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THE INTRODUCTION OF PHARMACEUTICAL PRODUCT PATENTS IN INDIA: "HEARTLESS EXPLOITATION OF THE POOR AND SUFFERING"?

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Abstract

The decision to require that countries grant product patents for pharmaceutical innovations as a condition of membership in the World Trade Organization was very contentious. Almost fifty developing countries were not granting patent monopolies for drugs during the period the Uruguay round of GATT was being debated and these countries fiercely resisted the inclusion of this requirement, claiming that vastly higher drug prices would be associated with such patents. On the other side, business interests in the West urged them to consider the beneficial effects such protection might bring both in terms of focusing more research on tropical diseases and encouraging greater domestic and foreign investment in local research activities. This paper discusses the various theoretical implications for a developing country of introducting product patents for pharmaceuticals. Using India as an example, it then brings together information gathered from both published sources and personal interviews to examine the potential magitude of these effects. While not arriving at a conclusive answer to the question posed in the title, there are some suggestions about the way events might unfold as the policy is implemented.

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The Introduction of Pharmaceutical Product Patents in India: "Heartless Exploitation of the Poor and Suffering" ? [1]

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I. Introduction

TRIPs, the intellectual property component of the Uruguay round GATT Treaty, gave rise to an acrimonious debate between the developed countries and less developed countries (LDCs). On one side, business interests in the developed world claimed large losses from the imitation and use of their innovations in LDCs. They also asserted that establishing strong intellectual property rights would actually benefit the developing countries by encouraging foreign investment, the transfer of technology and greater domestic research and development (R&D). On the other side, LDC governments adamantly opposed this view, worrying about the higher prices that stronger intellectual property rights would entail and about the harm that their introduction might cause to infant high tech industries.

No country was more actively involved in opposing this component of the GATT agreement than India and no part of TRIPs was, and continues to be, more sensitive than the proposal to require product patents for pharmaceutical innovations. The national sentiment on this issue is well captured in an often quoted statement made by Indira Gandhi at the World Health Assembly in 1982: "*The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death*."

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[1] Subtitle in a report compiled by the Indian Drug Manufacturers' Association (1996). I am indebted to a great number of people who have contributed to this project over the past year. They are acknowledged in Appendix I, but are in no way responsible for the comments and conclusions presented here. Contact address: Economics Department/ Yale University/ 37 Hillhouse Ave/ New Haven, CT 06511; or email: lanjouw@econ.yale.edu.

What is striking about the original TRIPs debate and the continuing discussions about pharmaceutical product patents is the divergence between the strength of the claims made by both sides and the weakness of the empirical foundations for those claims. Now that the treaty has been signed and most of the developing world is committed to introducing pharmaceutical product patents by the year 2004, not only do we not know how *much* this may effect their welfare, we do not even know the *direction* of the effect. This ignorance has political implications. India, for example, agreed to this aspect of the treaty much against her will, believing it to be harmful to her interests. As a result, the implementing legislation is currently on the shelf, unable to get through parliament. If it could be shown, empirically, that product patents, in fact, conveyed some benefits to the country, it would increase the local political will both to pass legislation and to enforce patentee rights with greater enthusiasm. If, on the other hand, it could be shown that the net effect of this part of World Trade Organization (WTO) membership will be, in fact, very costly to the developing countries, it would put them in a stronger position from which to argue that they should receive concessions on other fronts in future international negotiations.

Apart from the immediate interest in the effects of this particular policy change, the sheer size of the change, together with the fact that it was, essentially, imposed from without, makes it a rare opportunity to examine the economic effects of granting patent rights. In the aftermath of the signing of the GATT treaty, we are in a situation where a large part of the world is moving from no protection to full-fledged twenty year protection of intellectual property rights in the one area where, it is thought, patents really matter: pharmaceuticals. Further, unlike the historical introduction of pharmaceutical product patents in much of the developed world the group of countries which will be newly granting rights in product innovations have distinctly different demands for drugs than those which currently grant such rights. Thus, there is some hope for detecting incentive effects in the *pattern* of R&D spending.

This paper focuses on India. After a brief history, it sets out in Section III the various ways in which the introduction of product patents for pharmaceuticals may, in theory, benefit or hurt the country. In the sections which follow, it brings together information from a variety of sources to assess what can be expected, now, about the importance of each of these various potential effects. While firm conclusions must await further analysis as the treaty requirements are implemented, the paper gives some indication

of where one might or might not expect to see change occurring.

I obtained much of the information presented in this study while on leave in India from September, 1996, to March, 1997. Over the six months I was able to interview a wide range of people (see Appendix I). Executives from Indian firms and the subsidiaries of multinational corporations (MNCs) were very generous with their time, and also allowed me to tour their R&D facilities. Industry group representatives from the Organization of Pharmaceutical Producers of India and the Indian Drug Manufacturers' Association, as well as members of the National Working Group on Patent Laws, provided a great deal of documented information and as well as insight on the current and historical situation. Attendance at a conference held by the Forum of Parliamentarians on Intellectual Property, a meeting of the U.S.-Indian Business Forum, and a gathering of Indian medical professionals, scientists, and government representatives sponsored by Pfizer was invaluable for getting a sense of the domestic and international political aspects of the policy change. Details of the administrative, regulatory and enforcement issues were gained from interviews with the Drug Controller General, the head of the Chemists' Association and a number of Indian patent attorneys. Information was also provided by the Delhi branch of the Indian Patent Office, the Export Promotion Agency (CHEMEXCIL) and the Department of Science and Technology.

II. The Pharmaceutical Industry and the Indian Patent System

In 1970, India put into place a series of policies aimed at moving the country towards self-sufficiency in medicines. At this time, the national sector was very small, estimated at less than 25% of the domestic pharmaceutical market (Redwood, 1994). Of the top ten firms by retail sales, only two were Indian firms and the rest were subsidiaries of multinationals (see Table 1). Much of the country's pharmaceutical consumption was met by imports.

An important part of the policy package was the passage of the Patents Act 1970 (effective April, 1972). This legislation greatly weakened intellectual property protection in India, particularly for pharmaceutical innovations. Pharmaceutical product innovations, as well as those for food and agrochemicals, became unpatentable, allowing innovations patented elsewhere to be freely copied and

marketed in India. The statutory term was shortened to 5 to 7 years on pharmaceutical process patents and automatic licensing was put in place. (See Appendix II for details.) As a result, the number of patents granted per year fell by three-quarters over the following decade, from 3,923 in 1970-71 (of which 629 were to Indian applicants, 3,294 to foreign applicants) down to 1,019 in 1980-81 (349 Indian, 670 foreign) (OPPI, 1996a). Although all inventors were affected by the weakened patent regime, it is clear that foreigners, in particular, no longer found taking out a patent in India worthwhile.

Other aspects of the policy package set up to encourage the domestic production of pharmaceuticals included restrictions on the import of finished formulations, high tariff rates, ratio requirements (where imports of bulk drugs had to be matched by purchases from domestic sources at a fixed ratio) and equity ceilings on foreign participation. Further, the strict price control regulation which was introduced with the 1970 Drugs Price Control Order, while making the production of pharmaceuticals less profitable for all firms selling in the Indian market, made it relatively less interesting for foreign firms with market options elsewhere. Thus even the price control regime probably contributed to the shift towards a greater share of production being met by Indian firms.

Supported by this regulatory environment, by 1991, Indian firms accounted for 70% of the bulk drugs and 80% of formulations produced in the country (Hamied, 1993). Of the top ten firms by 1996 pharmaceutical sales, six are now Indian firms rather than the subsidiaries of foreign multinationals (Table 1). Domestic firms now produce about 350 of the 500 bulk drugs consumed in the country (Government of India, 1994a). Employment in the pharmaceutical sector was estimated to have reached almost half a million by 1995 (OPPI, 1996b).

III. The Economic Effects of the Introduction of Product Patents: Theory

There is a well-known tradeoff implicit in using a patent system to encourage innovation. On the one hand are the static costs associated with monopoly pricing and, on the other, the dynamic gains associated with innovation. We first briefly review briefly this tradeoff in the standard single country setting and then consider the new issues which arise in a multi-country world.

Figure A shows the demand in India for a newly marketed drug (the solid line marked D_I). If we assume that in the absence of patent protection innovations are freely available then, without protection, price is equal to marginal cost, MC, and output is Q_c. When the inventor is allowed to obtain a patent and prices the drug to maximize his profits from the Indian market, the price is P_m and output falls to Q_m. The triangle 'D' represents the welfare loss to Indian consumers associated with introducing product patents. In addition to this deadweight loss are the costs of administering the patent system and enforcing patentee rights through the courts when there are infringement disputes.

There are several possible sources of dynamic gains to be had from granting patent protection. The inventor's profits, the square marked 'P', is the most obvious source of dynamic gains. Without protection, inventors do not appropriate the benefits of new drug innovations and so have a sub-optimal incentive to invest in the research and development to discover, test, and bring them to market. Because patents allow inventors to appropriate more of the consumer surplus from their innovations, granting patents may increase welfare by stimulating additional R&D investment.

A second source of potential dynamic gains comes from the disclosure requirement today common to all patent laws: specifications must be written to enable any person “skilled in the art” to make use of the innovation. As patentees reveal their innovations in their patent applications, information about new technologies becomes more quickly available to others as an input into their own R&D.

Finally, the availability of patents may increase the efficiency of the production of drugs and the efficiency of the research to discover and develop new drugs by facilitating contracting between firms. The innovating firm is able to reveal its innovation without losing control and hence may be able to sub-contract parts of the development work at lower cost. Similarly, the firm may be more willing to license the patented innovation to manufacturing firms for production. Arora (1996) points to the role that patents play in providing a means to contract for the transfer of the ‘know-how’ associated with innovations, a component of knowledge which may be particularly important to firms in developing countries.

When considering the welfare of a single country which exists in a multi-country world, new considerations arise.

