Access to essential medicines and vaccines remains an uphill battle for approximately eighty percent of the two billion people living in low- and middle-income countries today. At the same time, efforts to shoulder the burden are routinely falling short in light of an ever-increasing disease burden and rising drug prices. Tiered pricing - a strategy that offers drugs and vaccines at more affordable prices to those that have less/ no ability to pay - has been proposed as a potential solution to this problem by a number of studies. It has been argued that, by charging different prices in different markets, pharmaceutical firms can promote access while also allocating returns on research and development (R&D) investments.

Any firm can price discriminate so long as different prices can be offered (and sustained) across consumers in ways that do not correspond to marginal costs. Pharmaceutical firms can - and do - regularly price discriminate by offering the same/ similar drugs at different prices in different markets. It is now widely known that a few pre-conditions need to materialize for a firm to engage in price discrimination. Firstly, that the selling firm should have a degree of market power to segment its markets. The idea being that in the absence of such market power, there would be a competitive market, and prices would get further undercut by other suppliers, leaving no incentives for the selling firm to

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1 The author is a Fellow, and Senior Advisor of the Global Access in Action Project, at the Berkman Klein Center for Internet and Society. The author is grateful to the support and advice of Prof. William Fisher, Prof. Ruth Okediji, Prof. Mark Wu and Mr. Quentin Palfrey, Harvard University. Comments by John Stubbs, Affiliate, Berkman Klein Center for Internet and Society, administrative coordination by Ms. Ashveena Gajelee, Fellow, Berkman Klein Center for Internet and Society, and research assistance by Ms. Sula Ndousse-Fetter is gratefully acknowledged. The research for this paper was funded by a gift of the National Federal Trade Commission Foundation of the USA.

2 Shinge Chisoro-Dube, Big Pharma Leveraging Their Dominance on Consumers, CCRED QUARTERLY COMPETITION REVIEW (Dec 20, 2017), https://www.competition.org.za/review/category/Shingie+Chisoro+Dube. According to the WHO, 80% of deaths due to chronic disease occurred in low- and middle-income countries, but the availability of medicines for communicable and non-communicable diseases are below 50% of what is required on average. See WORLD HEALTH ORGANISATION, NONCOMMUNICABLE DISEASES: FACT SHEETS (2018), https://www.who.int/newsroom/factsheets/detail/non-communicable-diseases. In the case of vaccines, in 2017, 19.9 million infants did not receive routine immunization services, 60% of which are in just ten low and middle-income countries. See WORLD HEALTH ORGANISATION, IMMUNIZATION COVERAGE (2018), https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases.

3 The Lancet Commission on Essential Medicines for Universal Health Coverage highlights high pricing of medicines as one of the major barriers to equitable access for all income groups, due to the dynamics of patenting and pricing in the pharmaceutical market. Affordability challenges are exacerbated for all diseases including cancer and diabetes, which are typically more expensive, and continue to persist for communicable disease (particularly chronic infections such as HIV/AIDS and Tuberculosis) despite a historical emphasis on funding in this area. See LANCET COMMISSION, TOWARD ACCESS 2030 (2016), http://www.thelancet.com/commissions/essential-medicines. See also Veronica J. Wirtz et al., Essential Medicines for Universal Health Coverage, 389 THE LANCET 415, 417 (2016); Ameet Sarpatwari et al., An Incomplete Prescription: President Trump’s Plan to Address High Drug Prices, 319 JAMA 2373, 2373 (2018) ("In March, a Senate committee reported that list prices for the 20 most-prescribed brandname drugs for patients older than 65 years had increased 71% since 2012.")

engage in such a strategy. Secondly, the selling firm should be able to discriminate amongst consumers based on price sensitivities. Finally, the selling firm should be able to control resale opportunities from the low-priced markets to the higher priced markets.

When these pre-conditions are met, economic theory suggests that price discrimination could simultaneously benefit the producer firm and consumers in different markets by providing incentives for the firm to charge lower prices in highly price-sensitive markets (with low ability to pay) and higher prices in the less price-sensitive markets (with higher ability to pay). Theory posits that the firm could continue its sales in each of these segmented markets to the point where the cost of production and distribution of additional units do not exceed the revenues from the sale in that market. In other words, it would charge higher prices in the higher ‘ability to pay’ markets, which along with the overall increase in penetration of sales in all markets, would subsidize the lower prices in the lower ‘ability to pay’ markets, resulting in a ‘win-win’ for all.

But this simple economic proposition rarely materializes in practice. Instead, as many studies show, price discrimination has become a trojan horse for firms with sufficient degrees of market power to offer different prices in different markets to extract maximum profits by targeting those who can afford it most, and not those who need it most. The large gaps between what can ideally be achieved and what is usually achieved through price discrimination has been the subject matter of international debates on pharmaceutical pricing and access for at least two decades now. With the coming in force of the Agreement on Trade Related Aspects of Intellectual Property Rights (hereafter the TRIPS Agreement), products protected by patents, market exclusivity, or both, have dramatically increased the power of patent holder firms in essential therapeutic categories, reigniting the ire over affordable pricing. The public health crises sparked off by HIV/AIDS in the 1990s in a large number of low and middle income countries prompted companies in the global pharmaceutical sector have sought to employ an inter-country tiered pricing strategy that differentiates specifically for consumers in low income countries as a means to promote access. But how low the prices are in comparison to those offered elsewhere, and whether they are low enough to systematically promote access to medicines remains an open question.

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5 In economics, price is said to be sensitive to demand if price variations can lead to large peaks and falls in demand. This precondition implies that the firms target different groups of consumers differentially bearing in mind their abilities to pay.


7 Proposed Shake-Up to Drug Pricing Framework Risks Middle-Income Countries Paying More, MEDICINS SANS FRONTIERES (2013), https://www.msf.org/global-fund-proposed-shake-drug-pricing-framework-risks-middle-income-countries-paying-more (“Tiered pricing,” the practice of selling drugs to different countries at different prices depending on their socio-economic status, allows pharmaceutical companies to maximize profit in all countries, as prices are determined according to the highest a country is prepared to pay. With their emerging middle classes now firmly on the pharmaceutical industry’s radar, middle-income countries are often left paying excessively high prices. Even poorer countries can lose out, as tiered pricing does not reflect the true lowest price of potential drugs, and acts against generic competition, which tends to deliver a lower sustainable price over the long term.”). See also Suerie Moon et al., A Win-Win Solution? A Critical Analysis of Tiered Pricing to Improve Access to Medicines in Developing Countries. 7 GLOBALIZATION AND HEALTH 39 (2011) [hereinafter MOON ET AL, A Win-Win].

8 Nabila Ansari, International Patent Rights in a Post-Doha World, 11 Currents: INTERNATIONAL TRADE LAW JOURNAL 57, 61 (2002). (“The tremendous public pressure generated by global activists led to the slashing of AIDS drugs prices by pharmaceutical companies, and an executive order from President Clinton that supported the use of compulsory licensing for sub-Saharan Africa”).

9 A number of pharmaceutical companies have a category 1 price (offering certain products on lower prices for consumers in low-income countries using the World Bank classification or least developed countries using the UN classification) for several drugs that have a public health relevance. The World Bank classifications of low income, middle income and high income, are assigned by gross national income (GNI). For the 2019 fiscal year, low-income countries (LICs) are defined as having a GNI of $995 or less; whereas low-middle income (LMIC) countries are defined as those with a GNI between $996 and $3,895; with upper middle-income (UMIC) countries have a GNI ranging between $3896 and $12,055; and high-income countries (HIC) possess a GNI above $12,055. See WORLD BANK, WORLD BANK COUNTRY AND LENDING GROUPS (2019),
Broadly speaking, current pricing practices employed by companies for inter-country tiered pricing give discounts for volume depending on variations in disease burdens among countries on a rough, ability- to-pay basis. But many other considerations, such as product leakage, public scrutiny, the presence of competitors, and the extent of intellectual property protection, also play a role in decision making introducing arbitrariness and in-transparency in pharmaceutical pricing. As a result, although some measures such as the Access to Medicines Index 2018,10 show how global pharmaceutical companies are expanding their portfolios to engage more and more in African countries, there remain serious concerns on pricing and its impact on access and competition.

Access to medicines scholars have argued that such voluntary inter-country tiered pricing gives too much control to large firms to decide which products are offered at lower prices in which markets. It has been argued that encouraging such pricing approaches on a wider scale – especially without a wider guiding legal framework that extracts accountability – is the reason for rising pharmaceutical prices not just in low- and middle-income countries, but elsewhere as well.11 Industry proponents counter these arguments with the argument that price discrimination is essential to allow firms to retain incentives to invest in the highly uncertain and risky pharmaceutical research and development (R&D) process.12 Defending the ongoing efforts for R&D and tiered pricing, they point to several market failures, including the inability of firms to segregate consumers appropriately, and the difficulties they face in controlling arbitrage (i.e., the leakage of products from low priced markets to higher priced markets undercutting firm sales), as critical problems.13

Each of these narratives offers a different perspective on how to tweak the incentives of firms to engage in socially welfare enhancing pricing. While the access to medicines scholars have called for a more controlled, regulated environment, others have argued for a ‘laissez faire’ market driven approach with governmental intervention mainly to let the market function. The differences in normative underpinnings notwithstanding, these narratives are shaping in distinct and overlapping ways the debate on pricing of pharmaceuticals, including its most recent reframing as ‘fair pricing’ that calls on the global pharmaceutical sector to engage in more transparent pricing practices.14

Given the recurring and extreme relevance of this topic, I begin this article by providing a theoretical and empirical perspective on inter-country tiered pricing with market developments in HIV/AIDS, Hepatitis C and Cancer categories as my main points of reference. Section II reviews the welfare effects of inter-country tiered pricing and shows that it is based on third-degree price discrimination; a mechanism that remains the most disputed form of differentiating prices in economic theory. It

https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending- groups. The UN least developed country classification is a listing of the United Nations that brackets those countries with the lowest indicators of socio-economic development, and the lowest Human Development Index ratings. In some cases, companies handpick several specific African countries to offer lower prices. As a result, there is a large range of options that companies use in practice to segregate markets.

10 The Access to Medicines Index is created by the Access to Medicines Foundation, an international NGO, and ranks 20 of the world’s largest research-based pharmaceutical companies on how they are improving access to medicine in low- and middle-income countries.

