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Remedies Against Excessive Pricing of Patented Medicines Under Competition Law

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1 Introduction

EXCESSIVE pricing of medicines is a concern all around the world. With 12.7% of the world population spending more than 10% of their household income on healthcare (WHO 2019), it is one of the major concerns for many countries. The COVID-19 pandemic has once again highlighted the severity of the issue. There have been complaints about steep price increases during the pandemic. But unlike the novel coronavirus, this is not a new problem.

Huge investments needed for research and development (R&D) are often cited as the reason for the exorbitant prices. The risky nature of the investment is also highlighted in the debates: not all investment into R&D results in new drugs. Price control through regulation is often regarded as a way out. But those against such controls argue that subjecting an originator drug enjoying patent protection to price control flies in the face of the very philosophy behind the intellectual property (IP) regime.

Attempts have been made to use competition law remedies to rein in the soaring prices. Almost all countries have a competition law in place today. However, it must be seen whether a law aimed at protecting the competitive process in the market was ever intended to shield consumers through direct price intervention. Whether such an action will adversely affect the incentives to invest and innovate and thereby run afoul of IP laws is another matter to be considered. Further, have there been instances of competition law enforcement against excessive prices? This paper tries to answer these questions and argues that competition law intervention is a good option to deal with excessive pricing of patented medicines.

Competition law treats the process of competition as an end in itself and provides the framework for competitive activity. It has been contended that protecting the process of competition is necessary to eliminate the effects of monopoly. Higher prices, fewer choices, inferior product quality and lack of innovation are some of the hallmarks of monopoly (Wish 2005: 4-6). Competition in turn is expected to improve allocative, productive and dynamic efficiency, resulting in overall consumer welfare. However, a brief survey of the United States antitrust laws and European Union competition law demonstrates that it is not only economic factors that led to the emergence of competition law. Consternation about big corporations undermining the authority of the state and emasculating democratic institutions also played a role, and controlling these corporations was one of the objectives. There may be differing viewpoints about such an assertion, but at the minimum it can be agreed that maximizing consumer welfare is the ultimate objective of competition law, and lower prices are a sure indicator of the same.

2 The Pharmaceutical Market

THE pharmaceutical market is unique in many respects. First, it is a highly regulated market. A maze of regulations governs the sector from the R&D stage onwards. In the lifecycle of a medicine, three different phases may be identified. Phase I is the R&D stage. This includes clinical trials to test the efficacy and safety of the medicine. Phase II is when the product is launched in the market. Because of the patent exclusivity protection, the drug does not face competition at this stage. This is the stage where the producer tries to recoup the investment made and the prices are generally very high. Given the patent protection period, other IP exclusivities and the time taken for getting regulatory approval, this phase may extend beyond 15 years (Abbott 2016: 286). Phase III begins after the expiration of IP protection. At this stage, depending on many factors including the size of the market, competition may set in. If substitutes emerge in the market, competition can bring down the price (OECD 2018a). In most countries, essential medicines are subject to price regulation at this stage. The competition concerns and considerations vary in each stage and the intervention decisions are hugely influenced by the phase of the lifecycle the drug is in.

The presence of patents and other exclusivity rights brings in interface issues with competition law. Price regulation of essential medicines in many countries is also to be considered. From the supply side, competition in the pharmaceutical market may be broken down into three segments, viz., therapeutic, intra-brand and inter-brand (OECD 2018b). Therapeutic competition involves the development of new, patent-protected and innovative drugs. It is research-intensive and seen as entailing risky investment. Companies enjoy dominance due to IP. Intra-brand competition arises due to parallel importing. Inter-brand competition generally occurs in Phase III where

the drug is out of patent and exclusivity protection and the originator drug faces competition from generic ones.