Static Effects

In a single country world, the identity of inventors is not important. The transfer of benefits from the hands of consumers, in the form of consumer surplus, into the hands of inventors, in the form of profits (the square P) arising from the price increase may have distributional implications, but the effect of the transfer can be offset by domestic policies. It is not a net cost to the country. In a multi-country world, however, the static costs to one country of introducing patent protection depend not only on the size of the deadweight loss 'D' but on who is doing the inventing. If, for example, the newly available patent rights for pharmaceuticals in India are assigned entirely to inventors elsewhere, then the loss of consumer surplus 'P' is a net cost to India. All of the profits accrue to foreign nationals in the form of royalties, if production remains in India but under license, or as export profits if the patented drugs are sourced from elsewhere and imported to serve the Indian market. If the latter occurs, and local production is replaced by imports, the cost associated with the introduction of product patents is exacerbated by a loss of employment, a negative shift in the balance payments, and a loss of self-sufficiency. (See Helpman, 1994, for a general equilibrium model of increasing patent strength which incorporates terms of trade effects.)

Of course, some of the newly granted patents will be owned by Indians. For these, the profits remain in the country and the situation resembles again the one-country case described above.

It is important to realize, in particular when trying to understand the strength of multinational corporations' (MNCs') lobbying efforts during the TRIPs negotiations, that in a multi-country world there are *two* relevant demand curves. That for India (or the group of LDCs) and the other for the patent protected world (see Fgure A; dashed line marked D_w). In the ‘world’, the patentee receives, each period, profits as indicated by the large dashed box--until the patent expires *and there is generic entry* to bid down the price. A crucial feature of India's lack of protection for pharmaceutical products is that it has enabled Indian firms to develop commercial production capabilities for on-patent drugs before patent expiry and move rapidly into the world market with them on the day the patents have lapsed. This means that the introduction of patent protection in India will confer an additional benefit on patent owners, over and above any profits obtained from sales in the Indian market: it will delay the erosion of the profits

derived from world sales of patented drugs which comes about with generic competition. Is this important? It has been estimated that just before patent expiry Glaxo-Wellcome was earning a profit of around 7 million dollars *per day* from sales of Zantac (*The Economist*, April 26, 1997).

The flipside of this gain to patentees is that introducing product patents imposes an additional cost on India, this time to Indian firms rather than consumers, by lowering the profits earned by Indian firms as a result of their first-mover advantage. (It also imposes a cost on 'world' consumers in higher prices, but they are not the focus of our analysis here.)

Finally, in a multi-country world one must ask where R&D will take place. The improvements in effeciency which may be obtained through licensing when patents are available, may go hand in hand with a shift from domestic, imitative, R&D to a strategy of purchasing technology from elsewhere, if these two strategies are substitutes. If, on the other hand, technologies purchased from others complement domestic R&D efforts then this aspect of the availability of patents may encourage greater domestic research efforts. In a multi-country world firms also have many options in deciding where to locate R&D facilities and obtaining this type of direct investment can be beneficial: local firms have been shown to receive positive spillovers from the R&D performed by neighboring firms (see Jaffe, Trajtenberg and Henderson). The position that a country takes towards intellectual property may influence whether it is viewed as a favorable location for such investment. (The evidence is mixed; see Maskus, 1996.) There may be real economic reasons why intellectual property laws matter to location decisions. Beyond these, a country's stance on intellectual property may be given further importance by being treated as a signal of its business climate more generally.

Dynamic Effects

We have seen that the static costs to a country which is introducing patent protection in a multi-country world may be higher than the standard one-country model would suggest. It has been argued that the offsetting dynamic gains to additional patent rights may also be minimal in a world where patents are already available to protect much of the global market. With profits coming from other patent protected markets, those created by the newly available rights are only incremental, may be small, and, with diminishing returns to R&D, may stimulate negligible amounts of additional innovation. (See Chin and

Grossman, 1990; and Deardorff, 1992, for formal models which capture this feature.) This suggests that the group of countries who are introducing product patents as a result of WTO membership may face higher consumer drug prices and a loss of industry profit and employment, for little gain in new pharmaceuticals.

There are grounds, however, for thinking that this paints too gloomy a picture. It may be the case that the incremental returns created by monopoly profits in these LDCs are, currently, too small to stimulate much new discovery research. But existing drug innovations are only useful if they are developed and introduced. Innovations are not, in fact, 'freely available'. The process of adapting pharmaceuticals products to local conditions, obtaining marketing approval and developing the market must be done in every country individually and it is a costly affair. While the profits associated with India's introduction of patent protection may have little effect on world drug discovery they may have a large effect on the willingness of foreign or domestic firms to invest in marketing in India drugs which would, in any event, have been discovered. As discussed below, the issues here are directly akin to those surrounding orphan drugs. On the other hand, it is also possible that an inventor with the ability to monopolize the market may, for reasons associated with the global market, chose to delay introduction longer than the time that domestic firms would otherwise have been able to launch their own imitative products. Thus it is not clear whether introducing product patents will speed up or slow the availability of drugs to Indian consumers.

Most important, perhaps, in determining whether there will be significant dynamic benefits to be gained from the new patent rights is the fact that demand patterns for pharmaceuticals differ. Although the new rights may contribute very incrementally to the overall returns to R&D, the additional profits may represent a sizable addition to the returns to doing certain types of R&D. Just as patent protection in India might make it profitable to obtain marketing approval in India for a new drug, it may also add significantly to the incentives to discover a cure for leprosy. Long ago Vernon (1957) observed "that inventors in the industrialized areas of the world may need some special incentive to concentrate their talents on products of special utility to underdeveloped areas." (Quoted in Seibeck, *et. al.*, 1982). The benefit to the 'South' of introducing patent protection when demands differ is explored formally in Diwan and Rodrik (1991)

IV. Evidence: Static Price Effects

To estimate the size of the deadweight loss that will be associated with the introduction of product patents in India one needs to know two things. First the extent to which prices will be higher for new on-patent drugs as a result of patent protection and second, the consumer surplus lost as the result of given price increases.

Pharmaceutical Prices

Consider first the likely increase in prices. How much the granting of legal monopoly rights to an inventor *enhances* his ability to raise prices above marginal cost depends, firstly, the extent to which it is possible to extract rents without patent protection. In India, this seems to be small for most drugs. The pharmaceutical market in India currently appears to be competitive. There are a multitude of manufacturers: in addition to 250 large pharmaceutical firms and about 9,000 registered small-scale units, the Indian Drug Manufacturers' Association (IDMA) estimates that there another 7,000 unregistered small-scale units producing drugs (Clippings, 12/93). Seven years after its introduction in India, there were 48 firms offering the important on-patent drug Ciprofloxacin for sale in the 1996 *Pharmaceuticals Guide*. The U.K. multinational Glaxo was faced with several local competitors from the first day that its subsidiary marketed its proprietary drug Ranitadine (Zantac) in India. Competition between MNCs also may be growing. One executive of an MNC subsidiary suggested in an interview that the gentleman's agreement which has, over the past decades, kept MNCs from selling other MNC's on-patent drugs in India is now beginning to break down.

That said, drugs are sold in India under brand names and early entrants with strong brands seem to have a persistent advantage in the market. Ghemawat and Kothavala (1996) report that Ranbaxy, one of the largest Indian pharmaceutical firms, is consistently able to charge a 5 to 10% price premium (on uncontrolled drugs, see below). This is partly a reflection of real quality differences in a situation where quality control is primarily assured by a firm's interest in its reputation. It is also a reflection of doctors' strong tendency to prescribe by brand rather than more difficult to remember generic names (interviews).

The third column of Table 2 shows the 1995 Indian prices of the four drugs with the largest sales in India among those which were on-patent in Europe in 1995. The following columns indicate, for each drug, the ratio of prices in Pakistan, the U.K. and the U.S. for the same dosage form relative to the price in India. Although the ratio of Indian prices to those elsewhere differs substantially across drugs, and this is a small non-random sample of drugs, it suggests that prices in India for drugs which are on-patent elsewhere are currently substantially lower than in the countries granting protection.[2]

Would they have been higher if India had had in place the type of protection it now is facing? This depends on what the patentees would like to do and what they would be *allowed* to do.

A number of factors might contribute to a high price elasticity of demand for a new patented drug in India and thus a monopoly price which is not substantially higher than the competitive price. First, incomes are low and, with less than 4% of the population covered by medical insurance, drug expenditures are mainly paid directly by consumers (Redwood, 1994).[3] As a result, consumers are likely to be more price sensitive than they are in the developed countries and quicker to switch to less effective but cheaper alternative therapies when they exist or to stop making drug purchases altogether. Currently many diseases and conditions do have multiple alternative drug therapies which are off-patent and competitively priced. In fact, as of the end of 1996, only eight drugs on the World Health Organization's 7th Model List of Essential Drugs were still under patent protection in Europe. Of these, five are designated as 'complementary' rather than 'essential' (Redwood, 1994). So the option to switch to a lower-priced drug often seems to be available. In addition, in interviews I was told by people involved in the sale and distribution of pharmaceuticals (not to mention friends residing in Delhi) that it is also relatively easy for consumers to switch between drugs in India. Chemists quite freely substitute alternative, usually lower priced, medicines for those prescribed, and will sell prescription-only pharmaceuticals without scripts. (The results of my own, sample of size one, trial buying Zantac in Khan Market fully support this view.)

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[2] Danzon and Kim (1995) provide examples of the sensitivity of cross-country pharmaceutical price comparisons to sample selection.

[3] In comparison, in 1987, about 75 percent of Americans had outpatient prescription drug benefits (OTA, 1993).

However, while all of the above considerations suggest that Indian consumers will be very sensitive to high prices on patented drugs, there are reasons not to take it for granted. Income per capita has been growing at about 5 percent per year during the past few years and the opening of medical insurance provision to private competition is a reform which is being discussed by government (IMF, 1997). One also cannot assume that alternative therapies will always be available to provide competition for patented drugs. Table 3 shows the percentage of the audited Indian pharmaceutical market going to drugs which are on-patent in the U.K. in various therapeutic areas, based on data from 1992. For example, 84% of the drugs sold to treat antipeptic ulcers contain substances on-patent in Europe. While there may be substitutes, the dominance of the patented drugs in some categories suggests that they are not very close substitutes and hence would not contribute much to holding down prices.

A look at history also does not give one much confidence that low incomes will put an effective lid on prices. In 1961, at a time when India had strong intellectual property laws, a U.S. Senate Committee headed by Senator Kefauver reported that "'in drugs, generally, India ranks amongst the highest priced nations of the world.'" (quoted in Hamied, 1993). Similarly, for the four major drugs shown in Table 2, the prices in Pakistan, which does grant product patents for pharmaceuticals, are 3 to 14 times higher than in India. Although Pakistan is somewhat richer than India (1995 GDP per capita was about $419 in Pakistan versus about $334 in India; IMF, 1997) the difference in income is too small to seem a plausible explanation for most of the observed price differential.

