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Analysis of Correlation between Patent Protection and Price of a Pharmaceutical Product

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ABSTRACT

Patent protection is a form of protection that gives the owner of the patent a right for making, using or selling a concept or an innovation and excludes others from doing the same thing for the duration of the patent. The present project deals with the correlation between the patent protection and its pricing. This study will deal with the pricing of the pharmaceutical products with respect to the patent protection. According to the TRIPS agreement, the World Trade Organisation member should be bound to implement these patents for pharmaceuticals. Several low-income countries contend that pharmaceutical patenting might result in a large increase in medicines rates, with detrimental health and welfare effects for their population. In contrast, world pharmaceutical firms based on research say that costs are unlikely to increase substantially because most of the patented medicines have therapeutic supplants. The pharmaceutical demand structure is very different in impoverished nations when nearly every medical cost is covered by such uncommon health insurance. The dynamic prices here will be emphasized upon.

Keywords: *Patent Protection, TRIPS, Pharmaceuticals.*

I. INTRODUCTION

The creator of a novel invention or concept might exclusively have the right to produce, market, use and/or acquire the item worldwide through patent protection. No other firm or person can produce, sell, use or acquire the same or identical goods. If another firm or individual violates the patent protection, legislation allows the proprietor to sue for a violation.[3] The aim of patent ownership is to let creators to be the sole producer and supplier of their innovation. A person can make maximum potential value with patent protection by leasing the concept to others or by just putting it his own creation. One of the finest ways of increasing the profitability of a commodity is by protecting patents, because it restricts others from creating an identical or extremely comparable product.[4]

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[3] BL Wadehra, Law Relating to Intellectual Property 34-40(Hemant Kumar Pandey, Lexis Nexis, 2018)
[4] VK Ahuja, Law Relating to Intellectual Property Rights 539-545(Third Edition, Lexis Nexis, 2019)

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Likewise, whenever we assess commodity prices, we analyse the pharmaceutical industry. In discussions over policies on intellectual propriety, the pharmaceutical industry has unique importance and has played a leading role in the domestic and global controversy about the links between intellectual property rights, its research and development(R&D), price and availability to medication. The creation of pharmaceutical goods involves huge research and clinical testing costs. Such expenditures are often fairly high per unit compared to the actual low cost of manufacture of the goods. Unless taxpayers bear such expenses via research grants, they must be borne by individuals patients both directly or via medical intermediaries (that can sometimes be in itself taxpayer-holded). The patent mechanism is usually employed to allow the first generation (and the corresponding intermediary) of patients, which endure this expense of innovation, a much greater price in comparison to the marginal price. Usually the cost lowers when the substance is discontinued, so that prospective customers are exposed to the minimal costs of producing and selling it.

As a prerequisite of joining the World Trade Organization (WTO), the states must recognise and implement regulatory approval in all sectors of science, including medicines, under the TRIPs agreement – concluded during the 1995 Uruguay Round of multilateral trade negotiations–. When the TRIPS Agreement came into force, many low-and middle-income nations excluded medicinal products, even though product patents were recognised in other sectors, since cheap access to life-saving medications and critical prescriptions has been considered a priority of public policy.[5] However, such nations had to establish or modify their laws on pharmaceutical product patents in order to fulfil their responsibilities under TRIPS, with transitional and less developed economies till 2005.

TRIPS talks and especially the pharma clauses were extremely controversial. Although it has been more than ten years since TRIPS was completed, substantial disagreement and controversy over its benefits persists. The major argument is that administrations in many impoverished developing nations say that insufficient pharmaceuticals patent protection leads to much higher pricing for medications, with negative effects on their populations' health and welfare.[6] Against this assertion, worldwide research-based pharma-firms that possibly lost huge sums of money as a result of breach of patents by reverse engineered Third-World corporations argue that it is improbable to substantially increase prices by introducing

[5] Journal: Shubham Chaudhuri & Pinelopi K. Goldberg, Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India, Volume 7, Indian Council for Research on International Economic Relations, 2009
[6] *Ibid.*

product patents as most patented products have many replacements for treatment..[7] They also allege that the dearth of patent protection has discouraged development on ailments that strike the world's poor excessively. In other words, patent protection for pharmaceutical products will definitely help underdeveloped nations by boosting innovation and technology sharing

II. ENCOURAGING TIERED PRICING: KEEPING DEVELOPING NATION PRICES LOW AND PREVENTING REVERSE FLOWS

Since there already is a very imperfect system, it has evolved to a layered and tiered pricing system. There are two main problems to improve the system to ensure that the cost in the developing country is modest and subsequently to prevent the reverse flows which might undermine difference in price.

A) Low prices strategy for the developing nations

The newly stated low price/earnings ratios leave question that prices in developing countries are maintained low solely by avoiding reverse flows. A collection of obstacles, such as taxes and regulations, are established by the developing nations individually. It is obvious that they must be removed to enable level pricing. The price practises of pharmaceutical companies are yet another category of obstacles. Likewise, these regulations may evolve towards greater voluntary pricing strategy and level price difference as proposed (and as verified below in the context of solutions to level pricing). This could, particularly, be the consequence of the worldwide issue around the importation into South Africa of HIV-drugs in the late 1990s, when a legislation allowed importation (India was expected to deliver this). In April 2001, a South African Lawsuit settled this case. The matter was settled with the resolution taking place amongst powerful political forces, shows the broad willingness of business to accept price levels even outside the poorest countries. But it may be essential to drive the sector in atleast certain situations (it can be particularly correct in states where highly skewed income distributions are maintained).[8]Multiple alternatives exists for these things. Goods (for public markets at least), as currently, for vaccinations, may be bought by price groups that are smart.

