building a tariff wall around India? A brief look at this industry is in order, because it is apparent that TRIPS revolutionizes Indian patent law with respect to this industry. While TRIPS will effectively change the compulsory licensing and license of right provisions as well as the patent term for the industry generally, the major effect comes with respect to the industries that have received special treatment, such as the pharmaceutical industry. To measure the change that is coming, it is helpful to look briefly at India's pharmaceutical industry.

VII. Indian Pharmaceutical Industry -- Past and Present

Of all the Indian corporate sectors that have seen growth since the independence of India from the British rule in 1947, the pharmaceutical sector is probably the most dramatic. The pharmaceutical industry has grown at a rapid pace, from around one hundred million rupees in 1947, to seventy billion rupees today, with exports exceeding twenty billion rupees. [FN86] At the time of independence, the output of one hundred million rupees basically consisted of the processing and compounding of imported drugs for making formulations. [FN87] Today, Indian manufacturers of bulk drugs and formulations not only dominate the Indian market but are among the most fiercely competitive in the world. Indian companies compete in the international race to exploit the huge market for generic drugs that is developing in the West. Indian industry has emerged as a world leader in the production of bulk drugs such as Ciprofloxacin, Dextropropoxyphene, Ethambutol, Ibuprofen, Norfloxacin, Sulphamethoxazole, and Trimenthoprim. [FN88]

India has become a net exporter of drugs and has earned a considerable reputation in the international market as a ***526** dependable bulk drug manufacturer. The bulk drug manufacturers are being courted by multinationals for partnerships involving manufacture, marketing, and even joint research. Companies like Ranbaxy, Dr. Reddy's Laboratories, Cipla, and Lupin have the potential to become billion dollar companies by the year 2000. [FN89] This tremendous growth during the past four decades has resulted from the comprehensive shielding of the industry against foreign competition by regulatory controls, high tariffs, foreign equity restrictions, price controls, and little or no patent protection.

In the early 1940s and 1950s, ninety percent of the drug market was under the control of foreign companies, and the country was totally dependent on imports for both bulk drugs (the active ingredients) and formulations (the medicines made from bulk drugs). As a result, Indian drug prices were then among the highest in the world. To counter this problem, policymakers erected a protectionist regime. The underlying objective of this regime was self-reliance through an indigenous industry that could break the foreign companies' stranglehold on both the availability and the prices of drugs. The government framed the Drug Price Control Order (DPCO) to shield consumers against high prices. All drugs were divided into four categories: (1) life saving (i.e., drugs required for the National Health Program -- drugs used to treat malaria, tuberculosis, and leprosy), (2) essential, (3) less-essential, and (4) non-essential. Ceilings were fixed on the retail prices of drugs in the first three categories, which effectively set a limit on the maximum amount of profit companies could make from their manufacture. This graded system of price control was aimed at making life-saving and essential drugs affordable. Price and production control mechanisms were put in place to ensure the production of essential drugs. The important drugs were reserved for the public sector.

At the same time, to encourage domestic industry, new drugs (many of them on-patent internationally) manufactured through indigenous technologies were exempted from price controls for five years. Additionally, formulations using novel

delivery systems developed in India were exempted for three years. Foreign companies in India were more interested in producing non-essential drugs that required low technological inputs. These companies acted as trading centers that imported drugs from their parent companies abroad. Little attempt was made to start ***527** production facilities in India, and the foreign sector did not bring in any new technology.

India's patent law was another instrument of public policy that decidedly shifted the balance in favor of domestic manufacturers. Indian companies could access the latest drugs all over the world, re-engineer them through new processes, and sell them in the domestic market. This resulted in the development of valuable process-engineering skills. Moreover, due to high tariff rates (as much as eighty to ninety percent on bulk drugs and intermediates), the Indian sector was forced to develop a complete manufacturing capability. It was only a matter of time before these companies became extremely cost efficient producers of bulk drugs and formulations, effectively marginalizing the foreign companies. Further, the price control mechanisms stymied the growth and profitability of foreign companies; the government-set price did not even equal their conversion costs or their raw material costs. By contrast, Indian companies were exempted from these controls for the newest drugs for five years. Thus, foreign companies lost out to low-cost domestic competitors.