The pharmaceutical sector is also unique from the demand side. A consumer in general parlance is a person who purchases goods and services for personal use. In that sense, it is the same person who makes the choice of the product to buy, pays for it and uses it. However, when it comes to pharmaceuticals, these three actions are not performed by a single individual. It is the doctor who prescribes the medicine depending upon the therapeutic value, it is the patient who consumes, and in many cases, it is not the patient who pays. In most of the developed world, the patient is covered by either medical insurance or a public healthcare system. Thus, the burden of payment is shifted to either the insurance company or the public health budget. In most of the developing world, there exists a two-tiered healthcare system operating in the public and private sectors. Those who can afford can access the private sector that offers high-quality healthcare. In that case, it is either the patient or the insurance company that pays for the medicine. But a vast majority of the people depend on the public healthcare system, where procurement of medicines is done by governmental agencies (OECD 2018c). In many cases, due to paucity of public funds, the medicine has to be bought from the open market and the patient might end up paying for it. This separation of the roles of user, decision maker and payer is unique to this sector. As the patient does not have much say in the decision, the demand side of the market is largely inelastic. This is particularly true in the case of life-saving medicines. In addition, access to "safe, effective, quality and affordable essential medicines" is a target to be achieved under the Sustainable Development Goals (Target 3.8; UN 2015).

The human rights dimension is another important factor to be considered here. The right to health is a fundamental human right crucial for the exercise of other rights. Article 25.1 of the Universal Declaration of Human Rights and Article 12.1 of the International Covenant on Economic, Social and Cultural Rights acknowledge the right to health and enjoin states to recognize "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health". Availability of essential drugs is an important element of this right. Each state party has an obligation to make available these drugs at affordable rates, i.e., economic accessibility (UN 2000). The

recent referral by the Competition Commission of South Africa in a case against Roche is an example of how the human right to health can be invoked in the interpretation of competition law. The Commission found that Roche's charging of an excessive price for the breast cancer treatment drug trastuzumab infringed several constitutional rights, including the right of access to healthcare services under Section 27 of the South African Constitution (Compcom 2022).

Competition law issues arise at all stages in the pharmaceutical market starting from the R&D stage to the retail sales stage, and cover all types of anticompetitive practices. Horizontal anticompetitive agreements include cartels involving price fixing, market sharing and bid rigging, boycott of certain drugs by pharmacist associations, and "pay for delay" agreements. In "pay for delay" agreements, an originator company on the verge of expiry of one of its drug patents enters into an agreement with a generic company to delay the entry of the generic drug in return for a cash payment. Prohibiting promotion and sale of products of competing manufacturers is a commonly practised vertical agreement. Refusal to license and supply, excessive pricing, misuse of regulatory processes, disparagement etc. are instances of abuse of dominant position. The potential for price hikes and abandonment of the development of new medicines are some of the concerns raised in relation to mergers in the pharmaceutical market. Of all these anticompetitive practices, this paper deals only with excessive pricing of patented medicines.

3 Excessive Pricing Under Competition Law

EXCESSIVE pricing is considered an abuse of dominant position under competition law. The anticompetitive practices adopted by a dominant firm can broadly be divided into two categories, viz., 1) practices adopted with an aim to exploit its position of dominance (exploitative), and 2) practices adopted to protect the position of dominance by making it difficult for potential competitors to enter the market (exclusionary).

Excessive pricing, a form of exploitative conduct, is one of the most controversial topics in competition law enforcement. A wide divergence can be observed between the European and the American approaches to this matter. The US system operates on the philosophy that "denying a lawful monopolist the fruits of its monopoly can diminish its incentive to compete in the first place" (OECD 2018d). Articulating this approach, the US Supreme Court in *Trinko* (2004) held charging of monopoly prices to be an important element of the free-market system. The Court justified this position by asserting that it was the possibility of charging monopoly prices that attracted business acumen in the first place, which in turn induced risk-taking resulting in innovation and economic growth. However, this does not mean that excessive pricing is not a concern for American antitrust law. The US Department of Justice and the Federal Trade Commission, two agencies tasked with the responsibility to enforce antitrust laws, focus on forms of antitrust conduct that result in high prices. These include price fixing and market allocation, reverse payment patent settlements, and abuse of processes like sham litigation etc. (OECD 2018d). In addition, in a merger scrutiny, resultant high price is a relevant consideration to block a merger (Jenny 2018: 7).

In the European Union on the other hand, Article 102(a) of the Treaty on the Functioning of the European Union (TFEU) treats "directly or indirectly imposing unfair purchase or selling prices" as an abuse of dominant position. In *United Brands v. Commission* (1978), the European Court of Justice came out with a two-part test to determine whether the price charged was unfair: i) "whether the difference between the costs actually incurred and the price actually charged is excessive"; and ii) "if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products". Competition authorities in Europe have scrutinized high prices in many sectors, including the pharmaceutical sector, to find out whether those were "unfair prices".

