

SOCIAL COSTS AND BENEFITS OF INTRODUCING PATENT PROTECTION FOR PHARMACEUTICAL DRUGS IN DEVELOPING COUNTRIES

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INTRODUCTION

THE EC, Japan, and the United States have all tabled proposals at the Uruguay Round for significantly greater harmonization and higher protection of intellectual property rights (IPRs). In the area of patents, industrial countries propose, among other things, that patents be granted in all fields of industry. Developing countries generally oppose these proposals. Probably the most contentious case is that of the pharmaceutical drugs. By looking at this industry, this paper will argue that neither side has a strong case in its favor and that more research is needed before an economically sound decision is made.

The paper starts in Section I by offering a political economy discussion of why industrial countries have reached a consensus in favor of introducing the patent protection for pharmaceutical drugs. The central point of the paper is then supported by analysis of Sections II and III, where I discuss the social costs and benefits of introducing patent protection for pharmaceutical drugs in developing countries. The paper concludes with brief final remarks.

I. POLITICAL ECONOMY BACKGROUND

At the Uruguay Round, industrial countries have made the following proposals in the area of patents:

- that they be granted in all fields of industry;
- that they should last for twenty years from the date of application;
- that compulsory licenses should be applied only in extraordinary circumstances; and
- that a strong dispute settlement mechanism be created to enforce compliance.

It is probably correct to assert that in the Uruguay Round, intellectual property rights is the one area where industrial countries have found the highest degree of agreement. It is probably also the case that this is the area where developing countries show the largest consensus in opposing the proposals of industrial countries. The consensus position of industrial countries on IPRs has no historical precedence. Furthermore, even in industrial countries, the intellectual debate on the pros and cons of patent protection has not reached a consensus on whether such

protection is always beneficial (see Machlup [14] for an exhaustive discussion).

Further insights have been gained since Machlup completed his study. But these efforts while illuminating certain theoretical and empirical aspects of patent protection, do not provide a solid basis for arguing always in its favor. For example, Nordhaus has presented the most thorough theoretical economic analysis of patents [21]. This model shows how patents are an inferior policy for promoting innovation; it also suggests that the degree of patent protection should vary by industry.¹

That patents have increased welfare has been concluded from estimates showing that the social return of innovations is higher than the private return (Mansfield et al. [17]). But these estimates have been made only on a few products; certainly they do not allow to jump to the conclusion that patents are always likely to increase social welfare, or that a patent duration of twenty years is always preferable to a duration of, say, fifteen years. Moreover, recent models show how patent protection in developing countries may lead to welfare losses (Maskus [18]) or even losses in world welfare (Deardorff [3]). Finally, and of importance for the design of balanced IPRs, is the finding that most industries do not appear to depend on patent protection for investing in R&D.

The weakness of the theoretical-empirical knowledge to assess the consequences of patent protection contrasts with the powerful insights emerging from the literature on, say, trade policy, or finance policy, or monetary policy. Then how can we explain the consensus of the proposal of industrial countries in the area of patents? One suggestion is that the clue to answer this question does not lie in the theoretical-empirical literature on patents but on the political economy considerations surrounding this policy, i.e., on the demand and supply of patent protection.

Table I from Levin et al. [13] shows the inter-industry importance of patents for appropriating the returns from innovation. In the underlying survey, the answers are rated on a one to seven scale. The figures in this table show that patents are most important to protect the process and product innovation of the drug industry; these patents were rated 40 per cent and 51 per cent higher than the industrial averages for processes and products, respectively. Furthermore, "only 5 of 130 industries rated product patents to prevent duplication higher than six [out of seven] points" [13, pp. 795-96]; drugs were one of the five.

The importance of patents for the pharmaceutical drug industry is not restricted to the United States. For example, in a classic study of the British patent system, Taylor and Silberston assert that the "pharmaceutical industry stands alone in the extent of its involvement with the patent system" [26, p. 231]. Clearly then, patents of industrial countries are a crucial policy instrument in determining the returns to innovative efforts in a core group of industries and particularly for pharmaceutical drugs. The explanation for this lies in the unique characteristics of chemical molecules and the fact that they are extremely easy to copy.

¹ Machlup shows that historically, the strength of enforcement of patent protection has varied quite significantly in the United States as well as in other industrial countries [14].

TABLE I
EFFECTIVENESS OF PROCESS AND PRODUCT PATENTS AS A MEANS OF
PROTECTING THE RETURNS FROM INDUSTRIAL INNOVATION

Industry	Process Patents	Product Patents
Pulp, paper, and paperboard	2.6	3.3
Cosmetics	2.9	4.1
Inorganic chemicals	4.6	5.2
Organic chemicals	4.1	6.1
Drugs	4.9	6.5
Plastic materials	4.6	5.4
Plastic products	3.2	4.9
Petroleum refining	4.9	4.3
Steel mill products	3.5	5.1
Pumps and pumping equipment	3.2	4.4
Motors, generators, and controls	2.7	3.5
Computers	3.3	3.4
Communications equipment	3.1	3.6
Semiconductors	3.2	4.5
Motor vehicle parts	3.7	4.5
Aircraft and parts	3.1	3.8
Measuring devices	3.6	3.9
Medical instruments	3.2	4.7
Full sample	3.5	4.3

Source: Levin et al. [13, p. 797].

Thus, patents are of major importance to only a few industries. If so, how do other industries appropriate the returns from their innovations? Levin et al. also show that most of this appropriation takes place through market-induced mechanisms such as lead times, sales and service efforts, and moving quickly along the learning curve [13, p. 794]. The relative importance of patents has led these authors to suggest that policy discussions—including those in the Uruguay Round—should focus attention on the chemical and pharmaceutical industries.²

These recent empirical findings about the relative importance of different ways of appropriating the returns from innovation help to rationalize the behavior of the R&D-intensive pharmaceutical companies and to understand the very particular juncture of the policy debate among different countries and, in particular, the consensus of industrial countries' proposal in the Uruguay Round. Several factors should be considered. First, the historically peculiar circumstances by which industrial countries agree on patent policies can be explained by the fact that the pharmaceutical industries of these countries have reached a stage where their financial capacity and the likelihood of being successful in drug innovation are high by historical standards. This is why many industrial countries—including Germany (1968), France (1960), Italy (1978), Japan (1976), Sweden (1978), and Switzerland (1977)—have only recently introduced patent protection for

² But focusing attention only on the industries for which patents are important, should not make the debate any easier.

pharmaceutical drugs, and why the views on the structure and extent of patent protection have converged so significantly among industrial countries.

This is not to say that within industrial countries there is a consensus on the extent of this protection. On the contrary, the debate is a continuing one and many groups—especially the elderly—are opposed to excessive patent protection, but those in favor of such protection have won the dispute. For example, in 1984, the United States extended the effective life of pharmaceutical patents by around 30 per cent. Likewise, the EC is studying this measure and will presumably increase effective patent protection for pharmaceuticals soon (*Financial Times*, April 15, 1990).³

Thus, this view of the world where pressure groups and domestic politics play a major role helps to understand the historically unique circumstances where industrial countries are in favor of strong patent protection for pharmaceutical drugs. But when policies are driven by interest groups, there is always the danger that the national interest will be harmed. In the area of pharmaceutical drugs, this could occur if patent protection were to include investment in R&D to a point where the social rate of return would be lower than that which could be obtained in other types of investment.

Thus, economic considerations and domestic politics in industrial countries help to rationalize their patent policies. As the role of interest groups in favor of patent protection has shaped domestic patent policies, demands have appeared to pressure developing countries to introduce patent protection for pharmaceutical products. In contrast, many developing countries have never provided such protection while others such as Brazil and Turkey have abolished it.

In response to these sector-specific demands, developed countries have implemented bilateral and multilateral measures to force developing countries to adopt such protection. In March 1987, only a few months after the Uruguay Round had been launched, Gerald J. Mossinghoff, president of the U.S. Pharmaceutical Manufacturers Association (PMA) declared that they were working with the U.S. Congress to get it to enact “the intellectual property revisions of the Omnibus Trade bill that would *strengthen the hand of the U.S. Government* in urging all of our trading partners to respect our rights in inventions and trademarks” (italics added) [19]. Certainly, the PMA has been very successful. For example, Section 301 of the Trade Act of 1974 was strengthened by the 1988 Omnibus Trade Act (Grinols [8]) and has been used to threaten and retaliate against countries which did not agree with U.S. policies regarding patent protection for pharmaceuticals. Thus, under strong pressure, Korea passed a legislation in 1986 that would allow patent protection for pharmaceutical products (Gadbaw and Richards [4]). However, the attack on Korea’s patent policies did not come only from the United States. In December 1987, the EC removed Korea from the generalized system

³ In the United States the extension of patent life for pharmaceuticals also included measures facilitating the marketing of generic drugs (Grabowski and Vernon [7]). For the time being, this latter policies are not included in the EC proposal on patent protection for pharmaceuticals (*Financial Times*, April 15, 1990). To my knowledge, pharmaceutical drugs are the only industry for which patent duration has been tailored to specific demands.

of preferences (GSP) because it did not provide adequate patent protection for the R&D-intensive pharmaceutical industry.