There is another consideration, one which did not exist historically but is of growing importance today, which may exert a strong upward pressure on the price that a patent-owning firm would choose to set in India. Patentees maximize global profits. Increasingly, drug prices in developed country markets are being regulated using global reference pricing. For countries which fix ceiling prices, the price for a newly introduced drug may be linked to its price elsewhere. This policy may be explicit, or world prices may be linked, but less directly, to regulatory decisions. In the U.S., Clinton's 1993 Health Security Act proposed using the lowest price in 22 other countries as a benchmark for determining the reasonableness of prices set for newly introduced drugs (Danzon and Kim, 1995). Faced with either situation, patent-owning firms may well chose to sell in India at a price substantially higher than P_m in Figure A because they do not want to put in jeopardy the prices that they are allowed in other regulated markets. The

importance of this reference pricing concern was brought up repeatedly in interviews with executives of MNCs' Indian subsidiaries (see Section VII for further discussion).

However, that an innovating firm would choose to sell at a higher price when granted patent protection is clearly beside the point if it is not allowed to charge a higher price. One cannot really think about the effect of product patents in the pharmaceutical industry without being equally attentive to the price control regime. India has had, and continues to have, price control on a large part of the drug market. There is nothing in the GATT treaty which prevents India from continuing to use price regulation to protect consumers against patented drugs being sold at high prices.

While appealing, and, on the face of it, simple, this policy is not straightforward. First, the Indian price control regime is set up such that ceiling prices are determined as a mark-up on input costs (see Appendix III). This means that there is a 'transfer-price loophole'. An MNC may export the patented active ingredient to its Indian subsidiary at an artificially high transfer price and thereby attain a higher controlled price for its formulations. News reports suggest that MNCs have not been restrained about using this loophole:

> "Pfizer charges $9,000 per Kg. for same material available from Italy @ $125 per Kg." "Sandoz imports @ $60,000 per Kg. item available from Germany @ 23,000 per Kg." Theobromine imported by an MNC subsidiary at 2,436 Rs/kg compared to a price of 1,088 Rs/kg on the international market. (*Scrip*, quoted in IDMA, 1996; and Clippings, 1993).

However, this practice can be controlled, if it is detected, by GATT rules on uniform global transfer prices.

A patent owner may also simply refuse to supply a drug placed under what it views as too stringent price control. While this is conceivable, it is unlikely that either a foreign or a domestic firm would relish the type of negative publicity that a refusal to supply would create. Domestic firms, in particular, could be subject to retaliatory pressure by the government. And the government would have a good case for waiving the restrictions on compulsory licensing as allowed by the GATT treaty in cases of

"national emergency or other circumstances of extreme urgency".[4] Because India has a well developed industry, allowing domestic firms to obtain compulsory licenses is a realistic alternative to supply by the patentee.

Finally, some patented drugs may be explicitly exempted from the price control regime by the government. Currently, in order to encourage domestic R&D investment, indigenously developed pharmaceutical products may be declared free of price control for 3 to 10 years, with the number of years depending on the extent of the domestic R&D input. As of 1996, the Department of Scientific and Industrial Research had issued 37 certifications of indigenous R&D efforts (Government of India, 1996b). These include two companies who received exemptions from price control for developing indigenous processes to produce Ranatidine (*Pharmaceutical Guide*, 1996).[5] In the future, some of the products exempted under this policy will also be patent protected in India.

In the end, the stringency of the price controls actually placed on patented pharmaceuticals will be the outcome of a complex bargaining process between the government and industry. The most that can be said with certainty is that granting inventors product patent rights, with limited scope for compulsory licensing, will strengthen the hand of firms in the negotiations.

The Deadweight Loss

The deadweight loss of Indian consumer welfare that will result from the introduction of product patents will depend, in large part, on how important patented drugs are in total pharmaceutical sales. Redwood (1994) gives two figures for June of 1993. At that time, the top 500 brands in the audited pharmaceuticals market contained 24 active substances under product patent in Europe. (See Table 4 for

[4] Redwood (1994) points out that compulsory licensing on the grounds that the patented item is being sold by the patentee at too high a price is not expressly forbidden in the treaty. The wording of this section is very vague, however, and the details will be fought out over time. To argue that it was granted to counter a threat to not supply would give India a strong case if a compulsory license were disputed by the country of the patentee.

[5] It would seem that the only possible benefit of this policy could be to firms with strong brands able, on that basis, to price at a premium, or to single suppliers. Otherwise, exemption from price control, given that competitor suppliers remain bound by price control, would seem rather uninteresting.

the names and years of patent expiration.) Sales of drugs containing these substances were only 10.9% of top 500 sales. Including all brands, 31 substances were on-patent in Europe, and sales of drugs containing these substances were just 8.4% of total audited sales. Since audited sales exclude small firms and government procurement, these figures probably overstate the share of sales in India of drugs which contain substances under product patent cover elsewhere. There is no indication here that the introduction of patent protection is going to have a large effect the welfare of most drug consumers.[6]

If the rate of new product innovation is stable over time, in equilibrium the introduction of new patented drugs will be matched by those going off patent. Supposing this to be the case, as exclusive marketing rights (EMR - see Appendix II) and then product patents are introduced in India, the percentage of the market under patent protection will initially grow but then top off by the year 2015, probably remaining at a rather low level.[7]

One question that it is important to ask here is whether it is reasonable to extrapolate into the future from current levels of on-patent drugs. Is the rate of pharmaceutical innovation likely to be stable? In the past innovation has come in waves, with important breakthroughs, such as the sulpha drugs,

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[6] Putting a clever twist on these statistics, which are repeatedly used by the supporters of the impending regime, the Indian Drug Manufacturers' Association (the industry lobby for the smaller domestic, and therefore opposition, firms) makes the following calculation:

Total production of formulations in 1994	Rs. 80 billion
Share covered by foreign patents at 10%	Rs. 8 billion
Estimated share of U.S. MNC's at 50%	Rs. 4 billion
Loss to U.S. MNCs as calculated by them and submitted, and accepted, by the U.S. Trade Representative	Rs. 14 billion
Gains to Indian manufacturers on same at at 4% of sales	Rs. 0.16 billion

(IDMA, 1996).

[7] It is not likely to be the same as the share of the market currently going to drugs on-patent in Europe for two reasons. First, some products will be patented in India which are never patented in Europe. Second, the higher prices arising from patent protection may either raise, or lower, the value of sales of the patented and substitute off-patent drugs relative to what they would have been if such protection were not available.

followed by incremental developments of the newly discovered families of drugs. There is a suggestion that drug research in recent years has been relatively unfruitful so we may currently be at a low point in terms of important drugs still under patent cover. While U.S. FDA approvals of new medical entities have been fairly constant over the past two decades, ranging from 12 to 30 per year during the period 1976-91 but with no obvious trend (OPPI, 1994), it is claimed that in recent years they have largely been for 'me-too' type innovations which do not represent significant therapeutic advances. The U.S. FDA reported that 84% of the new drugs placed on the market by large U.S. firms during the period 1981-88 had 'little or no' potential for therapeutic gain over existing drug therapies (Special Committee on Aging of the U.S. Senate, reported in Hamied, 1993). Similarly, in a study of 775 New Chemical Entities (NCEs) introduced into the world during the period 1975-89, Barral (1990) reports that a group of experts rated only 95 as truly innovative. If there is a new breakthrough in chemical-based drug research this pattern could change again, leading to a jump in important patented drugs. Further, biotechnology, and the inclusion of micro-organisms as patentable subject matter, present a whole new opportunity for finding important and patentable new drug therapies. If biotechnology fulfills its promise or if there is a new breakthrough in chemical-based research, then granting product patents for drug innovations could have a much more substantial impact on consumer welfare than the figures given above would suggest.

Focussing only on the part of the Indian market which will be patent protected, the deadweight loss of consumer welfare associated with those patents depends on the elasticity of demand for the patented drugs. Greater price sensitivity may result in lower prices (although, as noted above, Indian demand conditions may not be the overriding concern of patent owners when setting prices in India). However, for a given change in price, greater sensitivity implies a greater fall in sales and a correspondingly higher deadweight loss as consumers switch to less desirable alternatives or out of the drug market altogether.

A number of estimates have been made of the potential consumer surplus loss from price increases associated with introducing product patents in India. The general method followed has been to assume.a constant price elasticity demand function for patented drugs and a range of *ex-ante* industry structures. Then price and welfare changes are simulated under various assumed elasticities of demand and assuming that firms have pricing freedom and no global concerns (see Nogues, 1993; Subramanian, 1994; and Maskus and Eby Konan, 1994) . The most recent and detailed of these studies is Watal (1996)

who breaks down the market by patented drug and links the assumed elasticity to the level of therapeutic competition. Her results suggest a fall in social welfare of 33 million US dollars and an average increase in the price of drugs if patents had been available of about 50 percent..

V. Evidence: The Redistribution of Profits and Manufacturing Employment

As discussed in Section III, in a multi-country world, the static cost associated with the introduction of product patents depends in part on which countries' inventors receive the profits which are gained through higher prices in India and a longer period before generic entry in the world market. Given current patterns, it appears that most of these profits will, at least initially, go to foreign inventors. During the period 1975-1995 only 65 of approximately 100,000 patents granted in the U.S. for drug and health innovations were to inventors with an Indian address.[8] Initial 'black-box' applications to the Indian Patent Office (those submitted after January 1, 1995; See Appendix II) suggest too that foreign inventors will be the main beneficiaries of the new product patents regime. Of the drug-related patents *granted* in 1995 and 1996, and therefore process patents, 39% and 48%, respectively, were to domestic firms or inventors (based on the applicant's address) (IDMA, 1996). In a sample (about half) of the patent *applications* made in the first six months of 1995, again 50% of the applications for process patents were to India resident inventors. However, in contrast, just 14% of the applications for product patents were made by domestic inventors (CDRI, 1996a).