The competition law framework in most developing countries outlaws excessive prices as an abuse of dominant position. Article 17 of the Chinese Antimonopoly Law 2007 prohibits "selling commodities at unfairly high prices or buying commodities at unfairly low prices". Similarly, Section 8 of the South African Competition Act, 1998 prohibits a dominant firm from charging an excessive price to the detriment of consumers. The Indian Competition Act, 2002, in Section 4, prohibits imposing either directly or indirectly unfair or discriminatory prices including predatory prices. Section 10 of the Malaysian Competition Act, 2010 prohibits "directly or indirectly imposing unfair purchasing or selling price" as an abuse of dominant position.

4 A Case for Competition Law Intervention in Excessive Pharmaceutical Pricing

THE pharmaceutical sector is not immune to the trans-Atlantic divide on the approach to exploitative abuses. While the US remains an outlier in intervention, most other jurisdictions are increasingly interfering in cases of excessive pharmaceutical prices. National competition authorities in many European countries have started taking note of this exploitative abuse. The Competition and Markets Authority (CMA) of the UK recently found Pfizer and Flynn Pharma to be violating abuse-of-dominant-position provisions of the Competition Act, 1998 that mirrored Article 102 of the TFEU. The case concerned phenytoin sodium capsules, an off-patent drug used in epilepsy treatment. In 2012 Flynn Pharma acquired the distribution rights to the drug in the UK from Pfizer. Upon acquisition of the rights, the drug was "de-branded", thereby taking it out of the voluntary price regulation mechanism maintained by the National Health Service. This was followed by an overnight price increase of 2,300%-2,600%. The CMA found the price increase to be excessive and imposed fines on both the companies for abuse of dominant position (CMA 2017). Though the method of determination of excessive pricing was turned down by the Appellate Tribunal and Court of Appeal (2020), the decision is an important step in sending the correct signal to the industry that excessive pricing can invite competition intervention. Similar interventions have been made by the Italian Competition Authority (AGCM) in the *Aspen* case (OECD 2018e), and the Danish Competition and Consumer Authority (DCCA) in the *CD Pharma* case (OECD 2018f).

The Dutch Competition Authority (ACM) in August 2021 imposed a hefty fine of 19,569,500 euros on Leadiant for excessive pricing of its prescription drug CDCA-Leadiant that helps in the treatment of the rare metabolic disease CTX. In 2008 when it was introduced in the market, the drug cost 46 euros for a package of 100 capsules. In 2017, the cost of the drug had reached the

astronomical sum of 14,000 euros. ACM found that the price was exorbitantly high and unfair and imposed the fine (ACM 2021). This decision is of particular importance for the current discussion as CDCA-Leadiant was granted market exclusivity for 10 years in 2014 as it was designated as an orphan drug.

Some common points emerge from a close reading of the enforcement actions in Europe. First, there has been no intervention in cases involving patent-protected drugs. The CDCA-Leadiant case did not involve a drug under patent protection though the drug had market exclusivity rights for 10 years. Most of the cases relate to drugs that have been off-patent for a long time. This approach comes at a heavy cost to consumer welfare. Second, the interventions were warranted by sudden exorbitant increases in prices of drugs that have been in the market. Thus, enforcement actions were warranted by a "bolt from the blue" increase in prices that shocked the general public. Third, barriers to entry were very high owing to the special nature of the market for these drugs. These were essential drugs with no possible entry of competitors due to either regulatory hurdles or the small size of the market (OECD 2019a).

In the US, the general hands-off approach towards exploitative abuses is applied to the pharmaceutical market too. This approach is based on the belief that 1) it is better to leave excessive prices to the self-correcting nature of the market, 2) it is difficult to determine what is an excessive and what is a reasonable price, and 3) it will be interventionist to interfere in the pricing decisions of firms (First 2019). However, there have been demands for a rethink of this policy. It is pointed out that antitrust intervention is justified and needed as the ultimate objective of Sherman Act/antitrust laws is "to protect the public from the harm that can result from the oppressive exercise of monopoly power" (Abbott 2016).