11 See, e.g., Peter Loftus, Drug Firms Ring in Higher Prices, WALL ST. J., Jan. 11, 2016, at B1; Andrew Pollack, Cancer Specialists Attack High Drug Costs, N.Y. TIMES, Apr. 26, 2013, at B1

12 Frank R. Lichtenberg, Pharmaceutical Companies’ Variation of Drug Prices Within and Among Countries Can Improve Long-Term Social Well-Being, 30 HEALTH AFFAIRS 1539, 1540 (2011).

13 Reich & Bery, supra note 4, at 340. (“For this pricing system to be sustainable, however, shipments between national markets would need to be prevented, so that products offered at lower prices in poor countries would not be resold in rich countries. This system can require a high level of cooperation among governments and patent holders, to assure that appropriate regulations and safeguards are effectively implemented.”).

14 In 2017, the World Health Organisation organised the first Fair Pricing Forum in Amsterdam, The Netherlands, to enable stakeholders to discuss options for a fairer pricing system for pharmaceuticals. A subsequent forum was organised in 2019 in Johannesburg, and the World Health Organization adopted a landmark resolution titled “Improving the transparency of markets for medicines, vaccines and other health-related technologies” (See Agenda item 11.7, WHA 72.8, 28 May 2019). The resolution aims to promote more transparent sharing of publicly available information on the patent landscape of medical technologies and the costs of manufacturing medicines, vaccines, and health technologies to encourage pricing in the interest of consumers.

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highlights the reasons – both market-related, and institution-related – that account for the difficulties in aligning incentives between firms and governments to promote access to medicines by way of this approach. The section then presents fresh empirical evidence on tiered pricing in three chosen therapeutic categories to highlight how inter-country tiered pricing approaches perpetuate socially unequal outcomes, both for competition and access, and narrows down the factors that broadly account for this. This result, also supported by some other recent studies, suggests that often the option of tiered pricing performs much worse than that of compulsory licensing or generic competition to increase access to medicines on a global scale.\footnote{See Moon et al, \textit{A Win-Win}, \textit{supra} note 7, at 9. ("First, tiered pricing does not necessarily result in the lowest sustainable prices, nor does it reliably lead to price reductions over time. In comparison, when markets are sufficiently large and multiple sources of production exist, robust competition has consistently proven across different therapeutic areas to result in lower prices.").} While highlighting the fallacies of such tiered pricing practices, I argue that the reasons for failure of inter-country tiered pricing lies in the fact that it relies on third degree price discrimination, which sets the wrong incentives for firms from the outset itself.

Can these incentives potentially be altered by designing legal and institutional frameworks that promote new ways to engage in tiered pricing in an accountable manner? I address this question at length in Section III and argue that one way to eliminate several undesirable market outcomes would be to offer different price categories within a given country, as opposed to tier-price between countries, \textit{within an accountable regulatory framework} that oversees these pricing practices. Such an intra-country tiered pricing approach can deliver on the goals of access to medicines better. In this section, I also discuss ways to demarcate channels to differentiate within countries given that people of differing economic categories often seek treatment and obtain medicines differently owing to a variety of factors such as the cost of treatment, insurance coverage (private, public, hybrid or the lack thereof), transportation costs, time spent, and location of the household, among others.\footnote{Previous work by Berkman Klein Centre’s Global Access in Action Program has argued that such intra-country tiered pricing can offer a way to expand access and promote innovation for medicines. See Quentin A. Palfrey, \textit{Expanding Access to Medicines and Promoting Innovation: A Practical Approach}, 24 \textit{GEORGETOWN JOURNAL ON POVERTY LAW AND POLICY} 161 (2017). See also Ellen t’Hoen et al, \textit{Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016}, \textit{96 BULLETIN OF THE WHO} 185 (2018).} In Section IV, I discuss some ideas on how to implement intra-country tiered pricing strategies, aligning firm level incentives with greater access and dynamic competition in a systematic manner.

To clearly distinguish between price discrimination and tiered pricing, the paper uses the term 'tiered pricing' to denote the \textit{explicit shift in pricing strategy to create a balance between firm level profits and social benefits}. Thus, in a scenario of tiered pricing, firms would charge different prices based on the economic reality and access constraints faced by consumers with lower income, and \textit{not just for increased profits or convenience}.

\section*{2. A Historical, Empirical Perspective on Inter-country Tiered Pricing}

As opposed to a focus on fairness in debates on price discrimination from a legal perspective, economics analyses price discrimination solely based on its welfare effects.\footnote{See \textit{CORWIN D. EDWARDS, THE PRICE DISCRIMINATION LAW} 2-4 (1959). Edwards distinguishes between the "political" and an "economic" understanding of price discrimination, arguing how the principle of equal treatment remains the key political idea upon which the Robinson-Patman Act is based in the United States. For a detailed discussion of the different theoretical and normative underpinnings. \textit{See Daniel J. Gifford & Robert T. Kudrle, The Law and Economics of Price Discrimination in Modern Economies: Time for Reconciliation?} \textit{43 U.C. DAVIS L. REV.} 1235 (2010) (for a discussion on the differences between the legal and economic treatment of price discrimination).} Clearly distinguishing between the two, this section seeks to set out the current state of economic knowledge on price discrimination, with an intent to set out the theoretical basis for inter-country tiered pricing, listing out the market failures that vitiate the creation of incentives for welfare enhancing outcomes. Whether these incentives can be aligned, and what makes it harder in reality is then discussed. To test whether such market failures
might indeed materialize in practice, the section then sets out to present empirical evidence from three therapeutic categories in Section 2.3.

2.1. Inter-Country Tiered Pricing: Understanding the Welfare Effects

Economic theory, in general, warns against espousing the merits of price discrimination without considering the detailed setting in which it occurs. Three kinds of price discrimination (first, second and third degree) can exist depending on the kind of market power that firms possess, the nature of consumer markets, and the mechanisms available for segmentation. First-degree discrimination refers to situations where firms can identify and perfectly discriminate consumers on a one-on-one basis. In this instance, firms can clearly demarcate and control the sale of goods according to the specific income category of its consumers. In second-degree price or non-linear price discrimination, the same price is charged to all consumers, but differences arise based on units purchased. Examples include where firms offer different kinds of holiday packages. Theory dictates that in these two forms of discrimination, either the same amount of surplus is created as in a perfectly competitive market or at least a higher surplus than in a simple monopoly, since the firm can set the prices exactly according to the preferences of its consumers. In these two forms of discrimination, the total output of the selling firm (measured for instance, in terms of volumes of sales) increases on the whole but the surplus is skewed toward the firm and away from the consumers.

Inter-country tiered pricing strategies in the pharmaceutical sector, however, are based on third degree price discrimination. In this kind of price discrimination, different consumers are charged different prices, and prices do not vary according to the number of units bought. Whether a firm with monopoly power should be allowed to exploit its dominant market status by engaging in third-degree price discrimination is a controversial topic in economics, with debates spanning at least a century now. However, some important conclusions can be drawn. Firstly, given that the firms cannot be clearly ‘verified’ to be demarcating according to consumers’ paying thresholds in third degree price discrimination, the consensus point in theory is that when a monopolist firm moves from uniform pricing (one price for the global market) to charging different prices in exogenously identifiable markets, economic welfare (measured as the sum of consumer surplus and profits) is increased only when the total output of the selling firm increases. But if the total output of the selling firm remains the same or less than it was under uniform pricing, such price discrimination can be detrimental to social welfare. For example, if a market that was not earlier served will be served then we will have a welfare improvement. But if the new market is served without any significant increases in the firm’s

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19 Varian, supra note 18, at 600
20 Michael Schwartz, Third-Degree Price Discrimination and Output: Generalizing a Welfare Result, 80 AMERICAN ECON. REVIEW 5, 1259 (1990); Richard Schmalensee, Economies of Scale and Barriers to Entry, 89 JOURNAL OF POLITICAL ECONOMY 6, 1228 (1991) [hereinafter Schmalensee, Economies of Scale].
21 This issue of whether price discrimination in the third degree can increase or decrease social welfare has been a subject matter of interest at least since 1920 when Pigou offered an extensive critique of the topic. See PIGOU, supra note 18, at 199-200. Thereafter, economists such as Joan Robinson, Hal Varian and Richard Schmalensee debated the welfare effects of price discrimination in complex contexts. See JOAN ROBINSON, THE ECONOMICS OF IMPERFECT COMPETITION 188-95 (1933) (on how output is misallocated under third degree price discrimination when compared to a single monopoly price); Richard Schmalensee, Output and Welfare Implications of Monopolistic Third-Degree Price Discrimination, 71 AMERICAN ECONOMIC REVIEW 242 (1981) (extending Robinson’s approach mathematically)[hereinafter Schmalensee, Output and Welfare]; Hal R. Varian, Price Discrimination and Social Welfare, 75 AMERICAN ECONOMIC REVIEW 870 (1985) (discussing third degree price discrimination by multiple firms in multiple markets).
22 Michael Schwartz, Third-Degree Price Discrimination and Output: Generalizing a Welfare Result, 80 AMERICAN ECON. REVIEW 5, 1259 (1990); Schmalensee, Economies of Scale, supra note 20; Schmalensee, Output and Welfare, supra note 21.
23 See Schmalensee, Economies of Scale, supra note 20. On price discrimination in general see Varian, supra note 21. For more formal discussion that raises subtleties not pertinent to the present task, see, for example, Hal Varian, Price Discrimination, in HANDBOOK OF INDUSTRIAL ORGANISATION (Richard Schmalensee & Richard Willig eds.,1989).
total output, then the impact on welfare will be negative.\textsuperscript{25} In this case, the monopolist firm will price discriminate to simply skim off the rich consumers across all markets. Secondly, social welfare always increases when the firm shifts toward a lower price in third degree price discrimination since it will increase access to consumers.\textsuperscript{26}

So, in sum, although the increased output on the side of the parent firm is a necessary condition for third degree price discrimination to be welfare enhancing, it is not a sufficient one. This is especially the case in markets in the real world that defy conditions for perfect competition, and rarely classify as simple monopolies.\textsuperscript{27} In such complex markets, firms compete in monopolistic or oligopolistic environments, and several market imperfections can co-exist making it harder for third degree price discrimination to yield socially beneficial results.\textsuperscript{28} Intellectual property rights (especially patents, but also trade secrets, trademarks, among others) that confer monopolistic rights are one such market imperfection.\textsuperscript{29} Having strong intellectual property rights in a tiered pricing situation, where some firms already wield significant market power, can unduly promote the dominance of a few firms in many therapeutic categories thereby lowering competition and leading to price increases.\textsuperscript{30} Intellectual property rights, where they achieve these effects, can simply change a situation of monopolistic competition (where several firms compete with not a single one having a substantial power over price) to one where only one or two prevail as the key suppliers, with substantial power over price and markets.\textsuperscript{31} This distinction between monopolistic competition and market power is subtle and extremely relevant to economic analyses of welfare effects of price discrimination. Although monopolistic competition offers some level of market power, the extent of market power and when that becomes absolute monopoly power is determined by how many other players exist in that product space.\textsuperscript{32} In such cases, then, there can be no increase in social welfare unless the parent firm with the

\textsuperscript{25} Varian, supra note 23, at 622. ("On the other hand, if linearity of demand is not a bad first approximation, and output does not change too drastically in response to price discrimination, we might well expect that the net impact on welfare is negative.").