It is estimated that the capital costs of setting up a pharmaceutical plant in India is about one-third of the cost in the West. Indian companies had an advantage over foreign companies that were not in a position to take advantage of India's low manufacturing costs. This export competitiveness was reserved for Indian players only. The intense competition in the domestic market channeled the pharmaceutical manufacturers toward the export market. Over the past decade, drug exports have been growing at thirty-five percent annually, reaching 17.8 billion rupees in 1993-94.

Today, domestic production meets seventy percent of the bulk drug requirements and ninety percent of its formulations. Indian companies control seventy percent of the domestic formulations market and eighty-five percent of the bulk drugs market. They also account for eighty-five percent of the industry's exports. Basic drugs are mainly exported to developed countries, while the primary markets for finished formulations are developing countries and the former Soviet Union. However, given the development of this sophisticated generic drug industry in India, the question remains: has India, in spite of its lack of an effective patent law, contributed to the development of new drugs to treat diseases that affect its people more than those in the West? The answer unfortunately, but not unexpectedly, is no.

***528** Traditionally, scientific research in India, mainly a government-run activity, has been conducted under a few governmental or quasi-governmental agencies like the Atomic Energy Commission, Indian Space Research Organization, Indian Council for Agricultural Research, and Council of Scientific and Industrial Research (CSIR). Out of the total capital earmarked for scientific research, almost half is allotted to mission-oriented agencies, such as Space and Atomic Energy. Out of the small percentage of capital that goes to CSIR, which is mandated to develop and commercialize indigenous technologies in order to avoid importing technology, more than ninety percent goes toward the salaries of research staff, leaving very little for original research. In addition, there is a lack of synergy between government research and development (R&D) and private industry.

Today, however, pharmaceutical companies are trying to build technology muscle. A prime example is Ranbaxy Lab, Inc. (Ranbaxy), an $800 million market capitalized company. Recently, the company signed a $90 million joint venture with Eli Lilly & Co. to collaborate for drug research and development, manufacturing, and marketing. Ranbaxy is also purchasing a New Jersey drug company for about $25-30 million. [FN90] These developments reflect the influence of TRIPS and give some indication of what may well happen to the Indian pharmaceutical and other science-based enterprises in the next two to three decades.

VIII. Recent Changes in Science-Based Industries in India

Since 1970, the pendulum has been swinging sharply toward the domestic industry. However, this trend is reversing itself due to the recent shift toward capitalism in India and the prospect -- now the reality -- of TRIPS. Even prior to signing TRIPS, the Indian Government adopted a new drug policy in an effort to bring the pharmaceutical sector in line with India's liberalized industrial policy, while ensuring that the interests of consumers were not sacrificed. Many restrictions have been swept aside to facilitate foreign investment in the industry. Industrial licensing is being abolished, and the number of drugs under the DPCO is down from 142 to 73. [FN91] The span of control will be reduced from ***529** seventy to fifty percent. A national pharmaceutical pricing authority (nongovernmental) will be set up with a very transparent and responsive system of pricing, which will promptly revise drug prices. Previously, in the absence of a liberal pricing system, Indian companies with

a four percent profit margin could not invest heavily in R&D to match international standards, which are fifteen to twenty percent of turnover. [FN92]

Since 1991, foreign equity ownership of up to fifty-one percent is permitted, and foreign companies are treated on par with Indian drug companies. Coupled with a commitment to protect intellectual property rights (IPRs) effectively, these steps are clearly intended to attract investment and encourage faster technology transfer. Some other concerns, including the simplification of procedures, extension of quality control measures, and establishment of a national fund to promote research, still need to be addressed.