In most developing countries, the competition laws contain provisions for dealing with exploitative practices indulged in by dominant firms. Unfair/excessive prices are proscribed by law. The South African Competition Commission's actions in *Hazel Tau and others against GlaxoSmithKline and Boehringer Ingelheim* (CCSA 2003) and the ongoing case against Roche Holdings and Genentech Inc (UNCTAD 2019) are examples of action against pharmaceutical companies charging high prices. These interventions are discussed in the next section.

5 Excessive Prices, Patented Medicines and Competition Law

THE pharmaceutical sector is heavily dependent on innovation and makes huge investments in R&D. IP, especially patents and trademarks, plays a significant role in the market. This raises a host of issues from a competition law point of view. Exploitation of patents raises high price concerns directly and indirectly. When the patent holder decides not to grant a licence to other companies and exploits its patent by manufacturing the drug itself and selling it for abnormal profits, this directly results in high prices. On the other hand, if a licence is granted at an exorbitant royalty, that indirectly results in excessive prices. For a better appreciation of the issue, it is important to understand the interface dynamics between competition law and IP.

The interface issues have been discussed for a long period of time. Both sets of laws have different objectives and have evolved separately (Anderman 2007: 1). Indeed, both are often viewed as antithetical to each other (Ghosh 2009). IP involves a grant of monopoly power by the state to the holder. If such an exclusionary power is circumscribed by competition law on the ground that it restricts competition in the market, the IP would not have any meaning. Conversely, if IP is regarded "simply as convenient pegs on which restrictive agreements could be loosely hung", competition laws would lose much of their sheen, as IP, especially patents, is granted in every industry (Neale and Goyder 1980: 289).

Tensions arise because of the different policy objectives of these laws. One confers monopoly on the arguable premise that it promotes innovation, whereas the other proscribes monopoly because it inhibits economic development. The apparently opposing objectives of these laws have given rise to many conflicts in their interface. However, there are views that IP laws and competition laws try to achieve the same objective through different

means. As one of the objectives of competition law is to ensure dynamic efficiency by promoting innovation, it perfectly coincides with the objective of IP, which is also justified on the basis that it ensures innovation (Gallego 2010). In that way, both these branches of law are seen as complementary, as one comes to correct the abuses of the other. In this narrative, competition law steps in when the IP holder abuses monopoly power.

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) addresses the interface issues between IP and competition law both directly and indirectly. Articles 8, 31(k) and 40 of the Agreement contain important provisions relating to competition. Of these, Article 40, which comes under the section titled "Control of Anticompetitive Practices in Contractual Licences", directly addresses the IP-competition conflict. It allows WTO Member states to specify in their legislation licensing practices or conditions that may constitute an abuse of intellectual property having an adverse effect on competition in the relevant market. Further, it allows a Member to adopt appropriate measures to prevent or control such practices, which may include, for example, exclusive grant back conditions, conditions preventing challenges to validity and coercive package licensing. This provision is applicable to all types of IP and is not restricted to patents. However, it is applicable only to licensing practices and not to other types of unilateral actions like charging excessive prices and royalties, non-working of patents etc. Though this provision may thus not be directly applicable in an excessive price case, in the context of general public health it is highly relevant.

Even though there is nothing in national competition laws that prevents competition authorities from acting against excessive prices of patented drugs, there is general reluctance to intervene. This is justified on the ground of incentivizing innovation and allowing returns on "risky investment" by charging monopoly prices. The OECD Roundtable on Excessive Prices in Pharmaceutical Markets (2018) summarizes this policy tilt towards investment and innovation: "Monopoly prices are a reward for risky investment. Special caution is warranted in sanctioning excessive pricing with respect to products covered by IP rights because the misapplication of competition law might undercut incentives to innovation. As such, there is broad agreement that [there] should be no intervention against excessive prices for innovative products within a pharmaceutical product's patent life

and, in effect, no such case has ever been brought within the OECD to this moment" (OECD 2019a).

But this does not mean that there is consensus on non-intervention. Views expressed by the Netherlands in the same Roundtable reflect that. Pointing out that there is no hierarchy between IP and competition law, it argued that IP rights are granted irrespective of the level of innovation. Thus, innovation concerns are more limited in the case of IP protecting a variation on a drug which has been in the market for a long time. The tricky question is how to make the distinction between instances where high prices are a legitimate reward for risky innovation and those where they are not (OECD 2019b).