The size of the new profit opportunities in India, and hence the transfer from domestic consumer to foreign firms, depends, like the deadweight loss, on the local demand functions for patented drugs and the extent to which patent-owning firms choose and are permitted to set prices above costs. What about the other profit rectangle, the world generics market? This market is already large: in 1995, about half of all U.S. prescriptions were filled with generics (BCG, 1996). And it is projected to grow very rapidly. Being first into this market appears to matter. A report by Lehman Brothers (1996) notes that, in the U.S., the first generic entrant can sell at a 30% discount to the branded product, compared to a 75%

[8] Drugs and health includes all patents with an international patent classification in either A61 or A01N. Jonathan Putnam, Charles Rivers Associates, kindly provided these data.

discount for later entrants. Another newsletter reports that "Industry experts say...80 per cent [of profits] are milked out of a drug in the first 18 months of its reincarnation as a generic." CDRI (1996b). Being based in a country which does not grant product patents helps firms to get into the market earlier. McFetridge (1996) notes that when Canada stopped granting its generics manufacturers compulsory licenses to produce on-patent drugs, the firms "were exercised by their loss of 'first mover' advantages in U.S. and other foreign generic markets." In fact, Indian firms currently have two institutional advantages in trying to enter quickly with low costs. The lack of product patents means that an imitating firm can have many years of experience with the commercial production of an on-patent drug before the day that the patent expires in the U.S., in Europe and elsewhere. Indian firms also benefit from the fact that, in India, changes in a drug's production process do not require that it be re-approved for marketing, as is typically required elsewhere. Thus Indian firms are free to experiment to fine-tune their production processes.[9]

That said, Indian firms are likely to become important players in this market regardless of whether they have a first-mover advantage. India is a currently positioning to become a significant supplier of bulk drugs to the world. Many manufacturing facilities have been approved by the U.S. FDA, the U.K. MCA, and so on. In generics, low manufacturing costs are essential. Here labor costs are India's most obvious advantage, but one Indian firm recently estimated that its capital costs were also 50-75% lower than those in developed countries (Ghemawat and Kothavala, 1996). Most of the larger Indian firms have ambitious plans to expand their generic drug exports, either as suppliers, through joint venture agreements with foreign firms or by purchasing formulation plants overseas. For example, Cipla has formed a subsidiary with a local firm in South Africa to sell Cipla products in that country, as well as a marketing alliance with Novopharm, Canada (Cipla, 1996). Ranbaxy has purchased formulation plants in the U.S. and in Ireland, as well as forming a joint venture with Eli Lilly to market joint products in the U.S. Lupin has alliances with Merck Generics, U.K., Fujisawa, U.S. and McGaw Inc., U.S., to market their cephalosporin products. They have also just established a joint venture in South Africa and are negotiating further alliances in Russia and China. Forming alliances rather than direct marketing is the established route into the international market. A local presence is seen to be necessary both to speed

[9] I was told by an executive at one MNC subsidiary that in developed country markets firms will often continue to use an early process in commercial production, even when they know it to be less efficient than one discovered later, simply because of the high cost of getting a new process approved.

marketing approvals and increase customer acceptance of Indian made products.[10]

MNCs are also moving towards greater production of generics in India through their own subsidiaries or in collaboration with Indian firms. In 1994 and 1995 there were 50 applications per year for government approval of collaborations with foreign partners in the field of pharmaceuticals (including the establishment of subsidiaries; Government of India, 1994 and 1995). These are primarily to source generic bulk drugs. Thus, while generic sales may become less profitable for the Indian firms without the jump on other entrants, it seems unlikely that the introduction of product patents will prevent either Indian firms or India-based MNC subsidiaries from increasing their participation in the world generics market.

It is not entirely clear what the overall effect of granting product patents will be on the amount of pharmaceutical production taking place in India. Currently, over three-quarters of the bulk drugs and finished formulations consumed in India are produced domestically (see Section II). Most of these are off-patent drugs (see Section IV). There is no reason to expect that granting product patents would effect the production of off-patent drugs for the domestic market one way or the other and, as discussed above, it is not likely to dampen production for export to the world generics market.

Once patent protection is available, however, patent-owning firms may choose either to export their patented drugs to India, thereby replacing domestic production, or they may chose to produce in India through a subsidiary or under license to Indian firms. An executive of an MNC subsidiary suggested in an interview that the MNCs' concern about global price differentials makes local, low cost, production attractive as a way to justify Indian prices which are lower than those charged in developed country markets. On the other hand, the 'transfer pricing loophole' discussed in Section IV would give patent-owning MNCs an incentive to produce bulk drug inputs elsewhere and then import them into

[10] On this point, one executive of an Indian firm described a recent consumer opinion survey fielded in the U.S. which indicated that an Indian made health product was acceptable to the extent that it was used externally: shampoos and cremes were fine, toothpaste was more doubtful and pharmaceuticals were definitely considered suspect. This bias may carry over to the domestic market. An executive from an Indian firm told me that launching a new drug in India was impossible because of Indian doctors' view that a drug could not be important if it had not appeared in *Lancet*. On the other hand, in another interview I was told of a recent survey which had shown that, given the choice, Indian doctors prefer to prescribe drugs made by Indian companies--which, it was suggested, might be due to unethical detailing.

India. Another executive of an MNC subsidiary pointed out that, while the availability of strong intellectual property protection was necessary, other considerations, like tax advantages, were at least as important in choosing a manufacturing location for on-patent drugs.[11] Further, he noted that, unlike generic drugs, manufacturing costs are a small component of the price of patented drugs and therefore India's advantages as a low-cost manufacturer would not be particularly useful in attracting investment in local production facilities. So, while the largest part of pharmaceutical production should be unaffected, it seems likely that some part of the local production of on-patent drugs will be replaced by imports.

Since 1988-89 the pharmaceutical sector has made a positive contribution to India's balance of payments. (See Table 5 for trade details.) With the introduction of product patents, the resulting transfer of profit from domestic to foreign patent owners, via royalty payments or export profits on drugs sold to Indian consumers, will have an adverse effect on India's balance of payments. So, too, will the fact that Indian firms will no longer be able to export on-patent drugs to other countries, primarily in the former Soviet Union and in Africa, which, until now, also did not offer protection for pharmaceutical products. The latter effect is likely to be small, however. Comparing Table 6, which shows exports of major on-patent drugs, to Table 5 it is clear that on-patent drugs are only a small part of total exports by value. One can see too, in Table 5, that most of the growth in exports has been in bulk drugs, which are likely to have been headed to the West, rather than in finished formulations. The current and growing importance of generics in exports suggests that the introduction of product patents will not have a dramatic negative effect on the balance of payments, such as that experienced by Italy where the net pharmaceutical exports as a share of total trade fell by about 30 percent in the decade after product patents were introduced (Scherer and Weisbrot, 1995).

VI. Evidence: Administration and Enforcement

In the developed countries, the resource cost in terms of skilled labor required to run and enforce

[11] It is not entirely obvious why MNCs have not invested in Indian manufacturing of their on-patent drugs since, regardless, the drugs are imitated by local firms. When posed this question, the same executive stated there was 'always something to lose', particularly through employee job switching.

a patent system is given little thought. However, patent examiners, to take one example, typically have advanced degrees and work experience in the relevant sciences. In the countries strengthening their patent systems now, nationals with such qualifications are scarce, in high demand from industry, and consequently patent offices will either be under (or inappropriately) staffed or they will be very costly to run. For the year 1993-94, the Indian PTO cost the government about 330 thousand dollars (net of receipts; Controller General of Patents, Designs and Trademarks, 1996). By contrast, in the late 1980s the U.S. PTO was spending about 300 million dollars per year. Although one would not expect the Indian system be as costly as that in the U.S. (but note that India has a population roughly four times greater), improving the facilities and staff so that it can effectively deal with the coming expansion in the size and importance of the intellectual property rights system is certain to be expensive.

There is also a shortage of the complementary skills outside of the patent office required to maintain an effective patent system. In 1995 there were only 151 patent agents in the entire country (Controller General of Patents, Designs and Trade Marks, 1996). Because relatively few patents are filed, there is little experience with writing specifications, detecting loopholes in others' patents, and so on. According to a Delhi patent attorney, in the past two decades there have been just four or five patent infringement cases filed per year, so there is little local legal experience with patent litigation.[12] The types of problems encountered in a country inexperienced with intellectual property go further. He related a story of an early copyright infringement case, where the police stapled confiscated CD Roms into a notebook, thus destroying the evidence.

In recognition of the current shortage of awareness and skills needed to maintain and use a patent system, some training has begun. The Council of Scientific and Industrial Research (CSIR) has held more than 50 seminars across the country to increase understanding of intellectual property. A.K. Reddy, Chairman of Reddy's Group, has donated land to establish a National Institute of Intellectual Property. A primary goal of the institute would be to train patent agents.

[12] This does not, of course, mean that there is little infringement. With a short patent term, compulsory licensing with a royalty cap of 4%, and no reversal of the burden of proof, there has been little payoff to prosecuting infringements. According to an Indian patent attorney, patentees usually do better than the 4% royalty by settling disputes outside of court.

In discussions with people in the country involved with the patent system one becomes aware of the large range of expertise--within companies, among lawyers, the courts, the police, and so on--required to make a patent system work. Again, developing and using these human resources is expensive, and will be particularly so if strengthening the system leads to a rash of litigation. Of course, not all of the anticipated increase in administration and enforcement costs can be laid at the feet of pharmaceutical product patents, since changes in the IPR system will be more extensive. However, if the U.S. experience is anything to go by, most litigation can be expected over patents in this area (Lanjouw and Schankerman, 1997).

VII. Evidence: Diffusion

It was pointed out in Section III that the dynamic benefit of new innovation comes only after two steps: discovery and diffusion. One part of diffusion is moving a new pharmaceutical product from the laboratory to the market. This process includes adapting the product to local conditions, obtaining marketing approval, and introducing it to doctors and others in the distribution chain.[13] Diffusion also includes the spread of information about new discoveries to other firms, so that the information can become an input into their own research and development. In this section we consider what empirical evidence can say now about the effect that introducing product patents might have on the rate of the diffusion of pharmaceutical innovations to India, as information to firms and as new products to Indian consumers.