Probably the most notorious case of retaliation has been the action against Brazil which was undertaken after completion of a 301 investigation. Among other things, this investigation—initiated by the PMA—estimated the injury caused to U.S. firms by the absence of patent protection for pharmaceutical processes and products. Because Brazil did not satisfy the demands of the PMA, the United States increased ad valorem tariff rates to 100 per cent on a substantial number of goods imported from Brazil (*U.S. Federal Register*, October 24, 1988).⁴

The pressure is also explained by the increasing importance of developing countries' pharmaceutical markets, which I will discuss below. It can also be explained by the fact that in terms of present value, one dollar generated from patent protection today in developing countries is worth much more than one dollar generated through extending effective patent life in industrial countries which will be achieved around twenty years from now.

It is quite clear from all this that developing countries have confronted, and continue to confront, significant pressures from industrial countries. The choices for the developing countries have narrowed; either they increase protection for intellectual property and in particular extend patent protection for pharmaceutical drugs, or otherwise experience actual or threatened retaliatory actions by industrial countries.

There is always a level of retaliation that would make developing countries adopt what industrial countries want. This is crystal clear, but it might also be irrational. We want to know whether the adoption of patent protection for pharmaceutical products makes economic sense for developing countries and for the world. This question has apparently been avoided by all parties participating in the policy debate; yet it is of primary importance if countries want to introduce welfare enhancing policies. Sections II and III will provide a discussion of the social costs and benefits of introducing patent protection for pharmaceutical products in developing countries.

II. THE SOCIAL COSTS OF INTRODUCING PATENT PROTECTION FOR PHARMACEUTICAL DRUGS

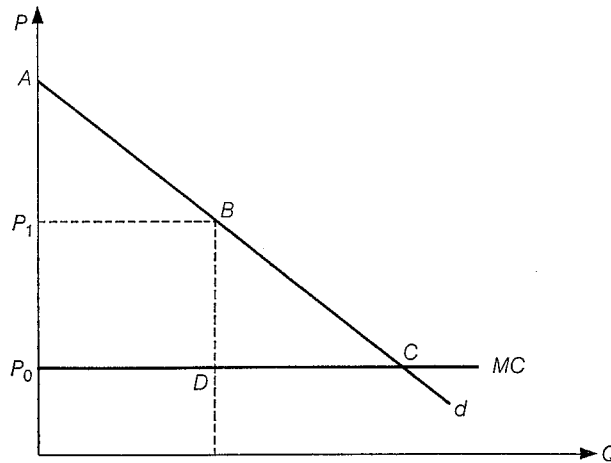
This section is divided into two subsections. In the first, I analyze the social losses incurred by the introduction of patent protection for pharmaceutical drugs, while the second subsection offers a rough estimate of these losses in a number of developing countries.

A. *Analytical Framework*

The social costs of introducing patent protection depend very much on the pre-patent structure of the pharmaceutical drug market. This is so because patents sustain monopoly prices and if the pre-patent market situation is characterized

⁴ Retaliation was terminated when Brazil made progress in a number of issues; trade liberalization policies were an important factor.

Fig. 1.



by competition, the introduction of patent will entail higher social losses than if that situation is characterized by a monopolistic behavior. Figure 1 shows what occurs when the pre-patent market behavior is characterized by perfect competition. I assume that the market is for a drug that fights a disease, say, Z and that marginal costs are constant.

The first is a simplified assumption. Some authors such as Rapp and Rozer argue that the presence of a large number of drugs within a therapeutic class is evidence of competition [22]. But within a therapeutic class, the quality of drugs might differ greatly and one drug might be dominant. It could also be the case that even within a therapeutic class some drugs are more appropriate for some particular type of patients. In both cases the market behavior is essentially oligopolistic and assessing the extent of competition by simply counting drugs would be erroneous. The second assumption apparently fits the productive conditions in the industrial countries (Grabowski and Vernon [6]), and may fit the supply conditions in developing countries.⁵

Also, production costs depend heavily on the efficiency of the chemical industry supplying basic inputs to the pharmaceutical industry. Many countries simply do not have a basic chemical industry and must rely on imported compounds; this may increase the production costs when—as I will discuss in the next section—multinationals resort to transfer pricing practices. Obviously, a protected and inefficient local chemical industry also increases the production costs of pharma-

⁵ The assumption of constant marginal costs is compatible with the concept that the pharmaceutical industry has constant returns to scale, associated with the traditional batch productive technology of the pharmaceutical industry. But the recent appearance of continuous flow technologies may have changed the optimal scale of operations. These issues should be taken into account for a correct assessment of the social effects of patent protection.

ceutical drugs. Clearly, as I will discuss further in the next section, we need to know more about the productive efficiency of chemical-pharmaceutical processes.

Somewhat more controversial is the interpretation of the demand curve. In picturing a single demand curve to all the drugs that fight a disease of type Z, I am making a couple of assumptions. First, that different brands of drugs are perfectly substitutable and second, that the demand curve reflects their social value.⁶ The first assumption depends very much on the knowledge of the consumer regarding quality and degree of bioequivalency of drugs from different brands. If the consumer believes that a drug from a particular company is superior to that of its competitors, then this company will be able to exploit product differentiation.

The existence of patents makes a great difference in this regard. The fact that patent owners are the first to exploit a market for a considerable period of time helps to create consumer loyalty in favor of the brand name drug; this loyalty is often reinforced by the medical profession.⁷ In this situation it has been found that upon patent expiration, brand name companies are able to retain a portion of the market and price their drugs higher than that of their generic competitors (Gorecki [5]).

Product differentiation is less likely to occur in developing countries where patent protection is not granted to pharmaceuticals. In the absence of patents, where several brands have been allowed to exist and compete, there is no a priori reason to suspect that some brands have been able to differentiate themselves significantly. In the absence of this presumption, it appears more reasonable to aggregate all brands of drugs that fight a particular type of disease, say, Z.

In the second place, I assume that the demand curve reflects the social contribution of the drugs under analysis. There is little evidence in favor of or against this assumption, and the little that exists is old and refers only to industrial countries. For example, Mansfield et al. showed that the social return to some pharmaceutical innovations was higher than the private return [17]. But, as previously mentioned, this finding was based on a few innovations and it cannot be concluded that systematically, the social rates of return to drug research are higher than the private rate. For developing countries, there is no evidence on the subject.

Keeping these issues in mind, let us see what is the social cost of introducing patent protection.⁸ In the competitive case, price equals marginal cost ($P_0 = MC_0$)

⁶ I am also assuming that the doctor-patient relationship is not affected by the introduction of patents.

⁷ Another way by which certain brands could enjoy short-run product differentiation is by maintaining a high quality reputation. In the United States for example in recent years, there have been investigations regarding the quality of drugs from certain generic companies. When this occurs the company that is being investigated loses its market share; but it appears that this loss is only temporary [9, July 1990]. More generally, there is no evidence of systematic quality differences between brand name and generic drugs; the regulations and testing requested by the Food and Drug Administration (FDA) have been formulated precisely to prevent this situation from occurring. Obviously, there always remains a possibility that problems may arise even after a drug passes the FDA process, but this may and has occurred also to brand name companies.

⁸ I will assume that the introduction of patents covers drugs whose patents in industrial countries have not yet expired. Policy discussions include the case of providing patent

and the consumer surplus of patients suffering from a disease Z is AP_0C . In this situation, the introduction of patents will transform a competitive market into a monopoly. Prices will increase from P_0 to P_1 , and patients suffering from a disease Z will lose P_0P_1BC . Society loses less because part of the loss to consumers is transferred as monopoly profits to the patent owner.