The recent decision by the Dutch Competition Authority in the *Leadiant* case (ACM 2021) mentioned above may be of particular value here. The price increase from 46 euros in 2008 to 14,000 euros in 2017 for an orphan drug with market exclusivity for 10 years raised all these concerns. The observation that "it is not market exclusivity that is under discussion, but rather the way in which that was used", is significant in the context of excessive prices of patented medicines. This decision is groundbreaking in yet another respect. ACM examined the claim of innovation and the cost incurred in obtaining orphan-drug status. In reaching the decision that the price charged was excessive, ACM took 15% as a reasonable return for investors, and considered only the cost incurred with regard to the particular drug in question. This may be due to the fact that the drug was not originally developed by Leadiant and was acquired by the company after it had been launched in the market. Even then, it is significant as many a time excessive prices are justified on the claim that pharmaceutical companies have to factor in the cost involved in R&D that did not result in product commercialization. Further, R&D costs are also shrouded in secrecy and often exaggerated by including other, indirect costs. Another significant aspect of this decision is that ACM examined the innovation introduced by the drug and held that "Leadiant did not introduce any innovation, and CDCA-Leadiant does not have any therapeutic added value compared with the previous CDCA-based drugs". The *Leadiant* decision can be a pathbreaker in bringing patented medicines under antitrust scrutiny for excessive pricing.

Even in the US the debate about the applicability of antitrust laws to excessive pricing of patented drugs is not over. Abbott (2016), pointing to certain

decisions, argues that antitrust intervention is possible in this type of case. In *FTC v. Actavis* (2013), the US Supreme Court held that a "reverse payment" agreement settling patent infringement claims can have anticompetitive effects and its validity can be challenged based on antitrust laws. But the Court refused to shift the burden onto the defendant to prove the pro-competitive effects of the settlement. However, the California Supreme Court went a step further in interpreting the state antitrust law and held that the burden is on the patent holder to prove that the settlement was not anticompetitive. Abbott (2016) argues that this essentially means that "if plaintiff prima facie establishes that a price is excessive, the burden may shift to the originator patent owner to justify the price as reasonable."

The South African Competition Commission's actions in *Hazel Tau and others against GlaxoSmithKline and Boehringer Ingelheim* (CCSA 2003) and the ongoing case against Roche Holdings and Genentech Inc (UNCTAD 2019) can provide guidance for developing countries in using competition law to tackle high prices for patent-protected originator drugs. In *Hazel Tau and others against GlaxoSmithKline and Boehringer Ingelheim,* the Commission investigated excessive price complaints against GSK and BI for their patented antiretroviral (ARV) medicines used in HIV/AIDS treatment. The Commission expanded the investigation and included the refusal to license on reasonable commercial terms. The Commission found that there was an abuse of dominant position by charging an excessive price for the patented drug. But before the Appellate Tribunal ruled over the finding, a settlement was reached between the Commission and the manufacturers, with the latter agreeing to grant licences to generic manufacturers and not to charge royalty in excess of 5% of the net sales.

The recent finding by the Commission that Roche has abused its dominant position by charging an excessive price for trastuzumab, a patented cancer drug, is an important development (Compcom 2022). Trastuzumab is used in the treatment of HER2+ breast cancer and is under patent protection in South Africa. On receiving complaints about the exorbitant price charged, the Commission started its investigation in 2017. As Roche declined to provide cost data, the Commission considered three benchmarks to determine the cost of production, viz., manufacturing cost estimates of trastuzumab biosimilar, prices of biosimilar drug supplied in South Africa, and value-based price benchmarks. The price charged was found to be excessive even

after allowing a reasonable compensation for R&D and innovation. The Commission estimated that over 10,000 HER2+ patients could not afford treatment due to the excessive price charged by Roche. The finding of the Commission has been referred to the Competition Tribunal for final adjudication. If the Tribunal agrees with the Commission, this would be the first instance where a patent holder is held liable for charging an excessive price for a drug.