One of the original arguments for having a patent system was that, in return for monopoly rights received from the government, the inventor disclosed his innovation in the patent specification. This was seen as an important mechanism for diffusing information so that others could build upon it and to avoid the replication of research efforts. While this argument makes sense in a one-country world, or, as in history, a multi-country world where communication links are poor, it does not carry through to the group of countries introducing produce patents today. The bulk of significant innovations are patented

[13] As one Indian R&D manager pointed out, the local conditions include climatic variation from the tropics to snowy mountains with unpredictable transport conditions and long shelve-life requirements. Ensuring stability is one of the foremost concerns in product development for the Indian market.

internationally and Indian firms are easily able to access world patent specifications. Interviews with the major Indian firms indicated that all of them had this capacity in-house, through computerized databases and the internet, and none considered access to frontier technical information a difficulty. For small and medium-sized firms, the Indian PTO operates a computerized patent search facility in the city of Nagper with access to patent specifications from all countries. They will perform searches and send copies of specifications for a low fee. Thus, there is, if anything, a negligible gain in additional information disclosure to be expected by the country's granting of new patent rights.

Will granting product patents speed the arrival of new drug discoveries to the shelves of Indian pharmacies? This depends on how quickly new drugs are arriving now, in the absence of product patents, and whether patentee control will speed or slow this arrival. Table 4 shows the on-patent drugs in the top 500 brands sold in India in June of 1993. The second column shows the year of first introduction somewhere in the world and the third column shows the year in which the drug was approved for marketing in India by the Drugs Controller General or, in a few cases, the year of introduction by an Indian firm. The forth column gives the introduction lag. With the exception of Cefaclor (and see below for a discussion of this case), for drugs where both dates are known the introduction lag was typically four or five years. Since the process of clinical testing and obtaining marketing approval takes about three years for the first applicant in India (estimated by the Drugs Controller General) and since executives of Indian firms stated in interviews that they usually waited to see the extent of a new drug's acceptance internationally before investing heavily in process development, this implies very quick imitation by Indian firms. The managing director of Glaxo (India) Ltd., noted that they had tried to be first into the Indian market with their patented drug Ranatidine (Zantac), but were met with seven Indian competitors at the time of launch. Whether the speed of imitation in recent years can be extrapolated into the future, when more difficult to copy biotechnology-based drugs become increasingly important, is, of course, again an open question.

Table 4 indicates the introduction lags for drugs which were, eventually, launched in India. In a presentation in India, one MNC representative suggested that product patents will increase the access of Indian consumers to new drugs by pointing to the fact that many 'important drug therapies' had not been introduced in India at all. However, to put this in context, consider again the study by Barral (1990) of NCEs introduced anywhere in the world from 1975 through 1989. As noted above, his group of experts

classified 95 of these 775 NCEs as therapeutically innovative. Among the innovative drugs, as of 1990, 31% were being marketed in fewer than six of the seven largest pharmaceutical markets.[14] In other words, even restricting attention to new drugs deemed to offer a therapeutic advantage, a significant portion were not introduced by the patentee in developed country markets that *did* grant product patents.

It is likely that failures to launch in India are for quite different reasons than the absence of product patents. One is administrative. The inventor, or an imitating Indian firm, may have tried to introduce the product but failed to obtain marketing approval. In India, by law firms are required to show only the safety and efficacy of new drugs in order to obtain marketing approval from the Drugs Controller General (as in the U.S.). However, according to the Drugs Controller General himself, in practice they are often also required to show utility, that is, that the new drug is needed. One company interviewee involved in this process from the industry side also asserted that this was often required and, further, that new drug applications were frequently rejected by the government on this basis. If this is the main explanation then changes in intellectual property laws will have little impact.

Another explanation lies in possible hesitation on the part of patent-owning MNCs in launching their patented drugs themselves, because of their concern about global reference pricing. This was brought up repeatedly in interviews with executives of MNC subsidiaries as an explanation for decisions either to delay launches or to never launch their patented pharmaceuticals in India. This is apparently a particularly important issue for American firms, but most European firms also pay attention to global price differentials (the pricing freedom given to Glaxo's Indian subsidiary, demonstrated in its race to enter the market with Ranatidine, seems to be a rare exception). For example, Bayer chose not to introduce its patented drug ciprofloxacin in India because it would have had to sell it at what Bayer viewed as, at that time, too low of a price. Instead, ciprofloxacin was introduced three years after its world launch by the Indian firm Ranbaxy (interviews and Clippings, 7/93).[15]

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[14] Clearly truncation could be part of the story. Some of these may have ended up being globally launched after 1990. However, truncation would only affect a few of the more recent NCEs.

[15] Danzon (1997) reports that Glaxo did not launch Imigram for several years after obtaining marketing approval in France because the government insisted on a low price.

Will this issue cause problems for India once inventors are granted monopoly control over the introduction of new products? More than seven years after its world introduction and long after the entrance of a multitude of local producers, Bayer also began marketing ciprofloxacin in India, at a price about a tenth of that in the U.S. (interview). Since regulatory attention to prices in developed countries is paid primarily at the time that drugs are initially introduced, it appears that global price differences become less important over time. Also, like a threat of non-supply in the face of price regulation, a failure to introduce could be combated with compulsory licensing (see Section IV). Nevertheless, these remedies do not operate immediately. A tendency on the part of patent-owning MNCs to delay the introduction of their innovative drugs in India could mean that, in the future, new drug therapies become available to Indian consumers more slowly than they would have if the current regime, which allows imitation, had been retained.

VIII. Evidence: Research and Development

In thinking about the possible effects of the introduction of product patents on investment in R&D, there are three separate issues. First is the effect of the incremental returns received by inventors as a result of these new rights on the incentive to invest in research on projects which are aimed at a global market. Second is the effect on incentives to invest in projects of particular interest to India. And finally there is the effect of granting product patents on the amount of pharmaceutical R&D that takes place in India, either within government or academic institutions, MNC subsidiaries or domestic firms.

Since it is difficult to anticipate the size of the profits which will be obtained by patentees as a result of product patents (see Section IV on price changes and Section V on the distribution of profit) and since we do not know very much about the elasticity of R&D investment in response to increased returns, it is difficult to guess whether the first effect will be significant. Given the enormous disparity in mean incomes between the developed countries and the LDCs, and given the small proportion of higher-income households within the LDCs, the contribution of profits coming from the LDC markets will probably be initially a quite small addition to total global profits (as suggested in Figure A). Table 7 shows that expenditure per capita in India compared to a range of other countries is extremely low. However, this may be set to change. India has a huge population and even with very low expenditures per capita was

already, in 1995, the 12th largest pharmaceuticals market in the world. (And this is with, it is claimed, only 30% of the population consuming allopathic medicines.) A possible loosening of restrictions on the insurance market is under discussion in the government and private insurance may be available in the next few years. One Indian executive said that his firm had an agreement already set up with an American insurance company interested in entering the Indian market and suggested that another Indian firm had a similar arrangement with a second American insurance company. Given the low starting level, there is much scope for increased pharmaceutical consumption in India as incomes grow and medical insurance becomes more prevalent. Thus, with a long time horizon, it might be the case that the introduction of product patent protection in India will have more than a negligible impact on new drug discovery.

It is possible to be more optimistic on the second point. The demand patterns of consumers in the group of countries now introducing product patents are quite different from those of the developed countries. For drug therapies relevant to LDCs, the incremental incentive generated by product patents may be significant even in the short run. There are two senses in which a drug therapy may be particularly relevant to India and to the LDCs as a group. First, disease patterns are quite different. Table 8 shows the diseases for which 99% or more of the global burden is in low- and middle-income countries (where burden is defined as the number of disability adjusted life years, or DALYs, lost to the disease. This includes years lived with disabilities as well as premature mortality.) Although India shares the diseases important in developed countries, and will increasingly as the population grows more wealthy, vast numbers of Indians also suffer from diseases, such as malaria and leprosy, which the developed world is largely free of.[16] Another sense in which particular therapies can be relevant is in the cost/efficiency tradeoff. Even within disease categories which are also of interest to developed countries, drug discoveries which have the potential to be very cost effective but not as effective overall may not be acceptable in those markets and hence not developed and commercialized in the present environment.

Currently almost all research on drugs for diseases prevalent in the LDCs is done either by internationally-funded organizations or the military in the developed countries and it is a very small part

[16] Even within diseases there can be differences in incidence. For example, AIDs cases in developing countries are the result of HIV which is a subtype different than the subtype common in the West which is the subject of vast amounts of R&D spending (WHO, 1996).

of world pharmaceutical R&D investment. For example, of the 56 billion dollars spent on health-related R&D worldwide, only 0.2% is on pneumonia, diarrhoeal diseases and TB, diseases which between them represent 18% of the global disease burden (WHO, 1996). In Barral's (1990) study of NCEs marketed commercially in the seven major industrialized markets between 1975 and 1989, only eight of 775 were specific to tropical diseases, and two of these were discovered in U.S. army laboratories. By contrast, the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases has developed 78 products in the past 19 years, 24 of which are already in use and of which another 35 are in clinical or field trials (*Scrips*, 1995). Although purchasing power in India, and the other LDCs, is low, the sheer size of this potential market may, once patent protection is available, make investing in drug discovery projects with primary markets in the LDCs sufficiently profitable that private firms become interested.

The example of orphan drugs may be instructive. In the early 1980s there was discussion in the U.S. about the problem of drugs which had been discovered but were not being developed and marketed by firms because they were useful only to a small population of sufferers. They were termed orphans because of the discoverers' lack of interest in these unprofitable drug candidates. In 1983, a bill was passed which offered firms seven years of market exclusivity for drugs with a potential market of fewer than 200,000 patients, even when a patent would otherwise not be available, as well as subsidies for testing. Although there is room for abusing this policy by carefully designing target populations so as to classify a drug as an orphan, there is no doubt that this legislation lead to a surge in investment in drugs which were legitimate orphans and which would not have been developed otherwise. In the decade before 1983 there were ten drugs for rare diseases approved by the U.S FDA. In the decade after passage of the Orphan Drug Act, 99 such drugs were approved, and 189 were reported to be under clinical testing in 1992 (BCG, 1996).