IX. The Expected Impact of TRIPS on India over the Next Decades

TRIPS requires India to establish, within ten years, a patent system that will provide effective protection for new drugs and the processes for making them. [FN93] Since a bias in favor of domestic ***530** manufacture cannot be used in compulsory licensing proceedings, one can expect the foreign sector to grow; however, Indian companies that are strong in R&D will also grow. There will be pressure on copiers who will not be able to copy the latest drugs. Therefore, one can expect that India will develop a vigorous and thriving R&D-based drug sector, [FN94] with a particular focus on new drugs for the treatment of diseases predominant in India, such as malaria, typhoid, and cholera. Since the domestic market is huge and Indians also have the same chronic and acute diseases that plague the industrialized West, one can expect that Indian companies will work on pharmaceuticals for these diseases as well. Given the wealth and talent of the country, one can expect that, within three decades, there will be Indian-based companies that rival those based in Japan and, perhaps, even those based in the United States, England, or Switzerland. Such changes could create enormous wealth that would be shared by both Indians and those living elsewhere in the world.

X. Will Indian Politicians Stop the Party?

The impending revolution in the pharmaceutical industry brought about by TRIPS has generated considerable controversy. For local drug companies, farmers, corporations, and national sovereignty, TRIPS is a source of great disagreement and confusion in India. Indians have simplified the whole trade morass to Dunkel, [FN95] the report that with one or two minor exceptions became TRIPS. A growing anti- Dunkel lobby in India has vociferously denounced TRIPS. "Reject Dunkel, Reject Imperialism" is familiar graffiti. Their insurmountable fears are the following:

1. Escalation of drug prices.

2. Local sector of the drug industry will be displaced.

3. Monopoly of multinational corporations in India.

4. Imports will increase.

5. Small farmers will be wiped out, since they will have to pay huge royalties to buy seeds from the multinational corporations.

***531** 6. Agriculture will turn into a capital intensive industry with multinational dominance.

The first four objections relate to the pharmaceutical industry, of which the most common fear is that, after the TRIPS implementation, the price of all new drugs will be increased as much as 2000-3000%. [FN96] Indians fear that the national drug sector, which accounts for seventy percent of the domestic market, will be totally devastated; that foreign companies will be the mainstay, and no R&D will take place; and that drugs will be imported to fulfill the working requirements of the patent, which will result in the out-flow of foreign exchange, with no technology assimilation in return. Another fear is that generic drug makers will be severely affected and the exports of drugs from India will plummet. [FN97] No longer will India's drug prices, which currently range from five to thirty times lower than the countries with product patents, rank among the lowest in the world. [FN98]

These fears are overblown. First, only new drugs (i.e., those patentable as of the effective date of the agreement) will be affected by TRIPS. Moreover, India does not have to provide actual patent protection for such drugs until 2006.

Significantly, such drugs will have to compete on price with unpatented drugs and will have to be reasonably priced in order to keep the sale of the patented drug in India profitable. Low purchasing power, in a health care system in which only about 3.7% of the population is covered by health insurance and around 75% of the expenditure on medicines is borne directly by patients, will contribute to maintaining low drug prices even for patented drugs.

Local prices depend on purchasing power and competition. Stiff competition among multiple producers of the same drug have made Indian drugs among the cheapest in the world. Drugs outside the price control regulations have experienced the sharpest fall in prices due to fierce competition. The large number of manufacturers with alternative processes has brought about competition, which can be seen in the export markets. As in the West, this type of competition will remain with respect to off-patent drugs. Only with regard to new drugs will TRIPS change the dynamic of drug development in favor of competition.

***532** TRIPS will disadvantage both those in India who will now have to pay higher prices for patented drugs that would have been developed and paid for by others in any event, and Indian companies that specialize in exploiting the new drugs on-patent in the West. TRIPS, however, will benefit the people of the world, who will have more new pharmaceuticals than they otherwise would have had (because the payments are higher to inventors of such pharmaceuticals). There will, of course, be winners in India as well -- the inventors who develop a local industry that creates rather than copies pharmaceuticals, as well as those who do not have to emigrate to work in the cutting edge pharmaceutical industry. Once India develops a viable and competitive world-class pharmaceutical industry, then there will be more winners than losers in India. After some period of time, even more world citizens will be advantaged by TRIPS. The users of patented drugs, which have no satisfactory unpatented substitutes, will have to admit that, in the absence of a worldwide patent system, the drug that may save their life may not have been developed.