In light of these developments, a competition law remedy is justified in cases of excessive pricing of patented medicines on the following grounds:

1. Legislative basis and intent: The competition laws of most jurisdictions, including developing countries, outlaw excessive prices as an abuse of dominant position. There is nothing in the law that prohibits a competition law intervention in such cases. Further, the ultimate objective of competition law, even from a very restrictive Chicago School perspective, is consumer welfare as reflected in lower prices. Laws conferring IP do not emasculate competition laws. Competition law intervention is permitted even under the WTO law. The TRIPS Agreement permits competition law actions for abuse of exclusivity granted by IP. Further, the Doha Declaration on the TRIPS Agreement and Public Health (2001) recognizes concerns about the effect of the TRIPS Agreement on prices. The following paragraph in the Declaration can remove any doubt about the applicability of competition law to excessive pharmaceutical prices: "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." It may be recalled here that "access to medicines" includes economic access, i.e., affordability.

2. Licensing on FRAND terms as an example: The difficulty in determining excessive price and the fear that competition authorities might turn into price regulators are two major policy arguments against competition law intervention. Licensing of standard essential patents (SEPs) under fair, reasonable and non-discriminatory (FRAND) terms may offer valuable guidance here. Violation of a commitment to FRAND terms is considered as an abuse of dominant position. Demands for excessive royalty end up in

antitrust investigation and litigation. In these cases, the competition authorities and courts are asked to determine whether the royalty is excessive or not. The Competition Commission of India's (*Micromax v. Ericsson* 2013) and subsequently Delhi High Court's (*Ericsson v. CCI* 2016) decisions in the disputes involving Micromax and Ericsson show that authorities and courts do not hesitate to determine what is a fair and reasonable royalty. This determination can provide guidance in determining what is excessive pricing. The *Leadiant* decision by the Dutch Competition Authority (ACM 2021) and the finding by the South African Competition Commission in the Roche case (Compcom 2022) are valuable precedents as they determined what was excessive price in the context of an orphan drug protected by market exclusivity and a drug under patent protection, respectively.

3. Effective remedy: Though there are different legal tools available to address the issue of excessive prices of patented drugs, competition enforcement is the most effective remedy. Regulation is *ex ante* and, in that sense, forward-looking, whereas competition law action against abuse of dominant position is *ex post* and, as such, can remedy past instances. This helps the affected party to claim compensation. In addition, there may be regulatory gaps that can be addressed under competition law. Chances of regulatory capture are minimal in the case of competition authorities as they are not tied to a particular sector.

4. Public health dimension: Another important consideration is the fact that access to affordable medicines is an aspect of the right to health. Quality healthcare, including access to affordable medicines, is recognized as a fundamental human right in many countries. For example, in the Indian context, providing access to essential medicines at affordable prices is held to be a core obligation under the right to life (*Mohd Ahmed v. Union of India* 2014). Today, there is an increased focus on human rights implications of competition enforcement actions. Though the developments on that front mainly relate to procedural fairness, actions against excessive prices in the pharmaceutical sector will further contribute to the human rights compliance of competition law. The recent finding in the Roche case deals with substantive human rights dimensions in the interpretation of competition law (Compcom 2022).

6 Remedies Under Competition Law

COMPETITION laws provide a range of remedies for abuse of dominant position. These include division of an enterprise, fines, cease-and-desist orders etc. Reviewing earlier US Supreme Court decisions, the Court of Appeals (DC Circuit) in *US v. Microsoft Corporation* (*Microsoft III* 2001) outlined the objectives of an antitrust remedy: "To unfetter a market from anticompetitive conduct, to terminate the illegal monopoly, deny to the defendant the fruits of its statutory violation, and ensure that there remain no practices likely to result in monopolization in the future." Thus, an antitrust remedy should stop the offending conduct, prevent its recurrence and restore competition (Shapiro 2009).

Depending on the nature, remedies are broadly divided into two categories: structural and behavioural. Structural remedies directly affect the structure of the market in question. Division of an enterprise is an example of this type of remedy. Behavioural remedies, on the other hand, try to address the anticompetitive conduct by requiring certain behaviour from the firm in question. A cease-and-desist order is an example of this. While structural remedies are easy to enforce and monitor, behavioural remedies require close monitoring and may require enormous resources to ensure compliance. A third type of remedy, which has elements of both behavioural and structural remedies, is classified as "access remedies". These grant access to third parties to resources and services that enable them to compete. Licensing of essential patents is an example of this. For excessive pricing of patented medicines, the following remedies may be issued.