This we can call the impact effect on social losses associated with the introduction of patent protection for the existing stock of patented drugs. Dynamically, new drugs will enter the market leading to further losses from monopoly pricing,⁹ while other products will go off patents. It is unclear whether the net dynamic effects of drug innovation will increase or reduce the social costs of patents in the initial stock of patented drugs. This depends on the productivity of R&D in pharmaceutical drugs as well as its therapeutic value; as I will discuss in the next section, the physical productivity of R&D in drugs has been relatively stagnant. In any case, lacking further evidence, I will assume that the bulk of the social losses associated with patent protection is attributed to the initial stock of patented drugs.¹⁰

It is likely that part of these monopoly profits will be used to finance R&D, which is in fact the basic justification for patents. If, as is very likely the case, R&D is carried out in the laboratories which the patent owner operates in industrial countries, then the loss to society is higher than the misallocation triangle BDC ; the extent of this extra loss depends on the amount of the monopoly profits transferred abroad.¹¹ The net social loss to society of the introduction of patent protection can be estimated by adding the consumption misallocation triangles (BDC) in the market of all patented drugs to the amount of monopoly profits which are transferred abroad for R&D purposes.¹²

B. *Estimates of Welfare Loss*

The purpose of this section is to provide a rough estimate of the welfare loss associated with the introduction of patent protection for pharmaceutical drugs

protection only for the drugs that will be marketed after the introduction of this policy. In this case, the social costs of introducing patent protection will be lower during the initial years but as new patented drugs enter the market, the social costs of patent protection will increase.

⁹ These new drugs may substitute for other more inefficient drugs which may still be patented.

¹⁰ In the case where patent protection is introduced only for the drugs to be patented, the initial effect on social losses is nil; nevertheless, as time passes and new patented drugs are introduced into the market, social loss will increase gradually. Given the dynamics of the market, one can presume that the social losses will increase until a relatively stable plateau is reached where the social costs of patented drugs remain approximately constant. Clearly, when patent protection is introduced only for the new drugs that will enter the market, the present value of the social loss is lower than when this policy also covers the existing stock of patented drugs. This appears to be an important point in the design of patent policies.

¹¹ Obviously, the new innovations financed by profits in developing countries are part of the benefits of patent protection. This will be discussed in the next section.

¹² For the stock of initial patented drugs, these losses will recur year after year for as long as the patent lasts. If patents on drug x are introduced in year 1 and expire in year n , the present value of the social loss ($PVSL$) is given by:

when the pre-patent situation in developing countries is characterized by competition. To repeat, this is a simplified assumption which will maximize welfare losses associated with the introduction of patent protection. The existing empirical evidence sheds little light on the market structure of the pharmaceutical firms in developing countries. The discussion is divided into three subsections. The first presents a simple methodology to simulate the consumer misallocation due to the introduction of patents. The second subsection will discuss the evidence of the impact of patents on sustaining high drug prices. Finally, the estimates on welfare losses will be presented.

1. Methodology

The discussion in the previous section argued that the welfare loss from the consumer misallocation as a consequence of the introduction of patent protection could be approximated by the losses observed in all the markets for patented drugs used to treat different diseases. As previously mentioned, the information necessary to undertake such an analysis—cost of producing different drugs and market demand schedules and market structure—is not available. Instead, I will apply a simple methodology that allows the use of very aggregate figures—the only available ones—on the importance of the market for patented drugs in some developing countries and the extent of copied drugs; with these figures I will simulate the social costs of introducing patent protection.

Figure 1 illustrates the methodology. This figure depicts the aggregate demand schedule for patented drugs (D) as a function of a price index (P) of these drugs. I assume that both the marginal cost and demand schedules are linear. Under these assumptions and the presence of monopoly, it can be shown that (Deardorff [3]):

$$\text{area } AP_1B = \text{area } BDC, \quad (1)$$

$$\text{area } P_0P_1BD = \text{area } (AP_1B + BDC) = 2 \times \text{area } BDC. \quad (2)$$

These equalities allow a simulation of the welfare loss from different assumptions regarding the extent to which the industry's income in period 1 (I_1) with patents exceeds the income in period 0 (I_0) without patents. Because we do not know the demand and supply schedules, it is impossible to estimate the extent to which P_1 exceeds P_0 and therefore I_1 exceeds I_0 . Thus, simplified assumptions are necessary. It is reasonable to assume that the monopoly income I_1 will be greater than that observed in the pre-patent situation. Thus:

$$PVSL_x = \sum_{t=1}^n \frac{(CM_x)_t}{(1+i)^t} + \frac{(OSL_x)_t}{(1+i)^t},$$

where CM = consumer misallocation, OSL = other social losses including the transfer abroad of profits for financing R&D, and i = social rate of discount. The present value of the total social loss ($PVTSL$) is given by:

$$PVTSL = \sum_{x=1}^z PVSL_x,$$

where z is the total number of drugs whose patents are still valid when the policy is introduced. In order to simplify and shorten the discussion, in the text I will ignore these dynamic consequences of patents.

$$I_1 = I_0 (1 + x), \quad (3)$$

where x is a percentage which measures the force of the patent monopoly for increasing income. From (2) and (3) the consumer misallocation (CM) can be estimated as:

$$CM = \frac{I_1(1-c)}{2}, \quad (4)$$

where c is the proportion of production costs in the value of sales of patented drugs.

In this section, the simulation will be based on the assumption of equality of efficiency between domestic and multinational producers. With this assumption, the supply schedule remains unchanged with the introduction of patent protection.

In order to perform the estimation of equation (4) we need figures for I_0 , x , and c . I_0 and c will be taken from the existing literature, and we need an estimate of x . I will provide simulations where x takes the values of 20 per cent, 50 per cent, and 200 per cent while c takes the values of 20 per cent and 40 per cent. The discussion of the price effect of patented drugs will show that the figures for x could very well be on the conservative side.

2. *Patents and drug prices*

An important question raised in Section I refers to the extent of price competition in the pre-patent situation. Evidence that there is price competition in the absence of patents has been provided by Coloma et al. for Chile [2]. For example, for broncho-dilatators, the analysis presented in this study shows that in late 1979, Glaxo introduced the patented drug Salbutamol under the name of Aerolin. It took three years for a domestic drug company to develop a generic competing drug to Aerolin under the name of Fesema. At that time (1984), the price of Aerolin, as shown in Table II, declined. Competition increased again in January 1986 when Laboratorios Chile introduced a third competing drug under its original name of Salbutamol; after this, the price of Aerolin continued to decline.

A similar pattern emerged in the analysis of other drugs, namely, that as the number of competing drugs in specific therapeutic groups increased, prices declined or the rate of growth of price increases diminished (see also Coloma et al. for the analysis of the antirheumatic and tranquilizer markets). The fact that there appears to be competition, in no way implies that it is close to perfect; market prices may still be well above marginal costs. For example, Katz and Groisman present evidence of monopolistic behavior of the pharmaceutical industry in Argentina [10].

Although this competition might be far from perfect, the introduction of patents will most likely raise drug prices and the question is by how much. Some like MacLaughlin et al. argue that price controls would prevent drug prices from rising above 5 per cent [15]. Nevertheless, the available evidence suggests that if competition prevailed in the pre-patent situation, drug prices would rise by much more than 5 per cent. For example, a study by Schut and Van Bergeijk yielded the following regression equation [24]:

TABLE II
REAL PRICE INDEX OF GLAXO'S AEROLIN: CHILE, 1979-86

Year	Real Price Index (1979-86)	Annual Price Changes
1979	100.0	—
1980	105.5	5.7
1981	118.6	12.4
1982	138.9	17.1
1983*	144.7	4.2
1984	118.8	-12.5
1985	101.8	-14.3
1986	92.3	-9.3

Source: Coloma et al. [2, p. 52, Table 8].

* Average price before and after introduction of competition.

$$\begin{aligned}
 P = & 38.53 + 1.43 \frac{GDP}{N} - 0.60 \frac{CV}{N} + 7.08 PP \\
 & (6.04) (6.69) \quad (-2.68) \quad (1.16) \\
 & - 15.72 DPC - 11.12 IPC + e, \\
 & (-2.30) \quad (-1.50) \\
 & \text{Adjusted } R^2 = 0.78,
 \end{aligned}$$

where

- P = price index of pharmaceuticals;
- GDP = gross domestic product;
- N = population;
- CV = volume of drug consumption;
- PP = dummy for patent protection;
- DPC = dummy for price controls; and
- IPC = dummy for indirect price control measures.

It was observed that the dummy variable for direct price controls took a value of minus 16 which implied that on an average, the existence of these controls reduces consumer prices by 16 per cent. This would suggest that the power that control authorities have on prices has been important, but on an average not necessarily as important as to counteract market forces which as I will argue, are likely to push prices up significantly when patent protection is introduced.

Furthermore, the power that regulatory authorities in developing countries now have, is likely to be eroded in the upcoming years. One reason is that the reforms discussed at the Uruguay Round on the protection of intellectual property refer not only to the coverage and duration of this protection, but also to the enforcement of these policies. In particular, a strengthened dispute settlement mechanism at the GATT will most likely be used by the industrial countries to enforce patent policies in other countries; otherwise, developing countries will continue to be threatened by 301 type policies.