XI. TRIPS, Patent Exhaustion, and India

One area where TRIPS could, but does not play a role, is the issue of exhaustion. A company owning a patent on an important new drug might decide to price that pharmaceutical in India at a price lower than that in the United States, Japan, or Europe, because it does not believe that the Indian market would sustain the higher price. However, if one or more developed countries would consider that a sale in India frees that product from the corresponding patent in the developed countries under an exhaustion theory, then the patentee might be unwilling to reduce its price in India. Therefore, it is in the interest of consumers in poorer countries to have an agreement with wealthier countries whereby sales by the patentee in the poorer countries will not be treated as an exhaustion of patent rights in the wealthy countries.

Fortunately for India, TRIPS preserves the current territorial nature of the world's patent systems because of Article 6, entitled "Exhaustion." Article 6 states: "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 above nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights." If Indian sales by the patentee exhausted the patentee's rights in other countries, this would aid the export of the patented drug from India and perhaps increase the number of jobs in India. However, patentees would also charge higher prices to Indian consumers. On balance, a country with 900 million ***533** people, which is a huge internal market, would be better off if patentees would price their patented products based solely on the Indian market. This requires that patent systems around the world continue to refuse to treat a sale of a patented product in India by the patentee as exhausting the patentee's rights worldwide.

XII. Conclusion

Within the next decade, science-based industry in India will be drastically restructured by TRIPS. The winners will include the talented class in India, who will not have to emigrate to contribute to the advancement both of themselves and of society at large. The winners will also be those who suffer from diseases that are endemic in countries such as India, as well as citizens in the rest of the world, who will benefit in the long run from the huge talents of the Indian people. The losers, if there are any, will be those who pay more for drugs that would have been developed in any event. Most of them are wealthy, some beyond the dreams of avarice, and can well afford the extra cost. There may also be a few losers who will be unable to obtain a necessary drug for which there is no satisfactory unpatented substitute. For those citizens, Indian society should provide a subsidy. A subsidy to those few citizens would be a small price to pay for the enormous benefits brought both to India and the world by TRIPS.

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[FN1]. Martin J. Adelman, The New World of Patents Created by the Court of Appeals for the Federal Circuit, 20 U. Mich. J.L. Ref. 979 (1987).

[FN2]. Martin J. Adelman, The Supreme Court, Market Structure, and Innovation: Chakrabarty, Rohm and Haas, 27 Antitrust Bull. 457, 461-66 (1982) [hereinafter Adelman, The Supreme Court].

[FN3]. Staff of Senate Subcomm. on Patents, Trademarks and Copyrights, Senate Comm. on the Judiciary, 85th Cong., 2d Sess., An Economic Review of the Patent System (Comm. Print 1958).

[FN4]. Id. at 80.

[FN5]. See Fritz Machlup & Edith Penrose, The Patent Controversy in the Nineteenth Century, 10 J. Econ. Hist. 1 (1950).

[FN6]. See Adelman, The Supreme Court, supra note 2, at 457-66.

[FN7]. The special arguments relating to the role of patent systems in developing countries are reviewed in George Y. Gonzalez, An Analysis of the Legal Implications of the Intellectual Property Provisions of the North American Free Trade Agreement, 34 Harv. Int'l L. J. 305, 310-13 (1993) (citing articles).

[FN8]. See Gerald J. Mossinghoff, Research-Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide, 2 J.L. & Tech. 307 (1987).

[FN9]. Id. at 320-21. See also Kate H. Murashige, Harmonization of Patent Laws, 16 Hous. J. Int'l L. 591 (1994).