\textsuperscript{26} Id. at 625.

\textsuperscript{27} See Lars Stole, Price Discrimination and Competition, in HANDBOOK OF INDUSTRIAL ORGANISATION VOL 3 (Mark Armstrong and Robert Porter eds. 2007). ("It is straightforward to construct models of price discrimination in competitive markets without entry barriers in which firms lack long-run market power (and earn zero long-run economic profits), providing that there is some source of short-run market power that allows prices to remain above marginal cost, such as a fixed cost of production.")

\textsuperscript{28} Varian, supra note 23, at 641, noting that the effects we see in simple monopolies also extend to monopolistic competition but at the same time, when there are multiple firms, many new effects can also arise.

\textsuperscript{29} See generally Simon P. Anderson & Régis Renault, Price Discrimination (2008), https://economics.virginia.edu/sites/economics.virginia.edu/files/anderson/pricedisc080808_0.pdf, (on how discriminatory pricing is tightly tied to the exercise of market power).

\textsuperscript{30} As early as 2002, Adam Jaffe and Josh Lerner presented a scathing critique of how the US patent system had lost its balance between rewarding the innovator and promoting social benefits. See ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT (2002). On competition effects of patents, see Frederick M. Abbott, Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health, 6 UC IRVINE LAW REVIEW 282, 283 (2016). ("Pharmaceutical products reflecting extraordinary price escalation are principally newly developed originator small-molecule and biological pharmaceutical (biologic) products. These products are typically protected by patent, regulatory market exclusivity, or both." See also Sara Eve Crager, Improving Global Access to New Vaccines: Intellectual Property, Technology Transfer, and Regulatory Pathways, 104 AMERICAN JOURNAL OF PUBLIC HEALTH 11, 85 (2014) (discussing the relevance of market entry for lower prices in the vaccines market); Aaron S. Kesselheim et al, The High Cost of Prescription Drugs in the United States, 316 JAMA 8, 858 (2016) (discussing how market exclusivity, in addition to patent rights, enables firms to set high prices within the United States).

\textsuperscript{31} EDWARD H. CHAMBERLIN, THE THEORY OF MONOPOLISTIC COMPETITION (1933). In Chamberlin’s definition of monopolistic competition, a number of firms are offering similar products, thus although they are in monopolistic competition not a single one of them is able to dictate price.

\textsuperscript{32} Abba Lerner was one of the earliest economists making this distinction clearly in imperfectly competitive markets. The Lerner index inversely relates to demand elasticity (see definition of elasticity, supra note 5). As a result, the index will be low as competition increases in a monopolistic market and demand becomes elastic. See Abba P. Lerner, The Concept of Monopoly and the Measurement of Monopoly 1 REV. ECON. STUD. 157, 169 (1934). Discussing the confusion between the terms’ monopoly power market power, Gifford and Kudrle note that:

"Even though Lerner employed the term monopoly power to refer to all situations in which price exceeds marginal cost, others have used that term differently. A leading industrial organization textbook, for
stronger monopoly position has a significant increase in total production of the firm, which is reflected in diverse and stronger penetration of different markets, and clearer shifts toward lower prices.

2.2. Can Incentives be Better Aligned in Existing Inter-Country Tiered Pricing Strategies?

Can these market failures in inter-country tiered pricing be corrected? Existing evidence on inter-country pricing approaches help demonstrate some of the shortcomings and how there might be no space for middle ground. Firms, on their part, recount three impediments for firms to engage actively and more widely in the mechanism: (a) the inability to control arbitrage (i.e. restrict the flow of products between the lower priced groups back to the high-income groups when they offer lower prices in low-income markets), 33 (b) the generalized concern that a reduction of prices in some markets may lead to a contagion effect where the parent firm is forced to provide reduced prices in others too (due to external reference pricing), 34 and (c) the presence of national supply side constraints/ leakages and inefficiencies. 35

Let us hypothetically review what it would take to fix this. To prevent arbitrage in a free market setting, firms would need assurances of no leakage of products from one market to another. This would enable them to control arbitrage, and effectively segregate markets, ensuring that the costs of control and oversight of tiered pricing are not much higher than the profits that a firm can potentially count on by expanding its customer base. If this is the goal, and essentially, if one were to focus on tiered pricing from the lens of creating sufficient incentives for firms to engage in it more wholeheartedly, the central question would revolve around the practice of parallel importation, i.e., the practice of importing drugs that are available much cheaper elsewhere to increase access to medicines within national boundaries.

Whether parallel imports are deemed legal or not depends upon how the question of exhaustion of rights is dealt with in national jurisdictions, where in principle, there are three ways govern exhaustion of rights: national, regional and international. 36 Exhaustion simply refers to whether the intellectual property holder’s rights include the control over the distribution of the good protected under intellectual property, thereby lending itself to two kinds of regimes: national or international. In a regime of national exhaustion, the exclusive rights of the intellectual property rights holder are “exhausted” upon first sale within that country only, as a result, the firm can control/exclude parallel imports from other countries into the local market. In such a regime, the rights of the intellectual property holder is entitled to restrict the importation of goods and services into those territories extends

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33 See Lichtenburg, supra note 15, at 1542. (“Price discrimination increases the manufacturer’s benefits by allowing it to charge higher prices where demand is less elastic. Hence, price discrimination makes it less likely that high fixed costs would prevent manufacturers from pursuing socially desirable investment opportunities, and thus increases social welfare.”) In general, companies are not inclined to offer significantly lower prices with too much third-party arbitrage (where exporter and importer companies can benefit from simply leveraging the observed price differentials in important pharmaceutical categories). Although options such as alternate labelling and packaging are often used by companies when they supply to different markets, it creates a large oversight problem for firms.

34 Countries use external reference pricing—the practice of comparing international prices of the same pharmaceutical product—in order to determine pricing parameters for negotiation with pharmaceutical companies. For a thorough discussion on external reference pricing, see Patricia M. Danzon, Regulation of Price and Reimbursement for Pharmaceuticals, in THE OXFORD HANDBOOK OF THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY (Patricia M. Danzon & Sean Nicolson eds., 2012).

35 In many countries, there are specific characteristics of the health systems that do not guard against leakages of the lower priced drugs into private sales (where they are sold for an additional profit), or the presence of wholesale and retail chain margins add up costs along the distribution chain thereby negating the access effects of the original lower price offered by the manufacturer.

to cases where the goods have been placed outside the territory without the consent of the intellectual property holder. A regime of international exhaustion, on the contrary, exhausts the exclusive rights of intellectual property right owners to control distribution end upon the first sale of the good takes place anywhere in the world. The firm, as a result, does not have the ability to control arbitrage that emerges from price differentials in different markets. By extension, in the case of regional exhaustion, a region can be defined within which the right of the intellectual property holder to exclude are exhausted upon first sale.

Article 6 of the TRIPs Agreement excludes the question of exhaustion of intellectual property rights from the purview of the Agreement. Regulating remains a question of national jurisdiction and countries have varied approaches to this question. Several national regimes have chosen international exhaustion of rights, and therefore embrace parallel importation as a means to curb the capacity of firms to engage in profit-enhancing arbitrage at the expense of consumers. For instance, both the United States of America and the European Union apply the first sale principle within their territories as an effective way of controlling market power and abuse of consumers that can arise from privately contracted exclusive territories. A number of studies recount the positive impacts that these measures have on creating better prices for consumers in these markets given that they induce the threat of cheaper products and thereby eliminate unfair margins. Juxtaposing the ambiguous welfare effects of inter-country tiered pricing against the positive effects of parallel importation, the access literature has frequently also proposed parallel importation as a tool to promote competition and reduce prices more widely, especially in low income countries.

More recently, the argument for promoting parallel importation as a means to keep prices under check has been all the more forcefully reiterated by two emergent, inter-related trends. The first trend - of rising prices for pharmaceuticals in diverse therapeutic categories across all countries - has led to a change in stance even in several industrial countries. For example, estimates show that the average price of cancer drugs has grown exponentially from $5000 to $10,000 in or before 2000 to an average of over $145,000 in 2015 exhibiting an average price increase of 12% per year. Sovaldi, the drug for the treatment of Hepatitis C (hereafter Hep. C) alone accounted for for 64% of all US public Hep. C related spending in 2014, totalling $12.3 billion. Similar trends have been observed in other disease categories,  

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38 Id. at 5.

39 Article 6 of the TRIPS Agreement states: "For purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4, nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights."

40 For an excellent overview of the functions of parallel importation for increasing access to medicines, and the ways in which it interacts with pricing of firms, see KEITH E MASKUS, PARALLEL IMPORTS IN PHARMACEUTICALS: IMPLICATIONS FOR COMPETITION AND PRICES IN DEVELOPING COUNTRIES (World Intellectual Property Organization, 2001). https://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/ssa_maskus_pi.pdf [hereinafter Maskus, Parallel Imports]. Some scholars have since long argued that because of these price effects of parallel imports (or the threat thereof), it should be considered an important aspect of pharmaceutical policy frameworks in all low and middle-income countries. See Carlos M. Correa, Public Health and Intellectual Property Rights, 2 GLOBAL SOCIAL POLICY 216, 271 (2002); see also ABBOTT, supra note 38.