This vulnerability may be avoided in various ways. One is to deal with the problem company-by-company – often enough and since diverse goods of firms may not be directly competing.

[7] J.J. Nogues (1993), Social costs and benefits of introducing patent protection for pharmaceutical drugs in developing countries, The Developing Economies, 24-53, 1993.
[8] JOHN BARTON, Differentiated Pricing Of Patented Products, 63 Indian Council For Research On International Economic Relations, 8-11 (2001)

The other is to ensure that the major talks take place under individual national governments or international organisations, for instance, in the public sector. This latter technique is almost definitely required if there is any group which really suggests pricing. The legitimate interests of industry under competition law must be recognised.

B) The Reverse flows

The backwards influx, that is, selling products from lower cost economies into premium priced markets, is one of the key issues involved in conserving or bolstering a stable price system – these flows are the big issues for industry wishing to protect it from price deterioration in its highest price markets. In the face of such arbitrary procedure, arbitration may likewise increase item price to customers in the low-price countries, even if the sector continues to provide accessible items. Therefore, avoiding reverse flows is a major challenge in the development of a worldwide price system. The current fluxes have few empirical data. Much more is accessible for cross-border sales inside the European Union, where a robust intellectual property/trade policy is implemented, which also allows the marketing of items placed on the market in any Member State. A new analysis reveals a significant increase in the number of UK import licences. Despite legally acceptable trade possibilities here, nonetheless, pricing discrepancies exist, nevertheless, irrespective of actual figures, this will be a more significant issue as a worldwide issue in the future. This goes back to the fundamental rights of the patent proprietor[9].

Arbitration is a natural response to pricing disparities and cross-border pharmaceutical trade is almost guaranteed to be made easier by the Internet and the size of foreign travel. (Internet sales have already become a local public health issue).

C) Complications in some developed states

The main obstacle here is maybe not what international law allows, and what's humanly achievable in defining the legislation of the industrialised country Here you may tell the basic US case. In late 2000, the United States had enacted a bill to allow some pharmaceutical items from overseas to be imported into the US. The bill was driven by lawmakers from certain areas whose residents complained about the cheaper pricing of prescription products in Canada. This was in accordance with a long pattern of US customer opposition to higher US costs, which made US companies less inclined to tier pricing even in the vaccine industry.[10] The US pharmaceutical bill from 2000 was highly protested and poorly written,

[9] VK Ahuja, Law Relating to Intellectual Property Rights 539-545(Third Edition, Lexis Nexis, 2019)
[10] JOHN BARTON, Differentiated Pricing Of Patented Products, 63 Indian Council For Research On

engaging only with the problems of approval of products and without specifically addressing questions of intellectual property. This list contained, mostly for OECD countries but also for South Africa, some products from a formal list of countries with highly advanced pharmaceutical clearance skills. In late December 2000, the "Health and Human Services Secretary Shalala" halted its functioning. And it goes well beyond America - many advanced nations have "reference pricing" schemes that guarantee that their customers (or national health bodies) pay nothing beyond that to the other countries. In any multinational tier price plan this connectivity and the core political problems must be addressed.

III. MECHANISMS BESIDE TIER-PRICING

The usage of price levels is not the only method that can enable patients in underdeveloped countries to access vital medications. Accessories and unique arrangements are some possibilities. It is great and, under certain situations, can be immensely beneficial. In relation to its willingness towards (and structure for facilitating) the availability of products on a long-term basis at marginalised price, it raises a crucial topic of sustainability. The greater sustainable is the strategy coordinated by UNAIDS, which provides contract rates for four large pharmaceutical businesses.[11] In a particular scenario, these solutions are simply tier pricing obligations. They profit from the fact that the items will surely be fairly valued, which are obligations for a price decrease of up to ninety percent.[12] In addition, special measures may be included in this type of agreement to guarantee that medicinal products are supplemented by medical capacity and to offer forms of bookkeeping that reduce re-export risks. If such agreements become the realistic tiered price mechanism, it is necessary to negotiate the deals in a way that is clear and avoids issues under competition law. The public sector actors therefore have a key duty here.

IV. RECOMMENDATIONS

Even though a large number of intermediaries are available, a fair example is a new medication price structure. These stipulations could involve:

a) necessitate the use of property rights or other equivalent import barriers by huge revenue generating markets to prohibit the reverse flow of tiered pharma prices.

b) Require poor countries to provide alternative healthcare and adequate help to avert reverse flow.

International Economic Relations, 8-11 (2001)

[11] IAIN M. COCKBURN, Intellectual Property Rights and pharmaceuticals: Challenges and opportunities For Economic Research, 2011

[12] *Ibid.*

c) Creation of a worldwide fund, secretariat, ruling mechanism to subsidise prices in the poorest countries in some ratio, negotiation of agreements similar as those that UNAIDS negotiates at present.

d) and/or help to assess the real amount to be used in pricing in the poorest countries in the world of marginal costs.

V. CONCLUSION

The pharmaceutical business has exceptionally extensive expertise and the economy of this sector is well understood to be especially sensitive to intellectual property rights. There have been some advances in recording and comprehending the interconnections involving intellectual property rights, complementing regulatory and policy measures and worldwide industry expansion and their effects on medication price and access, research and development, business and production. There are nonetheless many chances for generating and evaluating further data, especially in developing nations and regions with transition economic systems, in this complicated and essential industry. The above recommendations should be implemented in order to facilitate growth worldwide.

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