Regarding the low and nonsignificant coefficient of the dummy variable for the existence of patent protection, some observations should be made. First, the

TABLE III
CROSS-COUNTRY PRICE INDEX OF PHARMACEUTICALS, 1975

Country	Price Index Pharmaceuticals	Country	Price Index Pharmaceuticals
Malawi	60.83†	Uruguay	65.95
Kenya	50.63†	Ireland	73.58†
India	31.71	Hungary	57.25
Pakistan	38.76	Poland	53.98
Sri Lanka	15.22†	Italy	69.01
Zambia	96.58†	Spain	69.68
Thailand	48.01	United Kingdom	71.19†
Philippines	51.14†	Japan	81.88
South Korea	35.10	Austria	139.53
Malaysia	70.74	Netherlands	137.29†
Colombia	48.07	Belgium	101.73†
Jamaica	46.13†	France	91.56†
Brazil	63.83	Luxembourg	100.27†
Mexico	69.68	Denmark	157.56†
Yugoslavia	48.24	Germany (F.R.)	152.52†
Iran	70.42	United States	100.00†

Source: Schut and Van Bergeijk [24, p. 1144, Table 2].

† Listed in Schut and Van Bergeijk [24] as providing patent protection.

independent variable is a proxy for patented drugs. Second, patents might have been granted only to pharmaceutical processes and not products; process patents provide a very weak protection as there might be many ways of producing drugs that are bioequivalent. Unfortunately, the study under consideration does not distinguish between both forms of protection. Finally, as is well known, in the developing countries that grant patent protection for pharmaceuticals, generally such protection is provided only for the processes and/or the legal enforcement is weak and/or compulsory licensing policies are applied.

These comments imply that the impact of patents on drug prices cannot be estimated with precision with the regression used by Schut and Van Bergeijk [24]. A crude but clearer picture emerges with a simple partitioning of their sample which suggests that except for Japan and Austria, at the time of the estimation (1975), in all the high-income countries which granted strong legal patent protection for pharmaceuticals price indices were much higher than in low-income countries (Table III). This observation suggests that the per capita income variable—which in the regression equation is highly significant—is picking part of the effects of patents on drug prices.

On the basis of these results, let us go back to the original question, namely, what is a reasonable assumption for the extent to which drug prices will increase when patent protection is introduced. Ideally, such an impact could be assessed by analyzing the effects in countries where patent protection for pharmaceutical drugs has been introduced or abolished. But these radical policy shifts have rarely been undertaken in developing countries. The few exceptions are Brazil and

TABLE IV
COMPARATIVE U.S. PRICES BETWEEN GENERIC AND BRAND NAME COMPANIES

Brand Name	Generic Name	mg	Prices (U.S. \$)	
			Brand Name	Generic Name
Lidomet	Methyldopa	250	15.1	10.0
Ristocort	Triamcinolone	4	74.3	11.3
Actrim	Sulfamethoxazole	400	31.9	17.7
Enadryl-Cap/Tab.	Diphenhydramine	50	15.5	3.2
Ecadron	Dexamethasone	4	93.6	35.5
Iabinese	Chlorpropamide	250	28.0	7.8
Iuril	Chlorothiazide	250	6.0	3.7
Lagyl	Metronidazole	250	79.3	44.0
Ydeergine	Ergoloid Mesylat	1	31.8	14.8
Ygroton	Chlorthalidone	25	19.3	9.5
Ndocin	Indomethacin	25	28.1	17.0
Asix	Furosemide	20	9.0	5.5
Ibrax	Chlordiazepoxide	10	22.0	5.2
Rinase	Tolbutamide	500	16.5	6.4
Eriactin	Cyproheptadine	4	18.1	8.0
Ersantine	Dipyridamole	25	18.1	10.9
Erramycin	Oxytetracycline	250	37.2	10.8
Ofranil	Imipramine	25	20.4	4.5
Tylenol/Codeine	Acetaminophen	300	10.2	5.4
Asodilan	Isoxuprine	10	22.8	6.2

Source: Katz and Groisman [10].

Turkey which eliminated patent protection for pharmaceutical drugs in 1968 and 1971, respectively; unfortunately, the price effects of these policy changes have not been analyzed.

An alternative way of estimating what the likely impact of patent protection on drug prices will be, is to see what happens when patents expire in countries where the policy is enforced strictly. Some evidence on this is available for the United States which is known to have one of the strongest patent protection policies and where generic competition appears very fast in the market once such protection expires. Unfortunately, to my knowledge there has been no systematic analysis of the impact of patent expiration and the introduction of generic competition on drug prices; the evidence is spotty but abundant and worthwhile commenting.

For example, Scherer reports that for many years Pfizer sold the antibiotic Tetracycline at U.S.\$30.60 per bottle of 100 capsules [23, p. 390]. When Pfizer's patent was challenged, competing firms sold the generic product at U.S.\$2.50 per bottle. Furthermore, Scherer asserts that "many similar cases of price-cost margins on the order of 90 per cent for patented drug products have been identified" [23, p. 391].

Other examples illustrate the impact of generic drug competition. One hundred tablets of 2 mg pills of Valium are wholesale priced at around U.S.\$30, while

the generic Diazepam sells for around U.S.\$15 (Grabowski and Vernon [7]). One hundred tablets of 600 mg pills of Motrim are wholesale priced at around U.S.\$25 while the generic Ibuprofen is priced at around U.S.\$14. Another example mentioned by the president of the American Association of Retired Persons, asserts that its members pay U.S.\$15.95 for a three months' supply of Bolar's version of Dyazide and U.S.\$31.95 for the SmithKline brand name product. The same source asserted that there might be a ten to one difference in the price of different arthritis drugs (*Wall Street Journal*, September 6, 1989). Another piece of evidence is offered by Katz and Groisman who present the figures shown in Table IV [10]. Again, the numbers show significant price differences between generic and brand name drugs.¹³

Finally, major reductions in drug prices after patent expiration have also been reported in other countries. For example, Taylor and Silberston state that "U.K. price reductions of the order of a quarter to a half or more have been noted at this stage [patent expiration] of the life-cycle of important patented drugs" [26].

In conclusion, over time patents are a major factor in sustaining high drug prices; the appearance of generic competition results in prices of these drugs being much closer to marginal production costs than those of brand name companies. The literature has also noted significant price differences between drug prices in developing countries with weak or no patent protection and industrial countries providing strong patent protection. All this evidence supports the hypothesis that the introduction of patents is likely to have significant price effects. This implies that the monopoly-induced income effect (x in equation 3 above) appears to be important.

3. *Estimating welfare losses*

The extent of consumer misallocation and other welfare losses from patent protection depends, among other factors, on the size of the market for patented drugs. Table V presents the available information on this market from MacLaughlin et al. [15]; in turn these authors report that the figures have been collected by the Pharmaceutical Manufacturers Association.¹⁴ The figures show that in many developing countries the patented pharmaceutical drug market is an important segment of the overall pharmaceutical market. The figures also show that the relative importance of sales of copied drugs in overall sales of patented drugs varies significantly between countries.¹⁵ The highest proportion is observed in Korea, Argentina, and India, while the lowest proportion is observed in Brazil.

Simulations of consumer misallocations using equation (4) are presented in

¹³ These price differences develop even in markets where off-patent drugs were available. For example, Rapp and Rozer list Chlorthalidone and Methyldopa as two of the several anti-hypertensive generic drugs available in the U.S. market [22]. Yet, we observe in Table IV important price differentials with the brand name drugs.

¹⁴ Unfortunately, MacLaughlin et al. do not assess the accuracy of these data.

¹⁵ MacLaughlin et al. define line 2.2 in Table V as revenues accruing to patent owners before the introduction of patent protection. I assume that these revenues are derived from the sale of patented drugs.

TABLE V
ESTIMATES OF PATENTED PHARMACEUTICAL MARKET IN
SOME DEVELOPING COUNTRIES

(U.S.\$ million)

Variables	Argentina	Brazil	India	Mexico	Korea	Taiwan	Total
1. Pharmaceutical market size	1,200.0	2,000.0	4,200.0	1,000.0	1,000.0	500.0	9,900.0
2. Patented pharmaceutical market	771.6	1,750.4	2,546.0	852.5	308.0	197.4	6,425.3
2.1 Sales by domestic firms of copied drugs	231.0	93.8	920.0	136.5	188.0	27.4	1,596.7
2.2 Sales of drugs by firms who are patent owners	540.0	1,656.6	1,626.0	716.0	120.0	170.0	4,828.6
3. Ratio of (2) to (1) × 100	64.3	87.5	60.6	85.3	30.8	39.5	64.9
4. Ratio of (2.1) to (2) × 100	30.0	5.4	36.1	16.0	61.0	13.9	24.9

Source: MacLaughlin et al. [15].