41 Hagop Kantarjian & Yogin Patel, High Cancer Drug Prices 4 Years Later - Progress and Prospects, 123 CANCER 1292. The authors also note that the price of aging cancer drugs continues to rise by an average of 8-12% each year, instead of remaining close to the launch price (at 1295); See Jennifer L. Graber, Excessive Pricing of Off-patent Pharmaceuticals: Hatch it or Ratchet? 92 NYU LAW REVIEW 1146, 1150 (2017) (“...[p]rices of drugs that treat common diseases are also rising. For example, the price of Doxycycline, an antibiotic that treats many conditions, was ratcheted almost 10,000% between late 2013 and 2015.”)

placing a strain on the health budgets even in countries that allocate a significant part of their GDP to health care for the treatment of Cancer, Hepatitis C and other critical conditions.  

Some of the pendulum swings in pricing remain unexplained by reasons of R&D costs or other market expenditure lending to scrutiny on pricing practices as a phenomenon. In the United States, for example, the pricing of drugs like pyri-methamine (Daraprim), a 60-year old drug went up from USD 13.50 to USD 750 overnight thanks to a change in the ownership of the distribution license. Other examples of radical price changes include Sanofi’s colon cancer drug Zaltrap where, for instance, prices dropped from 11,000 to 5,000 USD when criticized by oncologists in 2012. In other instances, price differentials in inter-country tiered pricing do not seem to make sense. For example, the initial cost of Solvadvi in the United States was $84,000 when the lowest prices were offered in Egypt (which is a middle income country) where the drug was sold at $2000 per treatment. The difficulties of explaining away such price differentials with conventional economic rationale or any market-speak reinforce a point made by Judge Posner who famously disagreed with price discrimination in the US market noting pertinently: ”[T]he purchaser to whom the discriminating seller sells at a lower price may be no more efficient than the competing purchaser who is charged a higher price.

The expansion and increased reliance on intellectual property across many drug categories, especially in the originator small-molecule and biological (pharmaceutical) products categories is a second trend reinforcing the need to keep other check and control mechanisms open, including parallel importation. As well-summarised by several IP scholars, in recent years, there has been a general decline in the number of new drugs produced by pharmaceutical R&D, when compared to years past.

Despite this, patenting has been on the rise, with expanding instances of evergreening, i.e., the practice of applying for new patents over minor or incremental versions of existing drugs also known as ‘product-hopping’ or ‘forced switching’, whereby a parent company takes on patents on new formulations of the same product to preserve its profits by switching the market (or market antics) ever so slightly.

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43 Toon van der Gronde, Carin A. Uyl-de Groot, Toine Pieters, _Addressing the Challenge of High-priced Prescription Drugs in the Era of Precision Medicine: A Systematic Review of Drug Life Cycles, Therapeutic Drug Markets and Regulatory Frameworks_, 12 PLOS ONE 1, 3 (2017). ("On average, countries in the Organization for Economic Co-operation and Development (OECD) spend 17% of their health care budgets on pharmaceuticals; in some countries, this is even more."). For an in-depth discussion on competition and pricing, see FREDERICK M. ABBOTT, _Excessive Pricing Practices and Competition Law: Doctrinal Development to Protect Public Health_, 6 UCIRVINE LAW REVIEW 281 (2016).

44 The acquisition of the license by Turin Pharmaceuticals led to the steep price hike. See Graber, supra note 43, at 1148; Van der Gronde et al, supra note 43.


46 Danny J. Edwards et al, _Access to Hepatitis C Medicines_, 93 BULLETIN OF THE WORLD HEALTH ORGANISATION 779, 802. ("In Egypt, a 48-week course of peginterferon/ribavirin costs 2000 United States dollars (US$)."") The authors estimate that the cost of production for sofosbuvir/ribavirin costs 2000 United States dollars (US$).

47 RICHARD A. POSNER, ANTITRUST LAW 203 (2d ed. 2001).

48 Van der Gronde, supra note 43, at 8. ("R&D has recently yielded fewer drugs than in years past, since low-hanging fruits have already been harvested. Furthermore, there are many drugs with promising results in phase II settings that have not made it to phase III settings.")

49 See Roger Collier, _Drug Patents: The Evergreening Problem_, 185 Canadian Medical Association Journal 385, 385 (2013). ("Evergreening refers to possibilities through which the patent holder can artfully apply for new patents just before the end of its existing term, thus ‘evergreening’ its protection.") Kumar and Nanda (2017) identify the following common strategies of evergreening: (a) combinations of two or more drugs; dosing rage and dosing route; (c) biological targets for old molecule, (d) delivery profiles, mechanism of action; (e) derivatives and isomeric forms; (f) screening methods, dosing regimen; (g) packaging; and (h) different methods of treatment. See Arun Kumar & Arun Nanda, _Evergreening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in the USA, EU, India and Other Countries_, 6 PHARMACEUTICAL REGULATORY AFFAIRS 1, 1 (2017).

50 Gregory H. Jones et al, _Strategies that Delay or Prevent the Timely Availability of Affordable Generic Drugs in the United States_, 127 BLOOD 1398, 1399 (2016).
In a context of tiered pricing, such a growing reliance on intellectual property can become a mechanism to maintain critical advantages, altering the market power of some firms over others. Specifically, and in conjunction with a reluctance amongst policy makers to address competition issues, such pricing freedom can trigger a move away from market-based competition to a sub-optimal system where control on pricing and product choice decisions rest firmly in the hands of pharmaceutical companies. This can have a range of unintended effects, by enabling firms to segment markets, control product inflows and outflows, and potentially use it as a strategic tool to block competition. Over time, these effects on price and competition will leave all markets worse off with the patent owner firm benefiting from an abnormally high return on investment (ROI) at the expense of consumers everywhere.

Available secondary evidence available on the topic, albeit unsystematic, is points to this wider trend. For example, a study of average prices of pharmaceutical products across fourteen countries found several instances where high income countries had lower average prices when compared to low income countries. Another study seeking to document pricing practices of big pharma concluded already in 2009 that in many instances, prices of life-saving drugs have been set at exorbitantly higher costs than anticipated even in a tiered-pricing setting. Yet another study looking at several drug categories shows how in sizeable markets with a number of competitors, tiered pricing performed poorly when compared to competitive production of drugs to achieve sustained price reductions and affordable access to medicines.

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52 See Fisher and Syed, Differential Pricing, supra note 6 (discussing the implications of expanding intellectual property protection on the balance between innovation and access); See also Christopher R Leslie, Patent Tying, Price Discrimination, and Innovation, 77 ANTITRUST LAW JOURNAL 811, 812-814 (2011) (discussing how patents impose inefficiencies by expanding monopolies); See e.g., Keith E. Maskus & Jerome H. Reichman, The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods, 7 J. INT'L ECON. L. 279, 316-20 (2004) (arguing that continued advancements in global technology are dependent on a functional transnational system of innovation, especially maintaining access to public knowledge goods and inputs).

53 See generally, PHARMACEUTICAL PRICES IN THE 21ST CENTURY (Zaheer-Ud-Din Babar ed., Springer Int'l Publ'g Switz. 2015); See also MOON et al, A Win-Win, supra note 8.

54 Studies assessing the access to medicines implications of such pricing conclude that in the past, competition, especially through generic companies has performed better than tiered pricing in ensuring supply and saving public budgets. See Charles Holmes et al., Use of Generic Antiretroviral Agents and Cost Savings in PEPFAR Treatment Programs, 304 JAMA 3, 313, 317 (2010). ("Estimated yearly savings generated through use of generic ARVs increased over the 4-year period from $8 108 444 in 2005 to $214 648 982 in 2008, a total savings of $323 343 256 over the 4-year period.").

55 Patricia M. Danzon, Differential Pricing of Pharmaceuticals: Theory, Evidence and Emerging Issues, 36 PHARMACOECONOMICS 1395, 1398 (2018). ("Thus, economic theory concludes that, even without regulatory constraints, the profit motive leads a monopolist to charge prices across market segments inversely related to price elasticity, and this enhances social welfare compared with charging a uniform price. However, the absolute price levels charged by an unregulated, profit-maximizing monopolist may yield above-competitive return on investment (ROI) unless pricing power is constrained by the potential entry of differentiated substitute products and robust consumer price sensitivity, such that the market approximates monopolistic competition rather than pure monopoly."). See also Padmashree Gehl Sampath & Walter Park, Do Patents Lead to Market Concentration and Excess Profits (2018), http://www.ase.tufts.edu/gdae/Pubs/wp/19-02_Sampath_Patents.pdf


57 Carlos M. Morel et al., The Level of Income Appears to Have no Consistent Bearing on Pharmaceutical Prices Across Countries, 30 HEALTH AFFAIRS 1545, 1549 (2011).

58 Sean Flynn et al., An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries, 37 THE JOURNAL OF LAW, MEDICINE & ETHICS 2, 184 (2009), https://doi.org/10.1111/j.1748-7220.2009.00365.x

59 Moon et al, A Win-Win, supra note 13, at 15.
Moving on to consider the second issue that firms face: namely, that a reduction of prices in some markets may lead to a contagion effect where the parent firm is forced to provide reduced prices in other high-income markets. To be clear, rising drug prices have led to a reconsideration of price caps and price controls all over the world. Countries of the European Union, along with several other countries in the OECD and outside, now employ external reference pricing. A recent study comparing forty five different countries concludes that the metric employed for external reference pricing usually includes considerations such as: countries in similar socio-economic conditions, GDP levels, and geographic proximity to the other countries that offer price comparisons. This would imply that as opposed to the risk that the EU would use say, the price offered by a pharmaceutical company in Lesotho as its benchmark, the risk that Columbia or Brazil would use an African company as a benchmark is higher.

Whether such a contagion is welfare diminishing for social welfare is by itself an interesting question. First of all, the average per capita income in several middle-income countries is not much higher than that of low-income countries. So if a middle-income country would indeed use the price offered by a pharmaceutical firm to a low income country to reference price, the impact on firm level sales and profits would depend on the specifics of the case. Furthermore, one could also argue that given the wide variations in the distribution of income in many low- and middle-income countries, and large intra-country differentials between the rich and the poor, capping the price through such a mechanism only diminishes incentives for originator companies that hold monopoly positions in certain product categories from setting prices that target to the wealthy minority in each of the country categories. This would, on the whole, benefit the consumers.