[FN10]. Professor J. H. Reichman of Vanderbilt University School of Law has recognized this importance for many years in his many significant writings on the subject. He recently wrote a comprehensive analysis of TRIPS for the International Lawyer. See J. H. Reichman, Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement, 29 Int'l Law. 345, 345-46 n.3 (1995) (also contains a list of Reichman's writings on the subject).

[FN11]. See Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994 [hereinafter Final Act], reprinted in The Results of the Uruguay Round of Multilateral Trade Negotiations -- The Legal Texts 2-3 (GATT Secretariat ed., 1994) [hereinafter Results of the Uruguay Round]; Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994 [hereinafter WTO Agreement], Apr. 15, 1994, Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights [[[hereinafter TRIPS Agreement], reprinted in Results of the Uruguay Round, supra, at 6-19, 365-403. For U.S. congressional approval, see Uruguay Round Agreements Act, Pub. L. No. 103-465, ss 101-103, 108 Stat. 4809 (1994) [[[hereinafter URAA] (authorizing the President to accept the Uruguay Round Agreements and implement the WTO Agreement, but denying treaty status and domestic legal effect to the Uruguay Round Agreements as such, and excluding private actions under those agreements).

Article 27 entitled "Patentable Subject Matter" reads:

1. Subject to the provisions of paragraphs 2 and 3 below, patents shall be available for 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. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, 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.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
(b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this sub-paragraph shall be reviewed four years after the entry into force of the Agreement Establishing the MTO. TRIPS, supra, art. 27.

[FN12]. Article 33 entitled "Term of Protection" reads: "The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date." TRIPS, supra note 11, art. 33 (footnote omitted).

[FN13]. Article 28 entitled "Rights Conferred" reads:
1. A patent shall confer on its owner the following exclusive rights:
(a) where the subject matter of a patent is a product, to prevent third parties not having [the owner's] consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
(b) where the subject matter of a patent is a process, to prevent third parties not having [the owner's] consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.
2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts. Id. art. 28 (footnote omitted).
However, there are exceptions to the rights required by Article 28. They are set forth in Article 30 entitled "Exceptions to Rights Conferred," which reads:
Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. Id. art. 30.

[FN14]. Article 45 entitled "Damages" reads:
1. The judicial authorities shall have the authority to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of [the right holder's] intellectual property right by an infringer who knew or had reasonable grounds to know that he [or she] was engaged in infringing activity.
2. The judicial authorities shall also have the authority to order the infringer to pay the right holder expenses, which may include appropriate attorney's fees. In appropriate cases, Members may authorize the judicial authorities to order recovery of profits and/or payment of pre-established damages even where the infringer did not know or had no reasonable grounds to know that he [or she] was engaged in infringing activity. Id. art. 45.

[FN15]. Article 44 entitled "Injunctions" reads:
1. The judicial authorities shall have the authority to order a party to desist from an infringement, inter alia to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.
2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with sub-paragraph (h) of Article 31 above. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with national law, declaratory judgments and adequate compensation shall be available. Id. art. 44.

[FN16]. Article 34 entitled "Process Patents: Burden of Proof" reads:
1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28 above, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:
(a) if the product obtained by the patented process is new;
(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has

been unable through reasonable efforts to determine the process actually used.
2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in sub-paragraph (a) is fulfilled or only if the condition referred to in sub-paragraph (b) is fulfilled.
3. In the adduction of proof to the contrary, the legitimate interests of the defendant in protecting [the defendant's] manufacturing and business secrets shall be taken into account. Id. art. 34.

[FN17]. See id. arts. 41-43.

[FN18]. See id. art. 2; Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 25 Stat. 1372, T.S. No. 379 [hereinafter Paris Convention].

[FN19]. These issues are carefully analyzed by Professor Reichman, and there is no need to repeat his analysis here. See Reichman, supra note 10.

[FN20]. Paris Convention, supra note 18, art. 5(a).