TABLE VI
ESTIMATES OF CONSUMER MISALLOCATION FROM THE INTRODUCTION
OF PATENT PROTECTION

(U.S.\$ million)

Countries	$x=0.2$ $c=0.2$	$x=0.5$ $c=0.2$	$x=2.0$ $c=0.2$	$x=0.2$ $c=0.4$	$x=0.5$ $c=0.4$	$x=2.0$ $c=0.4$
Argentina	370.1	462.6	925.2	277.6	532.0	693.9
Brazil	840.2	1,050.2	2,100.5	630.1	1,207.8	1,575.4
India	1,222.1	1,527.6	3,055.2	916.6	1,756.7	2,291.4
Mexico	409.2	511.5	1,023.0	306.9	588.2	767.3
Korea	147.8	184.8	369.6	110.9	212.5	277.2
Taiwan	94.8	118.4	236.9	71.1	136.2	177.7
Total	3,083.0	3,853.8	7,707.6	2,312.3	4,431.9	5,780.7

Source: Methodology explained in text.

Table VI; under the assumptions made, the figures show that the losses from consumer misallocation could be as high as U.S.\$7.7 billion.¹⁶

As mentioned before, the loss to developing countries is likely to be smaller. For example, the dynamic justification for patents is that the monopoly profits

¹⁶ Assuming that (i) the size of the market remains stationary, (ii) patent protection of existing drugs will last eight years (half of what industrial countries are proposing at the Uruguay Round), and (iii) the average rate of discount is 15 per cent, the present value of consumer misallocation loss to the developing countries would be U.S.\$31.8 billion in the high loss case.

TABLE VII
WELFARE LOSSES TO DEVELOPING COUNTRIES AND INCOME GAINS OF
PATENT OWNERS FROM INTRODUCTION OF PATENT PROTECTION

(U.S.\$ million)

Variables	Argentina	Brazil	India	Mexico	Korea	Taiwan	Total
1. Income gains							
a. Minimum ($x=0.2$)	385.2	443.9	1,429.2	310.0	249.6	66.9	2,881.7
b. Maximum ($x=2.0$)	1,773.0	3,594.6	6,012.0	1,841.5	804.0	422.2	14,447.3
2. Welfare losses							
a. $c=0.4$, $x=0.2$	425.6	966.2	1,405.4	470.6	170.0	109.0	3,545.5
b. $c=0.2$, $x=2.0$	1,295.3	2,940.7	4,277.3	1,432.2	517.4	331.6	10,790.6

Source: Methodology explained in text.

received by the inventor will allow him to finance further research leading to new innovations. We have provided empirical evidence for the importance of patents for the pharmaceutical industry and there is no doubt that part of the monopoly profits that R&D-intensive companies will gain when patent protection is introduced in developing countries, will be used to finance R&D. From the point of view of developing countries, the monopoly profits of the multinational companies should not be treated as a social loss unless these profits are transferred abroad. But as mentioned previously, given the poor research facilities in many of these countries, it would appear reasonable to assume that an important proportion of the investment in R&D financed from income generated in developing countries, will be undertaken in the laboratories of industrial countries; this transfer of resources entails additional social losses.¹⁷

How important is this loss? The answer to this question depends on the propensity to invest in R&D. In recent years, the U.S. Pharmaceutical Manufacturers Association has estimated that investments in R&D as a proportion of sales is around 16 per cent (advertisement of the PMA in the *Washington Post*, November 17, 1989). By applying this coefficient to the additional income accruing to patent owners, the value of monopoly profits transferred abroad for R&D purposes fluctuates between U.S.\$1 billion when the income with patents is 20 per cent higher than the income without patents, and U.S.\$2.8 billion when the difference in income is three times.¹⁸

Finally, let me provide a perspective of the income redistribution consequences associated with the introduction of patent protection in developing countries.

¹⁷ Multinationals may or may not have a higher propensity to transfer profits abroad than do domestic firms. Lacking more precise evidence I will assume that—except for funds financing R&D—the attitude in this regard does not differ significantly according to the ownership of the firms.

¹⁸ Under the dynamic assumptions made above (footnote 16), this extra loss increases the social cost of providing patent protection from U.S.\$31.8 billion to U.S.\$47.6 billion.

Industrial countries argue that their companies are suffering tremendous losses from the lack of protection in intellectual property; in fact, much of the analytical work produced in these countries has the purpose of emphasizing this point (see for example MacLaughlin et al. [15]). Thus far, the analysis in this section emphasizes the losses to developing countries. Table VII provides a comparison between welfare losses to developing countries and income gains of patent owners. These income gains originate from two sources. First, there are the gains obtained by patent owners by shifting from a competitive (line 2.2 in Table V) to a monopoly pricing on the sales registered during the pre-patent period. In addition, patent owners will now receive the income for that part of the market previously supplied by domestic firms which were copying (line 2.1 in Table V), adjusted for monopoly pricing. The estimates of these income gains which accrue to patent owners are shown in lines 1a and 1b of Table VII. In contrast, lines 2a and 2b show the minimum and maximum welfare losses to developing countries. Depending on the assumption, the income gain of the R&D pharmaceutical industry might be higher or lower than the social losses to developing countries; averaging the minimum and maximum costs results in the approximate equivalence of these gains and losses.¹⁹

Obviously, this is a static analysis which ignores not only the dynamics of the problem but also potential social gains which patents could offer to developing countries. In any case, the similarities between income gains and social losses provide an understanding of the disagreements between industrial and developing countries at the Uruguay Round.

III. BENEFITS OF INTRODUCING PATENT PROTECTION FOR PHARMACEUTICAL DRUGS IN DEVELOPING COUNTRIES

In the previous section the social costs of introducing patent protection were simulated in a sample of developing countries; under extreme assumptions and existing statistics on the pharmaceutical drug market, these costs could be considerable. Those in favor of patent protection emphasize the positive consequences of introducing patent protection. These authors outline several social benefits associated with the introduction of patent protection for pharmaceutical drugs, stating that such protection will:

- eliminate domestic monopoly positions;
- provide positive externalities;
- facilitate the transfer of technology and direct foreign investment;
- reduce the lag in the introduction of new patented drugs;
- increase investment in R&D and domestic innovation of drugs;
- improve the access of domestic products to foreign markets;
- reduce the incidence of transfer pricing;
- diminish the inefficiencies of local production;

¹⁹ Note that if the PMA has been overenthusiastic in emphasizing losses to multinational companies, my figures will be overestimating social losses to developing countries and vice versa.

- eliminate the cost of retaliation; and
- improve worldwide innovation and worldwide welfare.

Based on the existing literature, the purpose of this section is to provide a discussion on these issues from the point of view of patent policies applied to pharmaceutical drugs in developing countries.

1. *Domestic monopolies*

When the pre-patent market structure is characterized by an oligopolistic behavior, the social loss associated with the introduction of patent protection will be smaller than when the pre-patent market structure is competitive. In the extreme case of a pre-patent monopoly situation, patents will not result in a loss from consumer misallocation; there is simply a transfer of monopoly rights. The potential loss in this case involves the profits that will be transferred from the domestic producers which were producing copied drugs to the patent owner who might have a relatively high propensity to transfer profits abroad (for example, to the home country, for undertaking R&D).

When is a monopoly situation more likely to exist in the pre-patent situation? The answer in part is determined by the regulatory-protectionist policies in developing countries. A relatively open and unregulated market should have resulted in a higher competition in the pharmaceutical drug market than a tightly regulated one. Another determinant should be the presence of a domestic competitive pharmaceutical industry. Even though it is easy to copy a drug, it is necessary to have a minimum of adaptable research facilities; it is also necessary to be able to produce it on a scale compatible with the size of the domestic market. When these conditions cannot be met in a developing country, then it will have to rely either on imports which might be overpriced, or on the multinational producer which will attempt to charge monopoly prices. Clearly, the issue of the extent of competition in the pre-patent situation is of major importance for determining the social costs associated with the introduction of patent protection for pharmaceutical drugs. Little is known on the subject and more research appears to be necessary.