What is apparent is that there is an overall coordination issues with pricing approaches as a whole, with some level of friction between external reference pricing and tiered pricing that adds uncertainty. A more thorough discussion on how these pricing mechanisms interact is required with a consideration of important trade-offs between price controls and availability of medicines around the world. Whether external reference pricing acts as a disincentive for firms to offer drugs in specific markets, and how this affects social welfare also needs to be systematically analysed. For example, the presence of external reference pricing in EU incentivizes the firms to first register in those countries with the highest willingness to pay, for example in the USA, thereby potentially delaying its availability in other parts of the world. Thus, in the EU, although the price ceilings offer greater access to all patients, working as a form of internal control mechanism for access, it deters market entry of drugs especially in certain categories such as cancer leading to a higher incidence of cancer-related deaths.

2.3. Inter-Country Tiered Pricing in Practice: Evidence from HIV/ AIDS, Hep C and Cancer Segments

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60 Panos Kanavos et al, Does External Reference Pricing Deliver What It Promises? Evidence on its Impact at National Level, 21 THE EUROPEAN JOURNAL OF HEALTH ECONOMICS 129, 129. (“In general, ERP operates on the basis of identifying prices from a basket of reference countries, the selection of which is based on four main criteria: (i) geographic proximity to the benchmark country; (ii) comparable GDP levels; (iii) similar socioeconomic conditions; and (iv) ad hoc considerations in the benchmark country, such as ‘desirable’ price levels.”)

61 For example, the per capita GDP in India, a middle income country, is around 2000 USD, whereas that of Bangladesh, a low income country, is around 1690 USD in 2019. In contrast, the per capita GDP of a middle-income country like Chile is 15,000 USD.

62 This question is dealt with further in section 3 of this paper.

63 See discussion in Section 4 of this paper.

64 Van der Gronde, supra note 43, at 3.

65 Sara Parker-Lue et al, The Ethics and Economics of Pharmaceutical Pricing, 55 ANNUAL REVIEW OF PHARMACOLOGY AND TOXICOLOGY 191, 194. (“Thus, although overall life expectancy is higher on average in Europe, European cancer survival rates are lower than the US survival rate. For example, the 5-year survival rate for men over age 75 diagnosed with prostate cancer is 92.1% in the United States but only 64.4% in Scotland. Between 2004 and 2008, the US Food and Drug Administration (FDA) approved 59 anticancer drugs, of which 46 were also approved in Europe.”). See also Jonathan Ingram, Eliminating Innovation: How Price Controls Limit Access, 32 JOURNAL OF LEGAL MEDICINE 115.
This section presents an empirical discussion using three different therapeutic categories of drugs – HIV/AIDS, Hep. C and Cancer – as its reference points. The therapeutic categories are chosen for the significantly different market structures, both globally and within countries. The scale of the HIV/AIDS epidemic has been such that tiered pricing, generic competition and international procurement (by agencies such as Global Fund for AIDS, Tuberculosis and Malaria (GFATM), the President’s Emergency Program for AIDS Relied (PEPFAR) and the Clinton Aids Initiative (CHAI)) have all been used as instruments in parallel. Thus, despite having been covered extensively in the past, HIV/AIDS is the therapeutic category with the kind of data needed to unfold the interplay between tiered pricing and competition in the presence of market imperfections such as intellectual property rights and bundling. Two other sectors - Hep C, where a single patented drug has been the main treatment available globally, and cancer treatments, which are now a large part of the growing health burden in all countries - are discussed as contrast points. To really compare and consider tiered pricing, compulsory licensing, voluntary and generic competition as solutions for promoting access to medicines, we would need a data set that is much different from the kinds of data that are available on hand today. To begin with, one would need information on what prices firms offer to different countries in a transparent manner, which is often considered confidential information. Secondly, we would need to compare prices obtained by compulsory licensing, or the threat thereof, with prices procured by international agencies through collective bargaining, and then compare them with prices offered by companies. Although such data is not available, in this section, especially for the discussion on HIV/AIDS, different kinds of data sources have been analyzed to present a comprehensive comparison of tiered pricing and generic competition.

2.3.1. HIV/AIDS

Despite rigorous interventions, HIV/AIDS remains a serious public health issue globally as also evident by the 90-90-90 target of the UNAIDS Fast Track Initiative for treatment. Data on global antiretroviral coverage suggests that treatment options remain insufficient, and only an estimated 59% of people worldwide living with HIV/AIDS are covered by antiretroviral therapy (figure 1).

Figure 1: Global Antiretroviral Coverage: 2000 and 2016

Source: Created using the World Development Indicators Database.

In the anti-retroviral (hereafter ARVs) market, access to generic options have been historically instrumental for steep reductions in prices bringing down the costs of first-line ARV therapies form USD 10,000-15,000 per year to just US$64–102 per year. Figure 2 below maps the relationship between originator prices and price reductions using data available with the WHO’s Global Price Reporting

67 http://apps.who.int/gho/data/view.main.23300REGION?lang=en
68 Eduard J. Beck et al, Does the Political Will Exist to Bring Quality-Assured and Affordable Drugs to Low- and Middle-Income Countries? 12 GLOBAL HEALTH ACTION 1, 1.
Mechanism (GPRM) to show that the price decreases are most evident in the case of those ARVs when there was widespread generics competition from Indian companies when compared to other categories of drugs (such as Raltegravir or Ertravirine) where the number of generic suppliers are limited. This is evident in trends for several drugs presented in figure 2 but applies especially to Lamivudine, Efavirenz and Tenofovir, where securing lower prices through generics competition also helped open up markets. In these instances, the option of securing these drugs at a cheaper price resulted in a surge in the number of countries purchasing generic ARVs from Indian companies from 11 to 96 between 2003 and 2008 respectively.

Figure 2: The role of competition in reduction of prices

![Graph showing the role of competition in reduction of prices](image)

Source: Author, using data from WHO's Global Price Reporting Mechanism Database.
Note: X-axis lists the main ARVs. Y axis plots the treatment cost per year and the number of generic competitors respectively.

a. Price effects of tiered pricing by originator companies versus generic competition

Competition has had two important impacts on restructuring the HIV/AIDS market over time. On the one hand, it prompted direct price competition with originator companies thus bringing prices of drugs down drastically and enhancing access to medicines as figures 3-11 show. On the other, it also

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69 The Global Price Reporting Mechanism is a database of the World Health Organization that records international transactions of HIV/AIDS, Tuberculosis and other drugs. See [https://www.who.int/hiv/amds/gprm/en/](https://www.who.int/hiv/amds/gprm/en/)


71 For a similar chart that uses data from the Médecins sans Frontiers database, see Moon et al, *A Win-Win*, supra note 8.

72 Some fluctuations in the prices can be seen, which may be accounted by erratic pricing of active pharmaceutical ingredients and other market shocks. See for example, Beck et al (2011).
compelled originator companies to offer price reductions to avert the threat of compulsory licensing in many countries. In particular, studies on the topic find that until the introduction of competition, tiered pricing offered by companies tended to remain relatively high even in the low-income markets, and in some cases, even after the introduction of cheaper generics, originator companies continue to offer higher tiered prices for the same products in countries that were obliged to procure the patented versions. A review of 7,000 developing-country purchase transactions from 2002-2007 found that the tiered prices for 15 of 18 antiretroviral (ARV) drugs were anywhere between 23-498% higher than the prices offered by the generic companies. Other studies find that international agencies procuring drugs saved large sums of money by purchasing generic alternatives from Indian companies than using tiered-pricing structures offered by originator companies. Studying the relationship between generic competition and the fall in the prices of originator drugs through tiered pricing in ARVs, artemisinin-combination therapy for malaria, treatments for drug-resistant tuberculosis, drugs for visceral leishmaniasis, and the pneumococcal vaccine, another study reviews the role of generic competition in Abbott’s pricing for Lopinavir/ Ritonavir, concluding that the initial tier price of USD 650 offered to several African and other least developed countries saw a reduction only up to USD 500 by the company until an offer by the President Clinton HIV/AIDS Initiative (CHAI) in 2009 that the same combination would be available at USD 470. At this point, Abbott brought down its price to USD 440.

To see if these effects are verifiable across the board, Table 1 compares prices offered through generic competition and tiered pricing across all first and second line ARVs for the year - 2014 - using data from the GPRM database and the data available with Médecins Sans Frontiers (MSF). In table 1, the first column (GPRM Originator) shows the price of the originator drug without tier pricing, whereas the third column (MSF originator) shows the tier price offer of the originator company for category 1 countries (mainly Low income countries, or least developed countries, which are offered the lowest price). Columns 2 and 4 show the available generic price, offered by generic companies across all the ARV therapies. A comparison of columns 2, 3 and 4 shows the differences between the tier price and the generic price. For example, for the NVP+(TDF+3TC) combination, the tier price is at USD 501 for the treatment per year, whereas the generic price would be anywhere between USD 96 and USD 106 for the same regimen.

Table 1: Tiered Prices Versus Generic Prices Across All First Line and Second Line Drugs, 2014.