[FN21]. For a detailed analysis by Fredrik Neumeyer of the world's compulsory licensing provisions as they existed in the late 1950s, see Staff of Senate Subcomm. on Patents, Trademarks and Copyrights, Senate Comm. on the Judiciary, 85th Cong., 2d Sess., Compulsory Licensing of Patents Under Some Non-American Systems (Comm. Print 1959). For a more recent review, see Cole M. Fauver, Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come, 8 Nw. J. Int'l L. & Bus. 666 (1988).

[FN22]. Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:
(a) authorization of such use shall be considered on its individual merits;
(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive.
(d) such use shall be non-exclusive;
(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
(k) Members are not obliged to apply the conditions set forth in sub-paragraphs (b) and (f) above where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent

authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

TRIPS, supra note 11, art. 31 (footnote omitted).

[FN23]. See supra note 11.

[FN24]. See T oshiko T akenaka, I nterpreting P atent C laims: T he United S tates, G ermany and J apan 193-286 (1995).

[FN25]. The current general rule that the sale by the patentee in a third country does not exhaust the patent right is treated in depth in Hanns Ullrich, TRIPS: Adequate Protection, Inadequate Trade, Adequate Competition Policy, 4 Pac. Rim L. & Pol. J. 153, 158-61 (1995).

[FN26]. See generally Suresh Koshy, The Effect of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective, 1 B.U. J. Sci. & Techn. L. 4 (1995); 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 (1987).

[FN27]. See B. K. Keayla, Patent Protection and the Pharmaceutical Industry, in Intellectual Property Rights 151 (K.R.G. Nair & Ashok Kumar eds., 1994) [[[hereinafter Intellectual Property Rights].

[FN28]. 15 & 16 Vict., ch. 83 (Eng.).

[FN29]. Indian Patents and Design Act, act 2 (1911) reprinted in P. Narayanan, Patent Law 1032-71 (2d ed. 1985).

[FN30]. See Keayla, supra note 27, at 152.

[FN31]. The Patents Act, 1970, No. 39 (1970) (India) [hereinafter Patents Act].

[FN32]. Patents Act, 1949, 12-14 Geo. 6, ch. 87 (Eng.).

[FN33]. Patents Act, supra note 31, ss 83(a), (b).

[FN34]. Parameswaran Narayanan, Intellectual Property Law 10 (1990).

[FN35]. Patent Act, supra note 31, ss 47, 83, 89 and 86.

[FN36]. Id. s 2(j).

[FN37]. Id.

[FN38]. Id.

[FN39]. Id. s 3(c).

[FN40]. Id. s 3(d).

[FN41]. Id. s 3(b).

[FN42]. Id. s 3(h).

[FN43]. Id. s 3(i).

[FN44]. Id. s 4.

[FN45]. Id. ss 5(a), (b).

[FN46]. Controller General of Patents, Designs and Trademarks, 21st Annual Report on Patents 26 (1992-93).

[FN47]. Patents Act, supra note 31, s 7(1).

[FN48]. Id. s 7(4).

[FN49]. Id. s 9(1).

[FN50]. Id. s 10(5).

[FN51]. Id. s 13.

[FN52]. Id. s 10(4)(a).

[FN53]. Id. s 10(4)(b).

[FN54]. Id. ss 10(2) and (3).

[FN55]. Id. ss 29-34.

[FN56]. Id. s 12(1)(a).

[FN57]. Id. s 12(1)(b).

[FN58]. Id. s 12(2).

[FN59]. Id. s 13.

[FN60]. Id. s 15(1)(b).

[FN61]. Id. s 15(2).

[FN62]. Id. s 15(3).

[FN63]. Id. s 23.

[FN64]. Id. s 25(1).

[FN65]. The grounds for opposition are:
1. obtaining invention wrongfully;
2. prior publication in any Indian specification or prior publication in any other document in India or elsewhere;
3. prior claim in a concurrent application;
4. prior public use or public knowledge in India;
5. obviousness and lack of inventive step;
6. invention not patentable under the Act;
7. insufficient description of invention;
8. failure to disclose information relating to foreign applications;
9. in case of a convention application, not made within the prescribed time. Id.