Perhaps the most difficult question is the last. Will the introduction of product patents lead to more R&D being done in India? For MNCs, strong intellectual property laws are certainly a pre-requisite for the choice to locate pharmaceutical R&D facilities in a country. A survey of U.S. firms conducted by Edwin Mansfield found that IPRs are very important to pharmaceutical MNCs when making decisions about R&D locations, less so for finishing generic drugs (United Nations, 1993). Currently, India fails on this count. India was the country most frequently cited by corporate respondants as having intellectual

property laws too weak to permit investment in the chemicals (including pharmaceuticals) sector (Mansfield, 1994). In recent years, Hoechst has been the only MNC with a subsidiary doing basic research in India (with a focus on natural products). The only other example is Ciba-Geigy, which had a basic R&D facility located in India from 1963-1989. That said, even more than in the case of manufacturing facilities, granting and enforcing intellectual property rights is likely to be far from sufficient to attract MNC investment. R&D tends to be quite centralized. For example, Pfizer has R&D centers outside of the U.S. in only four, developed, countries--the U.K., France, Germany and Japan--compared to manufacturing plants in 65 countries, of which 21 are in LDCs (Santoro, 1995).

It is frequently argued by proponents of the TRIPs accord that India, once new, WTO-consistent, intellectual property laws are in place, will be very attractive as a location for R&D because, by locating in India, firms can take advantage of a sizable pool of low-cost and technically skilled labor to escape part of the great expense of drug discovery and development. They point to the rapid growth in the Indian software industry, centered in the city of Bangalore, where a very large number of MNCs have located part of their software development. However, a head office R&D executive from a pharmaceutical MNC emphasized in an interview that cost is not a main consideration in their location decisions, even for development research. Further, it is not even clear that real costs are that much lower in India. Interviewees said that although customs restrictions on the import of equipment had been eased in recent years, this still posed a problem. A manager at one firm noted that they have an employee permanently stationed at the Bombay port to deal with 'time-sensitive' imports such as mice. While much of the equipment in R&D labs is now available from Indian suppliers, precision equipment is still imported and the difficulty and time necessary to obtain parts and servicing on foreign-made equipment was claimed by one interviewee as their biggest disadvantage in running a research lab. Even labor, while cheaper than in the West, does not appear greatly so. In one interview, a scientist just returning from graduate school and then five years at one of the U.S. National Institutes of Health, when asked about relative salaries, said that starting salaries were quite different: $4,500 in India against $35-40,000 for a comparably skilled person in the U.S. His own salary, however, he judged to be at least a quarter of the salary of someone at a comparable level in the U.S. In an interview at another Indian firm the same story emerged. Starting salaries for research scientists were judged to be about 20% of those in the U.S., but approaching 50% at higher levels. In many firm interviews it was also noted that salaries for researchers are increasing quickly. Taken together, the fact that costs are not their prime concern and the fact that the cost of doing

R&D in India does not actually appear to be dramatically lower than elsewhere suggest that there is no reason to expect that the introduction of product patents will encourage MNCs to locate R&D facilities for discovery research in India.

On the other hand, the story may well be different for Indian firms. In a paper which considers the likely response of Indian firms to obtaining the ability to purchase foreign technologies, Fikkert (1994) estimates that domestic R&D efforts would decline, but to very modest degree. In line with the efficency gains to be expected from licensing, he estimates that the switch to greater reliance on purchased technologies would be associated with a large increase in the productivity of domestic firms.

Looking at the domestic pharmaceutical sector today, a handful of firms have already begun increasing their total investment in R&D (from about 1-2% of sales to 5-6% of sales in the past few years). More significantly, some of them are beginning to allocate a part of that investment to the search for new molecules rather than imitative process development research. And there are signs that they will be successful in this new direction. As discussed in the previous section, the Indian firms have already demonstrated great expertise at rapidly devising new processes for patent products. A particularly dramatic example is Ranbaxy's development in 1991, after 20 million dollars and three years of effort, of a new process for producing Eli Lilly's patented drug cefaclor. In the words of a Ranbaxy executive, "56 processes were under patent (with Lilly) and we found the 57th" (interview). Since Eli Lilly's product patent for cefaclor expired in 1992 and the firm was expecting to protect its monopoly with process patents which were due to expire only in 1994, this gave great scope for a mutually advantageous agreement between the two companies.[17] A series of 50:50 joint ventures followed in the wake of Eli Lilly's recognition of Ranbaxy's superior research capabilities.

This was, of course, an example of process development. A few companies have also been successful in discovering new products. For example, Reddy's Research Foundation, a separately

[17] The magnitude of this achievement is brought out by this comment made by Eli Lilly's Pharmaceuticals President in February 1991, emphazing the protection offered by a difficult production process and a patent on a late stage intermediate: "when all factors are considered Ceclor (cefaclor) should 'remain a viable product for Eli Lilly beyond expiration of the patent'". And the Research Labs President: "'The Ceclor synthetic route is so long and so complex' that it will be difficult to duplicate....'a legal end-run seems extremely improbable.'" (quoted in OTA, 1993).

constituted research center established in 1992 which is part of Dr. Reddy's Group, *only* works on the discovery of new molecules. In June of 1995 they filed their first two product applications in the U.S. (anti-cancer and anti-diabetes substances) and now have ten more patent applications in developed countries. Dabur also has a self-standing research foundation which is 50% devoted to doing discovery research related to anti-cancer drugs. To date they have submitted two patent applications in the U.S. and two more in the U.K. (interviews).

An important aspect of the R&D being done by MNC subsidiaries and Indian firms in India is the extent of sub-contracting. Discovering a new molecule and bringing it to market involves many stages. Sub-contracting allows firms to focus initially on the parts of the process in which they have gained a comparative advantage. Organizing R&D through networks of research collaborations and joint ventures is becoming increasingly common with the advent of biotechnology firms. Commonly, biotechnology firms supply ideas, compounds, therapies, and applied research outcomes, while large pharmaceutical partners supply complementary research capabilities (where economies of scale are important), large-scale development and marketing. (See Gambardella, 1995, for examples of the complexity of these networks.) Most of the Indian subsidiaries of foreign MNCs interviewed said that they did some, and expected to do more, development work for their home offices. Several were very close to having their clinical testing results approved by the home office for use in U.S. FDA submissions. Recently, Hoffman-La Roche and Smithkline Beecham have sought approval from the Indian government to establish wholly-owned subsidiaries for R&D projects, in the latter case to develop new and existing Beecham vaccines (Government of India, 1994a and 1995).

For an Indian firm taking the first steps towards new molecule discovery, the ability to lower costs by sub-contracting or by joining up with foreign firms in research joint ventures, is particularly important. A surprising array of agreements have already been made. For example, Wockhardt just established a joint venture with Rhein Biotech GmbH, Germany, to do research in India on biotechnology products. One of Ranbaxy's joint ventures with Eli Lilly will be based in India and involved in development work.. Cipla undertakes custom synthesis under secrecy agreements. Dabur is in discussions with a U.K. company about doing development work for them. Two of the firms involved in discovery research send compounds to Daiichi, Japan, for screening. Compounds which look promising are pursued by the Indian firm and may result in a joint patent. In an interesting twist, Reddy's Research

Foundation has an arrangement with a Swiss firm whereby Reddy's sends them interesting compounds which the Swiss firm then develops.

What is not obvious is what the importance of Indian product patents will be in encouraging this process, given that product patents are already available to Indian inventors in much of the rest of the world. The cooperative R&D arrangements described above were made between Indian and foreign firms without product patents being available in India. Scherer and Weisbrot (1994) point out that Switzerland was a leading originator of important new drugs even in the period before it began granting product patents. Interviewed executives of R&D intensive Indian firms were all very clear that their target market for new drug discovery research is one hundred percent global. They are concentrating their efforts on drugs for important developed country diseases, such as cancer and diabetes, where U.S. FDA marketing approval is quick and even a moderately important discovery is likely to have a significant payoff.

The availability of patents in India may be important for encouraging innovation by smaller Indian firms and may facilitate contracting in the development of products for the local market. The advantage is that it will allow a firm to obtain a priority date with an Indian patent application at a cost far below a foreign application: $300-400 in India versus about $6,000 for a U.S. patent (interviews). A government official in the Dept of Biotechnology (DoB) described how the department had helped researchers apply for foreign patents (four thus far), in order to help them overcome the cost hurdle. He noted, however, that for products with a more limited local market, where a foreign patent would not be useful, the lack of patent protection in India was a stumbling block in getting innovations to market. Companies interested in commercializing DoB innovations were held back because, without patents, the DoB could not guarantee them exclusivity (Ghosh, 1996).

In the end, however, perhaps the main reason for thinking that the introduction of product patents in India will increase the amount of innovative R&D done by Indian firms has nothing to do with the traditional explanation based on enhanced returns. It is simply that they will soon be prevented from following a strategy which has been profitable, imitation, and must switch to something else in order to grow.

IX. Concluding Comments

It is too soon to draw any strong conclusions about what the effects will be of India's upcoming introduction of product patents for pharmaceuticals. In answer to the question posed in the title: "exploitation of the poor?" the answer is probably no--if nothing else because the "poor" in India are too poor to consume pharmaceuticals, even under the current regime. For the 70% or so of the population who currently does not have access to pharmaceuticals, the introduction of patent protection, and any price effects that may follow, are irrelevant. We have also seen that, of the drugs currently on the market, just under ten percent are on-patent in Europe. Extrapolating this percentage into the future, which may itself be questionable, means that even if product patents result in significantly higher prices, much of the pharmaceutical market will not be affected.

Considering only the part of the market which will be affected by the new regime, there are a number of reasons for thinking that the low incomes of India's consumers and the lack of medical insurance will not ensure low prices, as is sometimes suggested. Firstly, the latter two features are likely to begin to change in the next decade. Historical and cross-country evidence also does not give confidence that this will be the case. And, perhaps most importantly, patent-owning firms may not be setting prices to maximize profits in the Indian market. They maximize global profits, and the politics of drug price regulation may dictate a limit to how low they will be willing to set prices in India. Price control may also be ineffective in keeping down prices, since patent protection in combination with both the transfer-price loophole and a possible threat to not supply give firms non-negligible power in bargaining with the government over the price of patented drugs. Whatever eventuates, the fact that the industry is very competitive today means that any monopoly profits obtained by patent-owning firms once product patents become available can, with reasonable confidence, be attributed to the change in IPR regime.