Compulsory licensing can be an effective remedy when a patent holder does not license the drug and exploits its patent by charging high prices.

Compulsory licensing is an accepted competition law remedy in all major jurisdictions. In merger reviews this remedy is used extensively, including in the US. Even in abuse-of-dominance cases, compulsory licensing is resorted to by national competition authorities. The South African Competition Commission's attempt in *Hazel Tau* (2003) to issue a compulsory licence for a patented medicine may be of relevance here. In that case the Commission found pharmaceutical firms GlaxoSmithKline South Africa (Pty) Ltd and Boehringer Ingelheim, which held some patents on certain ARV medications used to treat HIV/AIDS, had abused their dominant positions in their respective markets, including by charging excessive prices. The Commission moved the Competition Tribunal to grant compulsory licences for these medicines. However, the companies reached a settlement with the competition authority, agreeing to license before a final decision was taken (CCSA 2003).

Cease-and-desist orders are the most commonly used remedy in competition law. In this remedy, the firm engaged in abuse of dominant position is ordered to desist from the practice. As a behavioural remedy, it requires supervision by the competition authorities. In case of violation of a cease-and-desist order, deterrent fines are prescribed.

Imposition of hefty fines is another competition law remedy for excessive prices. The objective behind this remedy is twofold: one, to deter further occurrence; and two, to make sure that the violating firm did not make any profit out of the exploitative practice. In addition, compensation can also be awarded to the victims of excessive pricing.

7 Conclusion

COMPETITION law intervention in excessive price cases continues to be controversial. There are concerns that such intervention would distort the market as price determination is a function of the market. The objection is severe when it comes to patented products. The impact that such intervention can have on innovation and investment is highlighted. This has resulted in reluctance to apply competition law in excessive price cases in general, and for patented medicines in particular. But, it is forgotten that the granting of IP itself distorts the market and that the price found by the market is artificial. This paper has tried to argue that competition law intervention is an appropriate remedy to rectify excessive drug prices. The wide range of remedies available at the disposal of the competition authority is one of the main reasons for advocating such intervention.

Competition law intervention in cases of excessive patented drug prices has resulted in huge public health benefits and thereby enhanced consumer welfare, the main objective of competition law. The South African experience of intervention in *Hazel Tau* (CCSA 2003) can provide important lessons. Upon a finding of excessive ARV prices in this case, a settlement was reached between the pharmaceutical company and the competition authority. The terms of the settlement included licences to generic manufacturers, licence to export to sub-Saharan African countries, import in places where no manufacturing facility existed, and not to require royalty in excess of 5% of net sales. An impact assessment of the settlement agreement showed significant positive impact on HIV/AIDS treatment in South Africa and other sub-Saharan African countries. There was a sharp drop in the price of medicines amounting to 11% per annum, resulting in an estimated cost saving of $887 million. Access to ARV medicines became easier, pushing the number

of patients receiving treatment from 47,500 in 2004 to 3,407,336 in 2016. The settlement resulted in generic competition, with 14 more drugs entering the market (OECD 2018c).

This experience should help especially the developing countries in using competition provisions to address excessive prices of patented medicines. As there is no bar either in national or in international law that restricts its use, competition law intervention will help countries to meet their public health challenges in a much better way.

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REMEDIES AGAINST EXCESSIVE PRICING OF PATENTED MEDICINES UNDER COMPETITION LAW

Exorbitant medicine prices, especially for medicines subjected to patent protection, are increasingly coming under the spotlight. This paper considers whether and how this serious concern can be addressed within the framework of competition law.

Differing perspectives exist over the appropriateness of intervention by competition authorities in cases of excessive pricing, particularly when these involve patented products. However, there are no legal barriers to such intervention; competition authorities can act – and have acted – against firms deemed to have charged unfairly high prices for medicines, including those under patent.

In fact, this paper contends, competition enforcement against excessive pricing of patented medicines would not only advance consumer welfare but also contribute to safeguarding the fundamental human right to health. The remedies available under competition law – such as compulsory licensing – can be effectively applied to keep a lid on the prices of essential, potentially life-saving medicines.

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