<table>
<thead>
<tr>
<th>WHO Regimen</th>
<th>Approved Treatment Cost Per Year (2014)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GPRM</td>
</tr>
<tr>
<td>First Line</td>
<td>Originator</td>
</tr>
<tr>
<td>NVP+AZT+3TC</td>
<td>452*</td>
</tr>
<tr>
<td>NVP+ (TDF+3TC)</td>
<td>1538*</td>
</tr>
<tr>
<td>NVP+ (TDF+FTC)</td>
<td>2570*</td>
</tr>
<tr>
<td>EFV+(AZT+3TC)</td>
<td>1200*</td>
</tr>
<tr>
<td>EFV+TDF+3TC</td>
<td>2285</td>
</tr>
<tr>
<td>EFV+TDF+FTC</td>
<td>3317</td>
</tr>
<tr>
<td>DTG+TDF+3TC</td>
<td>2572</td>
</tr>
</tbody>
</table>

Second Line

74 Holmes, *supra* note 55.
75 Moon, *supra* note 7, at 11.
76 These are the two most widely used and available databases on the topic. Year 2014 has been chosen because of the maximum availability of data points.
77 Companies do not have a standard list of what countries fall into category 1, but generally it is based on the World Bank classification of low-income categories, or the UN classification of Least Developed Countries. Some companies offer the category 1 price to all sub-Saharan African countries, and some other Asian LDCs.
<table>
<thead>
<tr>
<th></th>
<th>555</th>
<th>328</th>
<th>N/A</th>
<th>383</th>
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<tbody>
<tr>
<td>LPV/r+(AZT+3TC)</td>
<td>1641</td>
<td>304</td>
<td>532</td>
<td>355</td>
</tr>
<tr>
<td>LPV/r+(TDF+3TC)</td>
<td>2673</td>
<td>N/A</td>
<td>N/A</td>
<td>387</td>
</tr>
<tr>
<td>N/A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DTG+(LPV/r)</td>
<td>1399</td>
<td>N/A</td>
<td>652</td>
<td>337*</td>
</tr>
<tr>
<td>ATV/r+(AZT+3TC)</td>
<td>1719*</td>
<td>322</td>
<td>N/A</td>
<td>352</td>
</tr>
<tr>
<td>ATV/r+(TDF+3TC)</td>
<td>2804*</td>
<td>298</td>
<td>N/A</td>
<td>325</td>
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<tr>
<td>ATV/r+(TDF+FTC)</td>
<td>3836*</td>
<td>N/A</td>
<td>N/A</td>
<td>357</td>
</tr>
<tr>
<td>DTG+(ATV/r)</td>
<td>2563*</td>
<td>N/A</td>
<td>N/A</td>
<td>307*</td>
</tr>
<tr>
<td>DRV/r+(AZT+3TC)</td>
<td>3614*</td>
<td>1675</td>
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<tr>
<td>DTG+(DRV/r)</td>
<td>4458</td>
<td>N/A</td>
<td>N/A</td>
<td>1332*</td>
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</table>

**Third Line**

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<td>Ral+DRVr</td>
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<tr>
<td>DTG+DRVr</td>
<td>4458</td>
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<td>1295</td>
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<td>Raltegravir</td>
<td>675</td>
<td>372</td>
<td>675</td>
<td>1752</td>
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</table>

* Asterix indicates alternate year used for: GPRM Originator – AZT (2013), NVP (2013), ATV/r (2012), DTG (2015); MSF Originator – DTG (2017); MSF Generic – DTG (2017). Category 1 pricing is used for MSF Originator cost. MSF Generic prices are averaged across available data. All numbers are rounded to the nearest whole number.

b. Imperfect markets: patents, evergreening and bundling

The ARVs sector also exhibits several of the other market imperfections that come in the way of effective, and welfare maximizing tiered pricing.

Bundling refers to the sale of two products only in combination with one another, and is known to reduce welfare in the context of tiered pricing particularly.78 Ritonavir (trade name Norvir), originally patented by Abbott Pharmaceuticals (now AbbVie) in 1989, is frequently used as a booster in highly active anti-retroviral (HAART) combination therapies. The stand-alone ritonavir is most often used as a booster for protease inhibitor-based therapies such as Bristol-Myers Squibb’s Reyataz and Merck’s Crixivan. However, by the end of 2003, when these drugs began to appear in the market, Abbott hiked the price of stand-alone ritonavir by 400%, from $1.71 for the 100mg dosage to $8.57 per daily dose.79 Abbott did not, however, modify the price of its other product Kaletra—a combination therapy of ritonavir and lopinavir - thus ensuring that its own product remained the most cost-effective.80 This decision drove a large price discrepancy between Kaletra and other ARV therapies that use ritonavir as a booster. Prior to ritonavir’s price increase, two of Kaletra’s main competitors, atazanavir (Bristol-Myers Squibb’s Reyataz) and fosamprenavir (GlaxoSmithKline’ Lexiva) were sold at USD 684 and USD 480 respectively, when compared to Kaletra’s USD 580.81 Abbott’s pricing decision did not just raise the cost of drugs already on the market, but it also threatened the marketability of new drugs being developed in combination with ritonavir.82

In addition to the inconsistent pricing, Ritonavir has experienced excessive patenting that has delayed generic entry.83 The patent on Ritonavir was set to expire in 2014 but secondary patenting has extended its coverage to 2028, pushing back generic entry. The patents filed for ritonavir address elements such

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79 https://www.keionline.org/prices/ritonavir
80 Lancet 2004
as combination therapies, liquid and solid dosage formulations, chemical synthesis of the core compound and intermediates, as well as polymorphs and crystalline forms as Table 2 below shows.\(^4\) Table 2 contains the listing of a number of secondary patents that have been issued on all essential ARV therapies. A total of 12 secondary patents exist on Ritonavir, pushing the patent extension on the drug from 2013 to late 2020s or 2032. Similarly, Lopinavir/ Ritonavir has seven additional patents that push the patent expiration up to 2027 from the original expiration date of 2015.

Table 2: Secondary Patents on ARVs

<table>
<thead>
<tr>
<th>Drug Name</th>
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<th>Compound patent expiration</th>
<th>New patent</th>
<th>New patent holder</th>
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<td>Viread</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crixivan</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>With ritonavir,</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2027 [US8377952B2 – solid solution or solid dispersion of lopinavir and ritonavir in a matrix]</td>
<td>AbbVie Inc</td>
</tr>
<tr>
<td>Nelfinavir (NFV)</td>
<td>Agouron</td>
<td>2014 [US5484926 A]</td>
<td></td>
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<tr>
<td>Viracept</td>
<td>Pharmaceutical</td>
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\(^4\) [https://www.wipo.int/edocs/pubdocs/en/wipo_pub_946_1-tech1.pdf](https://www.wipo.int/edocs/pubdocs/en/wipo_pub_946_1-tech1.pdf)
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### Patent Information

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Sources: Patents were reviewed using the Google Patents database; see https://patents.google.com/ Patent numbers corresponding to each drug were obtained from the DrugBank Database (version 5.1.3, released 2019-04-02), see https://www.drugbank.ca/.

Efforts by Abbot to tier price Lopinavir/ Ritonavir for category 1 countries as presented in Table 1, for instance, when considered in conjunction with these evergreening realities presents an entirely different scenario. The combination therapy for people starting HIV treatment: TDF (tenofovir) with 3TC (lamivudine) or FTC (emtricitabine) is available from the parent holder companies for an original price of 1538 USD, with a category 1 price of 501 USD. But if the secondary patent on solid forms of Tenofovir had not been issued extending its monopoly from 2017 to 2035, the drug could have been made available at the generic price of 108 USD all over the world. Similarly, for Tenofovir (TDF) the category 1 price is USD 183, whereas the lowest generic price is USD 30, which could have been secured but for the patent on the solid form extending its monopoly until 2035.

### 2.3.2. Hepatitis C and Sofosbuvir

The Hep. C drug Sofosbuvir helps to underscore the pricing effects at the opposite extreme where little or no competition exists. Sofosbuvir is sold under two brand names – Sovaldi, which contains only Sofosbuvir and needs to be used in conjunction with other Hep. C medications, and Harvoni (a combination drug containing sofosbuvir and ledipasvir), widely acknowledged to be over 96% efficacious in curing the disease. Gilead, the patent holder for Sofosbuvir, prices Harvoni at USD 94,500.

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85 MSF database, 2017.
for a 12-week course in the USA while Solvaldi is sold at USD 84,000 in high income markets and 48,000 USD in middle income markets.\textsuperscript{86} Although Gilead has issued a voluntary licensing at a 7% royalty rate allowing some Indian manufacturers to produce the drug cheaply to 91 LICs,\textsuperscript{87} this does not really help over 75% of the 71 million globally who are infected with the disease and live in middle income countries. This prompted, most recently, Malaysia to issue a compulsory license on the product in 2017 and Chile to embark on a similar effort.\textsuperscript{88}

Competition for the drug has been slow to develop. AbbVie launched a competing product, Mavyret (glecaprevir/pibrentasvir) in 2017 at 26,400 USD, just as the WHO noted in a 2018 report that although three regimes exist to cure all six major HCV genotypes (sofosbuvir/velpatasvir; sofosbuvir/velpatasvir/voxilaprevir; and glecaprevir/pibrentasvir), they were being used only in three low and middle income countries in 2018.\textsuperscript{89} Amongst the main difficulties in negotiating prices, the WHO advocated the need to make available the prices negotiated by countries more widely to others; in addition to introducing competition in the market including through negotiating licenses through the Medicines Patent Pool.\textsuperscript{90} In late 2018, the Medicines Patent Pool entered into a royalty-free licensing agreement with AbbVie to improve access to Hep. C drugs worldwide. In an additional effort to resolve the crisis in this market, DNDi has licensed the rights for a new combination treatment (Sofosbuvir/Ravidasvir)\textsuperscript{91} from another company in 2017 and planned to make it available in several low- and middle-income countries at 300 USD per treatment.

### 2.3.3. Cancer Treatment

Cancer drugs have always been more expensive than many other therapeutic categories, but in recent years, their prices have become an additional cause of concern. Although, once again, systematic evidence on inter-country tiered pricing of cancer drugs is not available, but the World Health Organization estimates that a course of standard treatment for early stage HER2 positive breast cancer (doxorubicin, cyclophosphamide, docetaxel, trastuzumab) would cost about 10 years of average annual wages in India and South Africa and 1.7 years in the USA.\textsuperscript{92} Imitanib, for example, is a cancer drug developed by Novartis (brand name Gleevec), whose price almost tripled between the time it was first introduced (in 2001) and the time its patent was set to expire (in 2013). Despite Novartis’s initial admission that the original price would allow its R&D costs to be recovered in two years,\textsuperscript{93} price of the medication continues to rise.\textsuperscript{94} A detailed review conducted in 2017 tracing the journey of entry of

\textsuperscript{86} WHO, PROGRESS REPORT ON ACCESS TO HEPATITIS C TREATMENT (March 2018), https://apps.who.int/iris/bitstream/handle/10665/260445/WHO-PRC-18.4-eng.pdf?ua=1


\textsuperscript{88} The Chilean government came under pressure in 2018 to weaken national resolution 399/2018 that enables for the issuing of compulsory licenses in the interest of public health in the country in the context of this particular drug.

\textsuperscript{89} WHO, supra note 72, at x.

\textsuperscript{90} Id. at xi.