Indian firms are moving into the world generics market and, although the introduction of product patents will cause them to lose their first-mover advantage, their low manufacturing costs will continue to give them an advantage in competing for this market. It may become somewhat less profitable, since speed into the market seems to be important, but there does not seem to be any reason to expect that they

will not be successful in increasing their participation in the generics sector. The bulk of production for the domestic market is drugs which are not on-patent. As a result of these two features, the introduction of product patents should not have a strong adverse affect on employment in the industry or on the contribution of the pharmaceutical sector to the balance of payments.

The positive contribution of intellectual property comes in its dynamic effect on the creation and diffusion of knowledge. Considering first the diffusion of information, it appears that Indian firms are well able to access and information disclosed in patent specifications filed elsewhere. Since most important pharmaceutical innovations will be patented internationally, there is likely to be little or no additional benefit to be gained by Indians from specifications being filed domestically. In the case of diffusion of products into the market, granting protection may speed diffusion, for the traditional reason that having a monopoly position makes the process of adapting a product, getting marketing approval, and introducing it to consumers profitable. However, there are also reasons to think that giving patentees control over introductions may slow down diffusion. Currently Indian firms are quite quick to bring imitations to the market. An MNC with a new patented drug may delay a launch in India because of the concern over global price regulations noted above. If, for this reason, they hesitate to introduce a drug at a low price in the initial years of global marketing, with imitators prevented from entering because of the new patent law, innovative pharmaceuticals may actually become available to Indian consumers more slowly.

Finally, there are several issues regarding the effect of product patents on discovery research. It seems unlikely that, at the current levels of income in India, the profits to be made from having monopoly rights in that country will add substantially to the profits already available in the world for drugs which are of global interest. However, as discussed in the paper, very little R&D is done to develop drug therapies for the set of diseases which are relevant to Indian consumers but which are not important to consumers in developed countries. Almost all of it is done by government-funded development institutions or by the military. For these drugs, the introduction of product patents in India could create a substantial incremental increase in profits and encourage more commercial interest in their discovery and development.

The final question was whether the introduction of product patents will contribute to more R&D

being done in India. Although strong intellectual property rights are important to MNCs in deciding where to locate R&D facilities, given the centralized nature of R&D and fact that costs are not the paramount concern there does not seem to be any compelling reason for them to locate in India even after product patents are available. Further, a number of MNCs are already increasing their use of local subsidiaries to do development work. Although stronger intellectual property rights may make the Indian environment more appealing to MNCs as a location for R&D, it is unlikely that product patents will make a dramatic difference to their choices.

There is more reason to think that the upcoming introduction of product patents will make a difference to the amount and type of R&D being done by Indian firms. Already the larger firms are increasing their total R&D expenditure as a percentage of sales and they are beginning to move in the direction of new molecule discovery rather then concentrating solely on development research. Given that there is already patent protection available to Indian inventors in the rest of the world, if there is a role for Indian product patents in encouraging this process it is not in the incentive effect, but rather the fact that the strategy of imitation is being closed off. While some firms may not make the transition, signs thus far suggest that a number of Indian firms will successfully weather the transition and come out as more innovative companies.

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Figure A
Deadweight Loss and the Redistribution of Profit

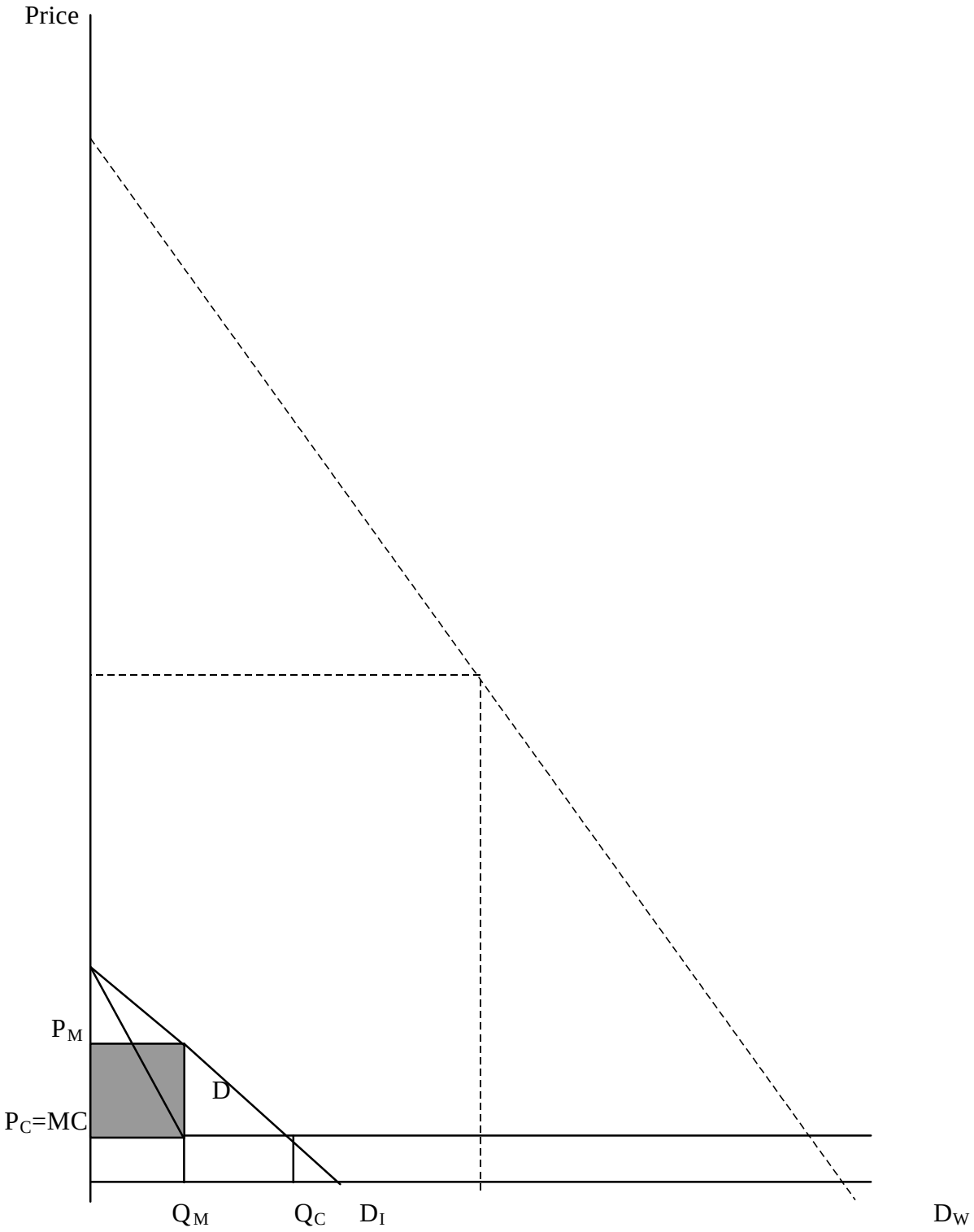

Table 1
Top 20 Firms by Pharmaceutical Sales
1996 versus 1971

Rank	Company - 1996	1996 Sales (Billion Rupees)	Company - 1971
1	Glaxo-Wellcome	4.97	Sarabhai*
2	Cipla*	2.98	Glaxo
3	Ranbaxy*	2.67	Pfizer
4	Hoechts-Roussel	2.60	Alembic*
5	Knoll Pharmaceutical	1.76	Hoechst
6	Pfizer	1.73	Lederle
7	Alembic*	1.68	Ciba
8	Torrent Pharma*	1.60	May & Baker
9	Lupin Labs*	1.56	Parke Davis
10	Zydus-Cadila*	1.51	Abbott
11	Ambalal Sarabhai*	1.38	Sharp & Dome
12	Smithkline Beecham	1.20	Sudrid Geigy
13	Aristo Pharma*	1.17	Unichem Labs*
14	Parke Davis	1.15	East India*
15	Cadila Pharma*	1.12	Sandoz
16	E. Merck	1.11	Deys*
17	Wockhardt*	1.08	Boots
18	John Wyeth	1.04	T.C.F*.
19	Alkem Laboratories*	1.04	Warner Hindu
20	Hindustan Ciba Geigy*	1.03	John Wyeth

Note: * indicates an Indian firm.
Source: ORG, Bombay.

Table 2

Price Comparisons - Four Largest 'On-Patent' Drugs by Sales in India

Drug Name	Dosage	Price in India (Rupees)	Times Costlier In:		
			Pakistan	The U.K	The U.S.
Ranitidine	300 tabs/10 pack	18.53	14.1	26.1	56.7
Famotidine	40 tabs/10 pack	18.61	14.0	27.1	54.0
Ciprofloxacin	500 mg/4 pack	28.40	8.3	10.3	15.4
Norfloxacin	400 mg/10 pack	39.00	3.2	6.5	23.2

Source: Keayla (1996), referencing U.S. Red Book 1995; U.K. MIMS, 1995; India MIMS, 1995; and Pakistan QIMP Annual 1991-92.

Table 3

Percentage of Sales to Drugs under Patent in the U.K. as of 1993
By Therapy Group

Theraputic Group	**Percentage of Sales to On-Patent Drugs**
Antipeptic Ulcerants	84.0%
Antiemetic, Antinauseants	19.7
Myocardial Therapy	0.7
Hypotensives	89.6
Antifungals, Dermatologicals	14.5
Other Dermatological Preparations	20.3
Oxytocics	0.0
Ampicillin/Amoxycillin	0.1
Macrolides & Similar Types	3.2
Cephalosporins	18.4
All Other Antibiotics	8.4
Quinolones	91.3
Muscle Relaxants	2.5
Non-Narcotics & Antipyretics	3.6
Antidepressants Thymoanaleptics	13.1
Anthelmintics Ex Schis	30.5
Antihistamines, Systemic	13.5
Opthal Oto Comb - Anti-infectives	39.4
Other Opthalmological	1.6

Source: OPPI 1994

Table 4
Introduction of On-Patent Drugs
In the Top 500 Brands by Pharmacy Sales, 1993

Drug Name	Year of World Introduction or by Inventor	Year of Indian Marketing Approval or Introduction by Indian Firm	Introduction Lag (Years)	Year of European Patent Expiry
Cefuroxime Sodium	1978	< 1988	< 10	1994
Cefaclor	1979	1991	12	1994
Netimicin	1980	< 1988	< 8	1994
Albedazole		< 1988		1995
Fluoxetine		1990		1995
Aciclovir	1981	1988	7	1995
Doperidone		< 1988		1996
Ranitidine	1981	1985*	4	1997
Cefotaxime Sodium	1980	< 1988	< 8	1997
Cefuroxime Axetil	1988	1990	2	1997
Ketorolac		1992		1997
Cefotaxime	1980	< 1988	< 8	1997
Captopril	1980	1985*	5	1997
Norfloxacin	1984*	1988*	4	1998
Pefloxacin		1991		1998
Ketoconazole	1981	< 1988	< 7	1998
Famotidine	1984	1989	5	1999
Enalapril Maleate	1984	1989	5	1999
Omeprazole		1991		1999
Astemizole	1983	1988	5	1999
Ceftazidime	1983	1988	5	2000
Ciprofloxacin	1986	1989	3	2001
Ofloxacin		1990		2001
Roxithromycin		1992		2001

Sources: Top 500 on-patent drugs and year of European patent expiry, Redwood (1994); Year of world introduction, either Barral (1990) or, if starred, year of first introduction by inventor, Keayla (1996); Year of Indian marketing approval, either IDMA (1997) or, if starred, year of introduction by Indian firm, Keayla (1996).