2. *Externalities*

Consider the following quotation analyzing the benefits of patent protection: “developing countries will be better off because of the positive externalities in an economy which typically result from innovations as a consequence of patent protection” (MacLaughlin et al. [15, p.102]). This might be true but there is no evidence in favor of or against it. The fact that most of the R&D for patented pharmaceutical drugs is financed by private companies, suggests that patent owners have privatized much of the externalities that this research could generate. It is much more likely that R&D of multinational pharmaceutical companies benefits from the externalities derived from basic research efforts that take place in universities and different government agencies; this research is not necessarily fostered by patent protection. For example, Nelson has shown econometrically that university research enhances technological opportunities and the productivity

of private R&D [20]; such a relationship is stronger in biological sciences, and medicine in particular. This interaction between basic and applied research suggests that there must be a balance in the amount of resources devoted to each of them; in particular it could be uneconomical to devote too many resources to R&D in industry, when basic research remains underfunded.

3. *Influence on technology transfer and direct foreign investment*

It has been argued that countries with strong protection of intellectual property benefit from the fact that technology owners are more willing to transfer their capital and knowledge to such countries (MacLaughlin et al. [15, p. 98]; Sherwood [35]). Despite the emphasis put on this argument the evidence is weak.²⁰ One could argue for example, that the decision to license and transfer technology depends much more on the legal strength of the licensing agreement and the adaptable capacity of the buyer to absorb the technology.

One of the significant ways of transferring technology to a developing country is through foreign direct investment. The hypothesis has been that investors would send more updated technology if patent protection and more generally intellectual property rights protection is provided. But again, there is no evidence to support or reject this hypothesis.

In the case of pharmaceutical drugs the evidence is also weak, and the little that exists suggests that patent protection is not a decisive factor to determine the extent of drug technology available in developing countries. For example, Kirim when studying the impact of the 1961 decision by Turkey of abolishing patent protection for pharmaceutical drugs, concluded that "licensing agreements did not depend in a systematic way on whether or not there was patent protection in the country" [12, p. 228]. Kirim also argues that the rate of new drug introduction into the Turkish market did not decline after 1961. He also concluded that in spite of the elimination of patents, investment continued to flow into Turkey's pharmaceutical industry. Furthermore, Kirim presents evidence on capital accumulation by subsidiaries of multinational companies and concludes that there was a "desire of foreign-owned firms to increase their capital even in the absence of patent protection." Thus, "no simple causal link can be made between patents and foreign investment" [12, p. 227].

An hypothesis here is that although patents are important for investment decisions in R&D, they are only of second order importance for making decisions on investment in physical assets; these decisions are more likely to be influenced by the investment climate of the country than by incentives to R&D. In any case, the little evidence that exists suggests that the argument that patents are important for the availability of drug technology remains a purely speculative consideration.

4. *Lags in the introduction of new drugs*

Suppose that a new drug is introduced somewhere in the world but that because of the lack of patent protection, developing countries do not have access to it

²⁰ For example, Braga cites OECD survey findings indicating that weak protection to IPRs is a barrier to licensing in developing countries. On the other hand, "...weak intellectual property [rights] systems can coexist with intense licensing activity" [1, p. 82].

immediately. Since the drug will become available only when domestic producers are able to copy and produce it, or when it can be imported from another copier, both of these situations entail a lag which results in social losses. The literature has shown different lags in the introduction of drugs among industrial countries; but these differential lags have been explained mainly by the extent of regulations in the approval for marketing new drugs (Grabowski and Vernon [6, Chap. 3] for a review). The United States for example has a longer lag than other industrial countries and this is due primarily to the more stringent drug safety regulations in this country.

One could consider a situation where a patent owner refuses to transfer drug technology while at the same time such a drug cannot be copied or produced easily in developing countries. The existence of these lags remains to be documented, but a priori these situations are not expected to be frequent or important; this is so because it is very likely that some country will be able to copy the drug and export it.

5. *R&D and domestic innovation*

The first section of this paper documented the relative importance of patent protection for the pharmaceutical drug industry. In light of this research and the strong lobby of this industry in favor of higher patent protection worldwide, there should be little doubt that in industrial countries patent protection is a major determinant of the amount of investment in R&D in pharmaceutical drugs.

For example, between 1985 and 1989 the total amount of investment in R&D by the U.S. pharmaceutical industry increased from around U.S.\$4 billion to U.S.\$7 billion (*Washington Post*, November 15, 1989). This increase of around 75 per cent in only four years must be attributed at least in part to the longer patent protection afforded by the Patent Restoration Act passed in 1984. More formally in the case of Japan, Kawaura found that the 1976 introduction of patent protection for pharmaceutical drugs resulted in a statistically significant increase in R&D [11]. In a regression equation explaining the investment in pharmaceutical R&D in Japan, the coefficient of the sales variable increased by 14–16 per cent after 1976.

Would developing countries experience the same impact as that observed in the United States and Japan? This would appear unlikely. First, for several years now, in several developing countries, physical investment has been declining. In many of the heavily indebted countries which also provide weak patent protection, the capital stock has been seriously eroded. In these economies, the discount rate is very high and probably private firms have a priority of investing in machinery which has a faster payoff than investment in R&D which has an uncertain return and will only come, if at all, several years after the investment funds have been allocated.

More fundamentally, in the case of pharmaceutical drugs, there appears to be a serious financial barrier to undertake R&D. The PMA has estimated that on average, it costs around U.S.\$150 million to produce, test, and market a successful drug. For the poorest of the developing countries it would appear that R&D in pharmaceutical drugs is simply not possible within the foreseeable future.

In the case of more advanced developing countries, the possibility of undertaking successful research would appear to depend on the size of investment relative to the size of the firms and the nature of the regulations. Let us look at these factors. First, the average cost of developing a successful drug varies with therapeutic categories. For example, Grabowski and Vernon cite findings showing that the average R&D costs of psychopharmacological and anti-inflammatory drugs is more than three times higher than that of anti-infectious drugs [6].

Obviously, the smaller the size of the investment that is necessary to undertake successful R&D the higher the probability that this activity can be undertaken in developing countries. Let us assume that it takes an investment of U.S.\$100 million to have good chances of producing a successful drug in a period of five years, i.e., U.S.\$20 million per year. In most of the developing countries this amount of money cannot be borrowed in capital markets; it must be self-generated. Let us assume furthermore that at least initially, firms would not be willing to devote more than 5 per cent of sales to R&D; this is the proportion observed in pharmaceutical R&D in Spain.²¹ This fact implies that a pharmaceutical company should sell drugs for a value of at least U.S.\$400 million per year to have a chance of entering the R&D competition in drugs. This size appears to prevent most of the firms in the developing countries from the possibility of undertaking R&D in pharmaceutical drugs.

The figure of U.S.\$100 million used above assumes that the drug safety regulations in developing countries are as stringent as in the United States. As mentioned previously, in this country, the high average costs of developing a successful drug is very much influenced by the extent of regulations enforced by the FDA. There has been a lengthy debate as to the costs and benefits of these regulations. Empirical estimates show that most likely the marginal social cost of these regulations is higher than the benefits (Grabowski and Vernon [6]). Thus, if the experience of industrial countries with drug safety regulations could be used appropriately in developing countries, the average expected cost of developing successful drugs could be lowered with a more balanced drug safety regulation framework than that applied in the United States.

The fact that there appears to be quite a variance in the R&D costs of drugs in different therapeutic categories and that perhaps more balanced drug safety regulations than those prevailing in industrial countries could be instituted, increases the probability that advanced developing countries could undertake R&D in pharmaceutical drugs. Nevertheless, the available statistics show that developing countries have contributed marginally to innovations in pharmaceutical drugs. Perhaps the reason has been lack of patent protection.

6. *Market access for exports*

In recent years, industrial countries have been very active in raising barriers against imports of goods and services that violate their intellectual property rights legislation. For example, in the United States, investigations under Section 337 of the Tariff Act of 1930 are available to firms seeking to restrict imports that

²¹ See "Nueva Ley de Patentes," *Expansión*, December 1985.

allegedly violate patent rights. The 1988 Omnibus Trade and Competitiveness Act increased the protection provided by Section 337 (Grinols [8]). For example, the following are some of the changes introduced by this act:

- increased penalties against noncompliance of desist orders;
- elimination of the injury test;
- elimination of the requirement that the investigation had to prove that the U.S. competitive industry was being efficiently and economically operated; and
- shifting the role of the president from an active to a passive one, i.e., seize and desist orders are put automatically into effect unless the president formally disapproves. Before, the president had to approve the order within sixty days for it to come into effect.

These changes have seriously increased the protectionist threats of Section 337. For example, it has been proven that the absence of the injury test in countervailing duty investigations has been associated with a greater incidence of positive findings. Thus we may predict that the elimination of this test in Section 337 investigations will result in positive findings more often than in the past. Likewise, the elimination of the proof that the domestic industry is competitive paves the way for increasing the number of petitions for investigations under Section 337. Finally, it is unlikely that the president will disapprove the retaliatory measures proposed for positive findings of Section 337 investigations. Thus, after the Omnibus Trade Bill, it is more likely than before that protectionist trade measures of Section 337 will be introduced when the findings of the investigations are positive.