[FN66]. Patents Act, supra note 31, s 25(2).

[FN67]. Id. ss 43(1)(a), (b).

[FN68]. Parameswaran Narayanan, Patent Law 492-509 (2d ed. 1985).

[FN69]. Id. at 550.

[FN70]. Patents Act, supra note 31, s 108.

[FN71]. Paris Convention, supra note 18.

[FN72]. N. R. Madhava Menon, The Dunkel Draft and Intellectual Property Rights, in Intellectual Property Rights, supra note 27, at 65, 69.

[FN73]. Patents Act, supra note 31, s 39.

[FN74]. Pravin Anand, The Intellectual Property Jurisdiction in India, in Intellectual Property Law 50, 58 (Sangal & Ponuswami eds., 1994).

[FN75]. Id.

[FN76]. Patents Act, supra note 31, s 53(1)(b). This section references all periods defining the life of the patent from the "date of the patent." The "date of the patent" is defined in s 45 as the filing date of the complete specification.

[FN77]. As explained earlier, sealing occurs in response to a request for a grant of a patent after all examination and opposition procedures, if any, are terminated.

[FN78]. Id. ss 53(1)(a), 45.

[FN79]. Id. s 83(a).

[FN80]. Id. s 84(1).

[FN81]. Id.

[FN82]. Id. s 86(1). Cases where "reasonable public requirements are deemed not satisfied" are defined in s 90 of the Act. Id. s 90.

[FN83]. Id. s 87(1)(a).

[FN84]. See Koshy, supra note 26, at 4 n.52 (citing Heinz Redwood, New Horizons in India: The Consequences of Pharmaceutical Patent Protection 17 (1994)).

[FN85]. Patents Act, supra note 31, s 89.

[FN86]. S.L. Rao, The Indian Health Care Industry: Role of Intellectual Property Rights, in Intellectual Property Rights, supra note 27, at 165, 166.

[FN87]. Keayla, supra note 27, at 151, 155.

[FN88]. Id. at 156.

[FN89]. Shivanand Kanavi, Leaders in Technology, Bus. India, July 1994, at 52, 54.

[FN90]. Sougata Mukherjee, Drug Unit Eyes $30 Million Purchase, Triangle Bus. J., Apr. 21, 1995, available in Westlaw, Allnews Database.

[FN91]. Department of Chemicals in the Ministry of Chemicals and Fertilizers, Govt. of India, Drug Policy, 1986 (issued on Sept. 15, 1994).

[FN92]. India Should Change Ground Rules on Patents, Marketletter, Aug. 22, 1994, available in LEXIS, News Library, Curnws File.

[FN93]. Article 65 entitled "Transitional Arrangements" reads in part:
1. Subject to the provisions of paragraphs 2, 3 and 4 below, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the Agreement Establishing the MTO.
2. Any developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1 above, of the provisions of this Agreement other than Articles 3, 4 and 5 of Part I.
4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2 above, it may delay the application of the provisions on product patents of Section 5 of Part II of this Agreement to such areas of technology for an additional period of five years.TRIPS, supra note 11, art. 65.

[FN94]. R&D spending among Indian drug firms averages 2% of turnover, as compared with 12%-16% in the West. Under the TRIPS regime, it could double within a few years. Indian Industry Seminar Discusses Patents, Marketletter, May 22, 1995, available in LEXIS, News Library, Curnws File.

[FN95]. Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT Doc. MTN.TNC/W/FA (Dec. 20, 1991) (submitted by former GATT Director-General Arthur Dunkel and commonly referred to in India as "Dunkel").

[FN96]. I.A. Modi, Dunkel and Drugs: Recipe for Disaster, Econ. Times, Nov. 25, 1993, at 9.

[FN97]. Id.

[FN98]. Future Shock Awaits Indian Drug Consumers, Bus. Express, Jan. 3, 1994, at 11.

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