\textsuperscript{91} DNDI has licensed the rights to Ravidasvir from Presidio Pharmaceuticals, California, which has developed the drug.

\textsuperscript{92} WHO, PRICING OF CANCER MEDICINES AND ITS IMPACTS xi (2018), https://apps.who.int/iris/bitstream/handle/10665/277190/9789241515115-eng.pdf?ua=1

\textsuperscript{93} Hannah L. Kushnick, Pricing Cancer Drugs: When Does Pricing Become Profiteering? 121 AMA JOURNAL OF ETHICS 4439, 4440 (2013) (“Thus the tripling of imatinib’s price over a decade was not needed for Novartis to cover the costs of developing it—according to the Novartis executive’s account, it was believed that the original price would allow those costs to be recouped within two years if market penetration were high enough.”).

\textsuperscript{94} See Joshua Cohen, The Curious Case of Gleevec Pricing, FORBES (Sept 12, 2018), https://www.forbes.com/sites/joshuacohen/2018/09/12/the-curious-case-of-gleevec-pricing/ (“At its introduction in 2001, the list price of Gleevec was $26,000 per year. At the time of its patent expiration, the price had risen to over $120,000 annually.”).
generic Imitanib in the USA highlights the following developments that helped the company preserve monopoly profits for six extra years from 2013 until 2019: 95

(a) Novartis filed to have its patent term restored for a period of time equal to the length of time the drug is under FDA review plus one half its clinical trial testing period (to a maximum of 14 years).
(b) Novartis also secured a pediatric exclusivity extension for Iminatib’s patent, which had the effect of extending the patent from May 2013 to July 2015 (with the patent term restoration of 586 days and the pediatric exclusivity of 180 days).
(c) Novartis applied for a number of secondary patents covering incremental changes to the active pharmaceutical ingredient. This extended its market exclusivity from July 2015 until Nov 2019 without offering any new benefits to US consumers.

One of the few studies that examine whether the pricing of cancer drugs corresponds to the income status of countries conducts an empirical assessment of the prices of cancer drugs across seven countries in the high income category (USA, Australia, United Kingdom and Israel), upper-middle income category (China and South Africa) and lower-middle income country (India) to capture both retail and discounted prices of these drugs. 96 The study concludes that while all the seven drugs were most expensive in the USA, they were more affordable in the other high income countries in the study (Australia, Israel and the United Kingdom) than in China and South Africa, where they were still priced in such a way that they were less affordable than all the high income countries. The drugs were least affordable in India by a large margin when compared to all other countries in the study. 97

3. The Problems with Current Approach to Tiered Pricing

Until now, this paper has established the difficulties in ensuring that third degree price discrimination, which serves as the basis for inter-country tiered pricing does ensure in welfare increases for the society. A review of key theoretical insights shows that be welfare enhancing for the society, the tiered pricing scenario has to be accompanied by a significant increase in total production with lower costs in price sensitive markets. Two other findings emerge from the review of the evidence on inter-country tiered pricing on the nature of imperfect markets in which firms currently function: on the relationship between tiered pricing and competition, and on the inadequacy of the country-based classification as a means to guide pricing.

3.1. On the Relationship between Tiered Pricing and Competition

The case study of the ARVs market underscores the suitability of dynamic competition as a more reliable and sustainable mechanism when compared to price discounts offered by firms for reducing prices. It also highlights that voluntary tiered pricing, on its own and without the threat of tiered pricing, does not really work to ensuring price reductions of the kind required to expand access to those who need it most. In these cases, just as theory predicts, firms tier price to skim off maximum profits, and might see some marginal increases in production outputs, but the society does not experience welfare increases as a whole. Especially, when firms have monopoly power over the market (that is, only one firm producing/ owning the patent on the drug in question globally), there does not seem to be sufficient incentives for them to tier price as theory would suggest for capturing greater market shares on their own.

A significant result from the empirical evidence discussed in section 2.3. is that competition and tiered pricing have a virtuous relationship that is poorly understood in the extant literature. In the ARVs market, it was competition that created incentives for originator companies to introduce tiered pricing that was closer to the average cost of production (factoring in the R&D investments). The presence of competition also created a contagion effect, working alongside the threat of compulsory licensing, to induce originator firms to continuously offer lower prices for specific groups of countries that now

96 Daniel A Goldstein et al, A Global Comparison of the Cost of Patented Cancer Drugs in Relation to Global Differences in Wealth, 8 ONCOTARGET 71548.
97 Id. at 71553.
belong to ‘category 1’. This finding suggests instruments for promoting access and innovation often work together to iron out market failures, and that competition, compulsory licensing and tiered pricing could be promoted at the same time.98

The analysis of pricing data with data on patents on the same drugs as conducted for ARVs, and to some extent the other two categories, underscores how intellectual property and market exclusivity helps convert market power into monopoly power of the kind that should become a consideration for competition policy. In these instances, it becomes easier for the monopolist firm to extract rents by targeting the top layer of consumers in all markets, and also engage in anti-competitive conduct such as bundling, tying in products, among others. Studies are beginning to connect the dots and raise questions. A recent study of 437 top selling drugs in the United States finds that secondary patents and market exclusivity are now so widely used by originator companies to extend the life cycle of products that only 40% of all the drugs in the sample experienced generic competition, and less than 18% of all drugs in specific therapeutic categories became available as generic formulations.99 As firms continue to strategically preserve monopolistic rents through secondary patents or other marketing arrangements, the question for society is wider. Should intellectual property protection preserve rents that are not apportionable to innovative investments, and should tiered pricing be allowed to explain away the extended monopolies and the undue accumulation of profits?

3.2. On the Inadequacy of Country Classifications

GDP-based country classifications offer a poor basis for discriminating prices, since it does not account for this skewed distribution of income within developing countries. According to the World Health Organization, over seventy percent of the world’s poorest live in what are classified as developing countries or middle-income countries.100 But voluntary pricing programs of companies, by relying on least developed country or low-income country classifications to offer preferential prices, exclude a large share of the poor that reside in middle income countries such as India and Brazil.

The inadequacy of GDP based country classification and its potential for misuse by large firms to deter competition were the reasons for the eschewal of earlier efforts to establish an international tiered pricing initiative by access to medicines proponents in 2013.101 In that instance, civil society organizations, first voicing support for the initiative, withdrew amid concerns that pharmaceutical companies were using tiered pricing to thwart generic competition with longer term consequences for the global pharmaceutical market.102 Other critiques emphasized that such an initiative promoted the pricing of drugs in terms of income categories of countries - into high, middle and low-income - thus

98 See also t’Hoen et al, supra note 16, at 192. The authors arrive upon a similar after a detailed review of the use of TRIPS flexibilities by countries. In their study, by collecting information on 176 instances of the possible use of TRIPS flexibilities by 89 countries between 2011 and 2016. The authors conclude that of the 100 instances of compulsory licensing, only 81 were implemented and 19 resulted in price reduction by patent holder firm (or donation in 6 cases), or a voluntary license allowing the purchase of the generic drugs from other producers (5 cases). What stands out is that without the threat of compulsory licensing, and the presence of other generic suppliers, the reductions in prices would not have been made available.


102 A number of civil society organisations came forth with the concern that such a tiered pricing initiative could strategically enable firms to exclude generic competition in global markets. See Open Letter by Civil Society to Mark Dybul, Executive Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria: Abandon the “Blue-Ribbon Task Force to Develop a Global Framework on Tiered-Pricing” 13 May 2014.
vitiating the objective of increased access given that MICs house over three quarters of the world’s poorest. 103

4. Enhancing Transparency: Intra-Country Tiered Pricing as an Option

So long as tiered pricing continues on a voluntary basis, there will always be open questions on its efficacy as an instrument of access to medicines. Pricing discounts and tiered pricing of drugs in general are negotiated per country/ set per groups of countries by the firms in confidence. 104 This, even in the best of the circumstances, will raise concerns on how it links to promoting (or recovering) R&D investments, access and future returns to society by protecting innovators. 105 Other market anomalies also affect the way firm-level incentives are structured. Key amongst these are information related, given that even in the best of the circumstances, well-meaning pharmaceutical firms lack the kind of information needed on all present and future markets for different drugs to be able to set prices in a way that clearly corresponds to their R&D and production costs. The current set up of pharmaceutical supply chains, with the presence of intermediaries and large retail mark ups, and the lack of supply chain accountability in several countries also impedes incentives to engage in socially welfare enhancing forms of tiered pricing. 106 This is because, even when the pharmaceutical firm offers a price discount upfront, mark-ups, tariffs and taxes can lead to different end prices than was intended by the discriminating firm in the first place, and to different prices generally in different countries thus creating additional incentives for third party arbitrage. 107 Given that this amounts to simply redistributing profit from the company to another local intermediary (rather than the consumers), it will erode firm level incentives to offer really low prices. All these reasons, in sum, continue to vitiate the consideration of tiered pricing as an alternative within a larger basket of options for increasing access to medicines.

Equally importantly, the complex and contentious global pharmaceutical landscape highlighted in this paper is a wakeup call for a more differentiated discourse on how to construct the global public interest for access and innovation in the pharmaceutical sector, working within a framework guided by social justice and good governance. Such a discourse should reconcile the complex interplay between industry and societal goals in the pharmaceutical sector and consider a framework/ strategy in which several access and pricing instruments work more closely with one another in a more accountable manner. There is a clear role for tiered pricing in such a framework for access, especially in a number of therapeutic categories where drugs are patent protected and options for generic competition are limited. In these categories, another kind of tiered pricing, namely, intra-country tiered pricing, with its option of segmenting consumers within countries, offers a better way to engage with and include pharmaceutical firms in promoting greater access to medicines.