Table 5

Production, Exports and Imports
Bulk Drugs and Formulations

(Billions of Rupees)

Year	Bulk Drugs			Formulations			Total	
	Prod'n	Exports	Imports (landed)	Prod'n	Exports	Imports	Exports	Imports
1980-81							0.76	1.13
1985-86							1.94	2.67
1990-91	7.30	1.58	6.70	38.40	6.85	0.85	8.43	7.55
1991-92	9.00	8.39	9.50	48.00	5.09	0.96	13.48	10.46
1992-93	11.50	4.09	10.00	60.00	9.65	1.19	13.74	11.19
1993-94	13.20	5.31	11.46	69.00	13.11	1.13	18.42	12.76
1994-95	15.18	8.43	13.54	79.35	13.36	1.73	21.79	15.27
1995-96							31.17	> 18.67
2000-01	45.33	27.32	32.86	183.54	19.95	n.a.	47.27	> 32.86

Sources: IDMA (1997); Projections from the *Report of the Working Group on Drugs and Pharmaceuticals for the 9th Five Year Plan.*; * provisional value from Chemexcil (interview).

Table 6
Exports of Three Major Drugs On-Patent in Europe
(Millions of Rupees)

Drug Name	April 1992 - March 1993		April 1995 - March 1996 (Est.)	
	Exports	Main Destinations[1]	Exports	Main Destinations
Ranatidine Bulk	144.8	Bangladesh Germany Spain Switzerland	243.4	Bangladesh Mexico Canada Spain
Ranatidine - Formulations	39.9	Bangladesh Mexico Germany Spain	202.0	Canada Ireland Spain
Norfloxacin Bulk	49.7	Thailand Jordan U.S. Italy Germany Spain Switzerland	86.3	Korea Mexico U.A.E. Jordan Germany Spain Switzerland
Norfloxacin - Formulations	7.2	Kenya U.A.E. Venezuala Italy Spain	58.9	Kenya Vietnam Sudan Iran Germany Belgium
Ciprofloxacin Bulk	108.3	Bangladesh Hong Kong Taipei Switzerland	121.3	Bangladesh Sri Lanka Venezuala Switzerland
Ciprofloxacin - Formulations	59.5	Hong Kong Taipei C.I.S. Chad Spain	94.8	Hong Kong Vietnam Eygpt Russia Chile
Total	405.3		806.7	

Note: 1) Includes destinations representing 5% or more of total exports of the indicated drug.
Sources: Chemexcil (1995) and interviews.

Table 7
Annual Drug Expenditure Per Capita - 1990

Country	**Expenditure (U.S. Dollars)**
Japan	412
Germany	222
United States	191
Canada	124
United Kingdom	97
Norway	89
Costa Rica	37
Chile	30
Mexico	28
Turkey	21
Morocco	17
Brazil	16
Philippines	11
Ghana	10
China	7
Pakistan	7
Indonesia	5
Kenya	4
India	**3**
Bangladesh	2
Mozambique	2

Source: OPPI (1994)

Table 8
Diseases for Which 99% or More of the Global Burden Falls on Low- and Middle-Income Countries, 1990

Disease [Number of Suffers - 1990]	Developing Country Burden as a % of Total
Chagas Disease [16 million]	100.0%
Dengue	100.0
Ancylostomiasis and Necatoriasis	100.0
Japanese Encephalitis	100.0
Lymphatic Filariasis [90 million]	100.0
Malaria [1 billion]	100.0
Onchocerciasis-river blindness [66 million]	100.0
Schistosomiasis [200 million]	100.0
Tetanus	100.0
Trachoma	100.0
Trichuris	100.0
Trypanosomiasis	100.0
Leishmaniasis	99.9
Measles	99.9
Polio	99.9
Syphilis	99.9
Diphtheria	99.8
Leprosy [12 million]	99.7
Pertusis	99.6
Diarrhoeal Diseases	99.5

Source: World Health Organization (1996); Number of sufferers, Barral (1990).

Appendix

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Appendix II

Patent Legislation

I. Indian Patent Act of 1970 versus GATT

Patent Act	GATT
1. No product patents allowed for pharmaceuticals, food products and agrochemicals. Only process patents. No patents for micro-organisms.	Both product and process patents for pharmaceuticals, food products and agrochemicals, and micro-organisms.
2. Process patents for the above have a statutory term limit of the shorter of 7 years from application or 5 years from granting.	All patents have a term of at least 20 years from filing.
3. Government retains wide powers to grant (non-exclusive) compulsory licenses 3 years after granting. In the case of pharmaceuticals, licenses are automatic, i.e. with no consideration of local working by the patentee or the ability of the licensee to produce. Maximum royalty of 4% of ex-factory price in bulk form [compared to typical royalty rates of 10-15%].	No automatic licenses. Compulsory licenses only in cases of national emergency, for public non-commercial use, or to remedy a practice found after judicial review to be anti-competitive. A non-exclusive compulsory license may be granted only after a license sought on commercial terms from the patentee and remuneration should reflect the economic cost of the license to the patentee.
4. Importation does not fulfill working requirement.	No discrimination between domestic production and importation.
5. In all cases, the burden of proof in an infringement case falls on the patentee.	In the case of process patents, the burden of proof lies with the alleged infringer. (Reversal of the burden of proof.)

Source: Iyer, *et. al.* (1996).

II. Recent Events and Future Changes

April 15, 1994 - The Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations was authenticated by 117 nations, including India.

January 1, 1995 - The Final Act came into force. India is one of the countries with a ten year transition period to implement the treaty requirements. This grace period ends December 31, 2004.

January 1 to March 31, 1995 - Patent Ordinance put in place by the government, temporarily implementing the treaty without requiring legislative approval.

January 1, 1995 - During the transition period, India must accept product patent applications for pharmaceuticals, so-called 'black box' applications, and grant Exclusive Marketing Rights (EMRs). These give the patent applicant the exclusive rights to sell and distribute the product for a maximum of 5 years. EMRs can only be obtained after the pharmaceutical product has been granted a patent and has obtained marketing approval in another signatory country *and* after marketing approval is obtained in India. Since EMRs apply only to innovations with priority patent application after January 1, 1995, very few product innovations are likely to qualify.

March, 1995 - Passage of the Patents (Amendment) Bill in the Lok Sabha (upper house) of parliament by small majority. Could not be introduced in the Rajya Sabha (lower house) due to opposition.

January, 1997 - U.S. requests that a WTO dispute panel be constituted to investigate India's failure to pass implementing legislation to enable the acceptance of black-box product patent applications during the transition period. (Although they are, in fact, being accepted at the patent offices in anticipation.)

December 31, 1999 - India must bring laws and regulations into conformity with WTO.

December 31, 2004 - India must examine and grant pharmaceutical product patents.

Appendix III

Price Control - Drug Price Control Order (DPCO) 1995

The Drug Price Control Order (DPCO) of 1995 is the fourth price control order, following those in 1970, 1979 and 1987. Currently 76 Bulk Drugs are subject to price control, down from the 142 bulk drugs controlled under DPCO 1987. Under the new order, a drug is subject to price control if annual turnover in the audited retail market is more than 40 million rupees. A drug with turnover above 400 rupees may be exempted if there are at least 5 bulk producers and at least 10 formulators, none with more than 40% of the audited retail market. Any bulk drug with turnover above 10 million rupees and a single formulator with 90% or more of the market is also subject to price control. Small-scale firms are no longer free of price control. The latter closes a loophole, preventing small-scale firms from being used as fronts by larger manufacturers attempting to avoid price controls.

Under DPCO 1995, the government claims that 50% of audited retail sales are now covered by price control, down from about 70% under the old order. The industry claims that the percentage of the market now subject to control is actually far higher (85% in 1993) than the governments' claim because the governments' claim is based on outdated 1990 sales data. There are also on-going disputes between the government and industry about drugs that the industry claims meet the DPCO criteria for exemption but which are nonetheless being controlled.

Maximum Retail Price calculation for a formulation:

$$Retail\ Price = (MC + CC + PM + PC) * (1 + MAPE) + ED$$

MC - Material cost including bulk drugs used and an allowance for wastage.
CC - Conversion cost - labor, energy, R&D etc.
PM and PC - Packing material and charges.

These values are based on industry norms for large-scale manufacturers. They are calculated based on a detailed survey last done in 1988. The government is trying to do a re-survey but firms are being uncooperative, not wanting the fall in actual wastage to be acknowledged.

MAPE - Maximum allowable post-manufacturing expenses. Currently a 100% mark-up. This includes minimum wholesaler and retailer margins of 8% and 16%, respectively.

ED - Excise duty - small-scale manufacturers have some exemptions, with the amount depending on the manufacturer's sales. Firms with sales under 3 million rupees annually are completely exempt.

In addition to controls on drug prices, maximum returns are also fixed, at 18% on net worth or 26% on capital employed. No producers come close to these ceilings so this part of the DPCO is currently not binding.

Sources: Interviews; Clippings (10/1994); and Government of India, 1994a and 1994b.