Clearly all these changes will be used to protect the U.S. market for intellectual property right owners from foreign competition. One can presume that this increased protection may exert a serious effect on U.S. prices as foreign competition from low-priced copied products will be substituted with domestic monopoly prices.

How does this increase in protection against imported copied products affect the economic analysis of pharmaceutical patent protection in developing countries? Clearly, the answer to this question hinges on the patterns of trade. Thus the higher the proportion of copied drugs exported to the United States the higher will be the cost to developing countries of increased protection in this market. There are no data on the importance of this trade, but an approximate estimation can be made by examining the data on trade in medicinal products which presumably would include the trade if any of copied drugs. The figures in Table VIII show that for the countries analyzed before, the value of these exports is very low. This suggests that the costs to these developing countries of increased protection against copied pharmaceutical drugs are quite small.

In summary, given the current volume and patterns of trade, for developing countries, there does not appear to be an important gain in terms of access to the U.S. market from providing patent protection for pharmaceutical drugs. One could argue that this is too static a point of view and that current exports to the United States are low precisely because the market is protected. Perhaps this is so, but for arguing the contrary, one has to assume that the United States is prepared to reduce significantly the trade surplus that it now enjoys in medicinal products (Table VIII) and that developing countries would enjoy a comparative

TABLE VIII
EXPORTS OF MEDICINAL PRODUCTS BY DEVELOPING COUNTRIES TO
THE UNITED STATES, 1980-88

(U.S.\$ million)

Country	1980	1981	1982	1983	1984	1985	1986	1987	1988
Argentina	9.1	11.0	12.1	5.7	8.0	5.3	5.1	2.3	1.7
Brazil	6.0	6.6	4.4	6.3	6.1	7.0	3.2	5.3	n.a.
India	3.7	1.5	4.4	7.7	13.8	2.4	n.a.	n.a.	n.a.
Korea	0.8	1.2	1.4	2.3	3.5	4.1	5.1	4.9	n.a.
Mexico	12.2	16.3	12.1	15.1	15.2	11.7	3.4	4.8	n.a.
U.S. exports	2,020.3	2,255.4	2,359.6	2,581.0	2,724.8	2,790.4	3,213.5	3,347.6	4,089.1
U.S. imports	803.1	918.9	931.7	1,171.1	1,500.1	1,718.0	2,084.1	2,498.0	3,234.6
U.S. balance	1,216.9	1,336.5	1,427.9	1,410.0	1,224.7	1,072.5	1,129.4	849.8	854.6
U.S. imports from developing economies	119.5	132.0	142.5	160.9	177.5	267.3	396.5	407.2	527.5

Source: COMTRADE data base. Data correspond to SITC54.

advantage in pharmaceutical drugs. Both of these assumptions are not very unrealistic.

7. *Reduction of the incidence of over-invoicing*

The practice of under- and over-invoicing of international trade flows has been documented by many authors. Over-invoicing of exports to developing countries by pharmaceutical drug companies has been documented among others by Katz and Groisman for Argentina [10].

This over-invoicing practice could be related to a number of factors including lack of patent protection, i.e., pharmaceutical firms over-invoice their exports to developing countries as a way of compensating themselves for the forgone profits from lack of patent protection. If so, one could presume that the introduction of patent protection would reduce or eliminate the incentives for over-invoicing and this should be counted as part of the benefits of introducing such protection.

There are two questions of interest here. First, how important is transfer pricing and second, whether the introduction of patents would reduce the incidence of this practice. Regarding the first question let me review the experience of Argentina. Table IX shows the average import prices actually paid and what the country would have paid had imports come from the lowest cost supplier. Adding over all imports for 1983, Katz and Groisman found that transfer pricing practices cost the country around U.S.\$80 million [10]. As a consequence, the government of President Alfonsín took an active role in checking import prices and according to Katz and Groisman, these government-company negotiations enabled the country to save around U.S.\$30 million [10].

In 1983 the total imports of chemical compounds (SITC51) and medicinal products (SITC54) by Argentina amounted to U.S.\$603 million. Thus, transfer pricing practices accounted for around 13 per cent of the value of these imports.

TABLE IX
OVER-INVOICING OF PHARMACEUTICAL IMPORTS: ARGENTINA, 1983

(Price per kilogram)

Product	Average Import Price	Reference Price	Country of Reference
Propilenglicol	2.7	1.2	Brazil
Dobesilato de Calcio	211.3	20.0	Italy
Lactato de Penilamina	661.7	136.0	Italy
Amitriptilina HCL	416.3	80.0	Switzerland
Diclofenac Sodico	1,923.7	250.0	Italy
Metroprolol	565.7	140.0	Italy
Propanolol	121.9	17.0	Italy
Sulfato de Salbutamol	1,962.6	440.0	Finland
Etilefrina HCL	727.8	150.0	Switzerland
Atenolol	935.6	200.0	Italy
Metionina	2.8	2.0	Switzerland
Probucof	275.0	140.0	Spain
Sulocidil	478.0	90.0	Italy
Clotrimazol	716.5	141.0	Italy
Nitrato de Econazol	1,037.6	130.0	Italy
Timidazol	338.0	30.0	Italy
Ornidazol	536.7	170.0	Italy
Dipirona Magnesica	13.2	9.0	R.F.A.
Fenilbutasona	35.2	12.0	Hungary
Oxifenbutazona	166.1	31.0	Italy
Nifedipina	1,117.0	168.0	Switzerland
Piritioxina	408.0	140.0	Italy
Dipiridamol	494.0	110.0	Italy
Trimetoprim	269.0	423.0	Italy
Domperidona	4,597.0	2,600.0	Switzerland
Carbamacepina	229.0	115.0	Switzerland
Diazepan	411.0	40.0	Italy
Troxerutina	155.0	46.0	Italy
Ergotoxina	45,545.0	4,800.0	Italy
Oxitetraciclina	65.0	21.0	R.F.A.
Cefalexina	223.0	138.0	Spain
Cefradina	529.0	275.0	Italy
Eritromicina Estear.	185.0	72.0	R.F.A.
Blufomedil	576.0	424.0	Switzerland
Cimetidina	196.0	93.0	Switzerland
Aminociclytol	2,663.0	350.0	Hungary
Ketazolam	1,922.0	1,100.0	Spain

Source: Katz and Groisman [10, Table 11].

If the introduction of patents were to terminate with transfer pricing practices, there would be two sources of gains. First, a greater quantity of drugs would be sold, which would increase the consumer surplus. Second, at the post-patent equilibrium, the country would save in excess remittances abroad which now would go through transfer pricing mechanisms.

It is clear that one can visualize a situation where the cost of transfer pricing would be so high that its elimination would provide a net social gain even if the

new equilibrium were one of monopoly. Nonetheless, my presumption is that transfer pricing will not necessarily end with the introduction of patent protection. In 1983, Argentina was characterized by extreme distortions and policy instability; the country was starting to travel the debt-ridden road and at the time, it was using protection and capital control policies as major instruments to deal with the crisis. Several authors have estimated that the political economy situation of Argentina and other developing countries led to an impressive amount of capital flight. In this scenario, it would be unrealistic to assume that over-invoicing of pharmaceutical imports—one of the means of undertaking capital flight activities—would necessarily end with the introduction of patent protection.²²

In summary, transfer pricing practices of pharmaceutical products have imposed high costs to Argentina and perhaps to other countries. Given the widespread incentives to capital flight in many developing countries, it is most unlikely that transfer pricing practices would end simply because patent protection is introduced into the country.

8. *Reducing the cost of relative inefficiencies*

Some observers have argued that the production of copied products in developing countries might be promoted by relatively inefficient firms, whose production costs are higher than those of patent owners (Maskus [18]). Such inefficiencies must be distinguished from the monopoly behavior discussed in the previous section. In turn, these inefficiencies could arise from overprotection (X type inefficiencies) or the existence of scale economies which makes uneconomic the technology and plant size used to produce for the small domestic market. If so, the introduction of patent protection could result in the adoption of more appropriate productive techniques or the substitution of domestic output with imports. In this latter case, whether society loses or benefits depends on the price of imports. If these prices are higher than in the pre-patent case, society will incur additional losses in both consumer and producer surplus. This issue carries an important weight in assessing the consequences of patent protection; unfortunately, the literature has not addressed it.

9. *Reduction of retaliatory effects*

The discussion in this paper started by emphasizing the retaliatory spirit of industrial countries and particularly the United States against developing countries for resisting the introduction of a level of patent protection commensurate with their demands. To my knowledge, there is no full account of these retaliatory threats, but countries such as Korea have been the number of GSP products reduced significantly because of their resistance to introduce patent protection for pharmaceuticals; for some countries this type of retaliation could be associated with significant costs.

²² This paper was completed in 1990. Since then, the government of President Menem has introduced far-reaching stabilization and structural reform measures. These measures—including those in the health care industry—have increased competitive pressures quite significantly and the country is now attracting significant capital inflows part of which is likely to be flight capital.

In order to avoid retaliation, some countries have introduced or agreed to introduce or increase patent protection for pharmaceuticals within a time frame. But for some countries which showed no flexibility to U.S. demands, retaliation through 301 investigations has been applied; in the case of pharmaceuticals the most notorious case has been Brazil. On July 21, 1988, the United States determined that Brazil had engaged in acts, policies, and practices with respect to the denial of patent protection for pharmaceuticals, that are unreasonable and restrict U.S. commerce. On October 24, 1988, the *U.S. Federal Register* listed the products imported from Brazil for which the United States would raise tariffs to 100 per cent, i.e., making them prohibitively expensive. I have estimated that during 1986 the value of the imports of the products against which the United States was retaliating amounted to around U.S.\$50 million.²³ This case portrays the worst scenario; retaliation worsened the exports of Brazil and increased protection for U.S. industries. Also, at the political level, bilateral tensions increased.

In summary, although retaliation is a politically and economically dangerous and costly policy, so far it has had the effect of moving countries closer to the U.S. position. Also, there is always a degree of retaliation which can result in social costs that are higher than those incurred by the introduction of patent protection. When this occurs, the economic logic suggests that faced with the choice between two unfavorable conditions, developing countries should choose the least costly which in some cases could imply the introduction of patent protection. But putting developing countries under such a dilemma, might not necessarily be a socioeconomically sound policy.

10. *Impact on world innovation and welfare*

Mansfield has suggested that weak patent protection in developing countries could be a depressing factor for total investments in R&D [16, p.26]. The evidence suggests that this is very likely the case but only in industries where patent protection is important. I have speculated above that at least part of the higher profits that big multinational pharmaceutical firms would make in developing countries, would be used to finance higher investment in R&D. In this case, Mansfield's suggestion that strong patent protection in developing countries could result in higher world technological dynamism appears plausible. Note that even if the industry's profits were to remain unchanged after the introduction of patent protection, it is likely that worldwide investment in R&D would increase as profits would shift from local firms with low propensity to invest in R&D, to multinational companies with high propensity to invest in R&D.

Our simulation in Section II suggested that the higher income accruing to multinational companies from patent protection in a sample of developing countries could, under certain circumstances, reach U.S.\$14.4 billion (Table VII). Assuming that these companies would invest 16 per cent of their increase in income to R&D (the ratio invested by U.S. pharmaceutical companies) and that on an average it costs U.S.\$150 million to market a new drug, the additional investment in R&D could be expected to generate fifteen new drugs per year. But only part of this

²³ This figure was practically the same as that of the annual losses to U.S. pharmaceutical firms reported by the PMA. See MacLaughlin et al. [15].

will be invested in the United States, which is the only country for which I have a cost estimate for the production of a new drug. From the figures cited by MacLaughlin et al. it can be estimated that 45 per cent of the additional income would accrue to U.S. companies.²⁴ Thus, it can be estimated that the new drugs to be developed by firms in this country could number eight per year; this represents around 37 per cent of the average annual number of drugs introduced by the United States in recent years.²⁵

Measured in this way, the contribution of patent protection in developing countries to worldwide innovations is potentially very important. However, the extent to which developing countries would benefit from the innovations they help to finance, depends on a number of factors. First, in industrial countries most of the research activities in pharmaceutical drugs deal with diseases that are prevalent in the industrial countries, including heart diseases, high blood pressure, Alzheimer's, arthritis, diabetes, Parkinson, etc. (PMA's ad in *Washington Post*, November 17, 1989). Obviously, these are diseases for which pharmaceutical companies can expect to make the biggest profits. However, the incidence of diseases in developing countries is not always correlated with the incidence in industrial countries. If so, R&D undertaken by multinational companies would not necessarily provide important benefits to developing countries.

Second, one cannot forecast as bright a future for pharmaceutical drug innovation as it had been in the past. There is evidence that the productivity of R&D in pharmaceutical drugs has decreased (Grabowski and Vernon [7]); that on an average, the contribution of new drugs to medical therapies has declined (*Economist*, August 1989, p. 61) and that a reduction of discovery opportunities might be taking place (Grabowski and Vernon [7]). All these are fundamental determinants of the social productivity of R&D in pharmaceutical drugs and therefore of patents. We are not in a position to pass a judgment on these issues but if these findings accurately reflect the current situation, it could very well be the case that the introduction of patent protection in pharmaceutical drugs could entail a loss not only to developing countries' welfare but also to that of the world; in this latter case, the reason would be overinvestment in R&D.

FINAL REMARKS

In the Uruguay Round, industrial countries have proposed that developing countries extend patent protection to pharmaceutical drugs. The figures show that billions of dollars surround such a policy decision. Would this policy increase world welfare? Would it increase the welfare in developing countries? The discussion offered in this paper suggests that these questions have not been researched and that important policy decisions are being taken with at most weak and anecdotal

²⁴ This is the proportion of U.S. companies in the total losses accruing to patent owners in the sample of countries studied by MacLaughlin et al. [15].

²⁵ Between 1980 and 1989 the new drugs introduced in the U.S. market numbered 12, 27, 28, 14, 22, 30, 20, 21, 20, and 23. Note also that in the United States private firms are marketing the great majority of all the new drugs each year.

basis. Although the first question is of great importance—for example, in theory it is conceivable that there is a structure of patent protection that maximizes world welfare but we have no clues as to whether the existing situation is close to the optimum—most of this paper addresses the second. Therefore, we recommend that more research should be done before the world moves to a stadium of quite higher patent protection. This appears to be particularly important in light of the fact that it is the interplay of different interest groups and not welfare considerations, that are apparently driving the design, implementation, and enforcement of patent policies.

Much of the discussion in the economic literature and in political circles, looks at patent issue from the point of view of the enterprises. Such a literature comes to the quite obvious conclusion that domestic pharmaceutical companies that are copying patented drugs will most likely lose from the introduction of patents. This conclusion stems from the fact that in developing countries, these enterprises do not have the size and financial strength that would allow them to engage in successful research for the development of new drugs. But in an integrated world, the important question is not what will happen to domestic enterprises, but whether the consumer will be better or worse off and this is the issue that has been addressed in this paper.

In arriving at the conclusion that we do not know whether higher patent protection will benefit consumers in developing countries, we have uncovered some areas where additional research would be helpful in providing more solid foundations to very important policy decisions. The first and most important is whether in developing countries, the market of copied pharmaceutical drugs are competitive or monopolistic. If the pre-patent market situation is monopolistic, and if such a situation is expected to remain unchanged, then the introduction and/or increase in patent protection will not entail important losses; there would simply be a redistribution of monopoly rents. The literature surveyed in this paper only provides spotty and indirect evidence on this topic.

Moreover, under some circumstances, we can predict that there could be important net additional consumer gains. The most important of these gains would be forthcoming from the additional new drugs that the profits under higher patent protection enjoyed by the multinational inventive companies would help to develop most likely, in laboratories located in industrial countries. The figures offered in this paper suggest that the impact of introducing patent protection in developing countries on the discovery of new drugs might be very important and therefore, this potential gain is not trivial. Other undocumented gains could be forthcoming from shorter time lags in the introduction of new drugs and more generally, in a higher availability and faster transfer of drug technology to developing countries.

On the other hand, if the pre-patent situation is characterized by a high degree of competition, then the introduction of patent protection will most likely entail an important increase in drug prices and in the short run consumers will suffer a loss in welfare. Such losses could eventually be reversed as the new drugs that profits in developing countries will help develop are marketed. Whether these gains outweigh the short-run welfare loss will depend very much on the extent

of monopoly pricing and whether the new drugs help to cure and/or prevent diseases that are prevalent in developing countries. Economic incentives suggest that pharmaceutical companies allocate their research funds primarily to the discovery of drugs that have the highest payoff and these are to cure diseases that are prevalent in industrial countries. Therefore, the gains from additional drug discoveries financed by patent protection in developing countries might be important only for those countries whose pattern and incidence of disease is similar to those of industrial countries; most likely these are the most advanced of the developing countries.

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