4.1. Welfare Enhancing Price Discrimination Effects of Intra-country tiered pricing

The wider issue with inter-country tiered pricing policies in the pharmaceutical sector has been that it allows for price discrimination in markets with linear demand functions. Through this, the monopolist

103 Médecins sans Frontieres, supra note 89.
104 The WHO or MSF have access to pricing information of certain categories of drugs only.
105 A detailed analysis of over 150 US FDA approved cancer drugs by the World Health Organization shows that the sales revenues of a majority of cancer medicines are significantly above the risk-adjusted costs of R&D as estimated in the wider literature. See WHO, supra note 78, at 10. In the case of Hep C, similarly, reviews conclude that Gilead’s prices have little recourse on grounds of R&D given that Gilead Sciences bought out the drug, sofosbuvir (Sovaldi) from Pharmasset, a start-up, and marketed the drug at double the cost that Pharmasset had intended to charge. See van der Gronde, supra note 43.
106 PRASHANT YADAV, DIFFERENTIAL PRICING FOR PHARMACEUTICALS (DFID, 2010) at 5, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/67672/diff-pricing-pharma.pdf (“Channel margins (wholesale, retail) are much higher in low and middle-income countries and constitute a very significant part of the retail price; the ex-manufacturer price is not reflective of the price paid by the end-patients. The wholesale and retail margins can be as high as 500 per cent in some developing countries, due to lack of competition and other inefficiencies (Cameron et al 2009). Thus, even when pharmaceutical companies try to set differential prices, the end-patient prices for poor patients in low income countries could be high due to price-gouging at the wholesale or retail levels due to lack of retail or wholesale competition.”)
107 See Lichtenburg, supra note 33, at 1542.
firm caters to the marginal consumers in both markets (middle- and high-income countries in this instance) but does not necessarily increase the total surplus created, thereby reducing allocative efficiency. The offer of some price reductions in low income countries on a voluntary basis presents short-term relief, but it does not ensure longer term, dynamic welfare to consumers as a whole. These effects are especially grave in those categories where sufficient generic competition is not available. What is needed, effectively, from an access to medicines perspective is the opposite of this: namely, to cater to poor people that are segregated on more effective ‘means to pay’ basis across all countries with a strategy that is more tailored to public-interest oriented tiered pricing.

Intra-country tiered pricing creates a more accountable and transparent method of segregating consumers to offer different prices, given that firms will have to create discrete groups of consumers to offer different prices within each country. The unsuitability of the consumer groups – if prices are created wrongly/ inaccurately – can easily be revealed through demand inelasticities of the consumers especially in those markets with large numbers of people who are not insured. This eliminates the tendency for arbitrary pricing, and creates both the conditions for social welfare increase within national contexts – a significant increase in production output, and significantly lower prices – both of which can occur with national legal and institutional frameworks.

Another benefit of intra-country tiered pricing is also that rather than slice up the pie by country denomination, it offers a better and a more direct way to link access to price. Especially in light of rising inequality within all countries, there are segments of the population which are increasingly vulnerable and left out without social safety nets, especially for health care. For instance, the U.S. Center for Medicare and Medicaid forecasts that prescription drug spending in the USA is expected to increase by 6.1% each year through 2027 in the United States due to rising costs and use, particularly for chronic disease. It is estimated that despite efforts to increasingly substitute branded drugs with generics, rising drug costs alongside rising inequality will have drastic consequences for public spending and access.

In this context, if explored within a good basket of options that seek to promote access to medicines, and guided by a wider ethical framework, intra-country tiered pricing might offer an important strategy particularly in the case of medicines where there is no generic competition in sight to even out the market immediately in favour of those who need it most. Particular categories where this could be applied are R&D intensive drugs, such as biosimilars, where the market looks substantially different with just one or two companies ruling the roost in many categories. In these categories, bringing generic drugs to the market might be costly, time consuming, and fraught with economic, research and legal complications, leading to substantial delays in introduction of alternatives. Demarcating these instances and promoting intra-country tiered pricing as an option can enhance access. This needs to be done in a wider policy framework that accounts for competition, for instance, by checking for IP misuse (secondary patents, or evergreening), or bundling or other anti-competitive practices.

4.2. Implementing Strategies for Intra-Country Tiered Pricing: A Brief Discussion

Strategies to enhance intra-country tiered pricing pose particular difficulties of segregating consumers within countries in an effective manner. In order to be effective, they will also call for a rethink/ review of national supply chain mark-ups and organization, which may go a long way to promote access to medicines as well. Despite these difficulties, there is evidence from countries where such a mechanism has been implemented, showing that price differentials between market segments within a country can

108 In the USA, for example, existing estimates suggest that one of every two US families diagnosed with cancer file end up in bankruptcy due to the costs of health care. See Goldstein et al, supra note 96, at 71554.
110 Brian W. Tempest, Editorial 14 JOURNAL OF GENERIC MEDICINES 107, 107. The author notes that In 2018, for example, generic drugs represented 90% of all drugs prescribed in the USA, demonstrating a 75% rise from 2009, making 2018 the first year of declining drug prices in the USA in 46 years.
be preserved.\textsuperscript{111} This section presents some thoughts on implementation based on these existing country experiences.

4.2.1. Segregating consumers more effectively: Channels in the developing and developed countries

There exist channels to segregate consumers in a large number of countries worldwide, these just need to be clearly demarcated and policy enabled. For instance, in low- and middle-income countries, there are at least two important ways to segregate consumers. In a large number of these countries, given the shortcomings in public insurance systems and out of pocket expenses, healthcare is segregated into two kinds of channels: the publicly financed government health care delivery channel and large privately funded out of pocket private channel. There remain national and disease level differences in how patients use these systems. Evidence from countries like Bangladesh, India and Tanzania, shows that there remains an overlap in disease categories treated in both public and private channels, but people from different socio-economic segments of the population seek treatment in each of these.\textsuperscript{112} While the poorest and the most vulnerable still try to access the public health care system to the extent possible, the more well-to-do segments of the population resort to out-of-pocket private treatments that are costlier (but often associated with better medical professional advice and infrastructure). A second possible venue of distinction for price discrimination is the location: on an urban and rural basis, but the distinction between urban and peri-urban locations can also offer an effective basis for offering intra-country differential pricing.

Ideally, firms could use a combination of the two - i.e., offer cheaper prices to those who access public healthcare channels in rural or peri-urban areas in all countries, to increase access to medicines. From a governmental side, this would require some effort to put in place adequate safeguards to prevent the diversion of the product or patients from one channel to another.\textsuperscript{113} Firms can also rely on a more effective system of medical representatives (which are already widely prevalent in a large number of countries), offering them additional incentives to oversee as an additional private safeguard, and offer separate packaging of products (including branding). Hospitals, in public distribution channels, and health care suppliers, will need additional incentives and monitoring mechanisms that offer a better system of accounting for firms.

Despite all this, there will be the risk of some product-switching between private and public channels, especially amongst those consumers who will now find it easier to save and access cheaper medicines that is more in line with their income and savings capacity in the intra-country tiered pricing scenario. These cases will still qualify overall for a better outcome from an access to medicines perspective but will not result in lower income for the firms since they will continue to increase volumes of sales, while keeping a wider channel of higher price category sales intact in all countries.\textsuperscript{114} Given that all countries in the developing world will gradually exhibit skewed income differentials as they embark on stronger development trajectories, moving firms from a system of voluntary tiered pricing of the third-degree to the more socially useful intra-country tiered pricing, several of the ills of the current system can be averted.

In the industrialized countries, evidence from the USA similarly indicates that the kind of health care facilities and the location offer serve as a basis to delineate those who have little ability to pay. But there are other complexities in the health care market, where current price differentials are based on a more complex system of discounts that are determined by negotiated volume-rate contracts between manufacturers, pharmacy benefit managers (PBMs), wholesale distributors, pharmacies, and health insurance companies. Thus, as opposed to segregating prices between the rich and the poor, or the insured or the uninsured, the current system is one where the price is dependent on the ability to sell specific volumes of certain drugs or achieve a certain share of a specified market. An intra-country pricing mechanism could help restructure the market differently without much leakage. It would also

\textsuperscript{111} YADAV, supra note 29.
\textsuperscript{113} Id.
\textsuperscript{114} Yadav (2010) models some of these results, showing how the system will not adversely affect pharmaceutical companies.
prevent many of the inefficiencies that arise from the current market structure that is centred around actors (PBM in particular) negotiate the cheapest prices only on the basis of offer large purchases that in turn, fortify the market shares of large firms and promote the choice of one/ some drugs over others in an artificial manner. These usually end up favouring the rich, or the well-insured, leaving those who need it to deal with the highest prices.

4.2.2. Policy Support and the Role of the Government

To enable the separation at the intra-country level, governments will need to play a key role in helping to segregate markets, and keep prices and competition in check. Towards this end, the following national regulatory changes can be considered by governments as part of a national tool kit:

(a) Enact regulations that mandate patient-based background information that can certifiably declare their income status to avail of lower priced drugs. This could be done for example, by using the newly available digital identity system in many countries that contains repositories of individuals’ socio-economic status.

(b) Enact national regulatory frameworks on tiered pricing (see next section) which identify/ allow for the enlisting of health care institutions that are equipped to offer differentially priced health care.

(c) Enact rules for enlisted health care facilities on how to segregate consumers by setting criteria on economic background, social status, and other criteria.

(d) Enable the tracking of such institutions, with rules for auditing and accountability to the government, with penalties for any arbitrage, to offer a transparent framework for firms to collaborate in the scheme.

In some particular cases of public health importance, to increase generic access, governments could also consider working with companies’ ready to engage in promoting access, assisting them to directly also monitor the effectiveness of their programs.

In countries that engage in external reference pricing and offer universal insurance with coordinated frameworks for public and private insurers within their national boundaries, there is already a system of a similar nature in place. There are questions about the existence of price caps and availability that have been raised earlier in this paper, which remain important to resolve.

4.2.3. A Wider International Policy Framework to Enforce Intra-Country Differential Pricing

Pricing is inexorably linked to access, and given the difficulties in current pricing approaches identified in this paper, a wider policy framework for the coordination of pricing, innovation and access should be considered. National tiered pricing frameworks can only work when there is an agreement to eliminate voluntary pricing mechanisms of firms, to one where firms work alongside governments within more accountable frameworks to ensure greater access. In the past, suggestions have been made by Paul Hunt, the UN Special Rapporteur on the Right to Health, on a similar basis, suggesting the application of human rights principles to the pharmaceutical sector in two separate reports. These suggestions, widely known as the ‘Hunt Guidelines’ describe a duty by pharmaceutical firms to take all reasonable steps necessary to make life saving medicines available as much and as soon as possible in line with a viable business model. The intra-country differential pricing model proposed in this paper can be one such model, but one that clearly places the onus of ascribing responsibilities to businesses to national governments with the following principles.

Principle 1: Promote intra-country tiered pricing in the context of a broader competitive market scenario

There is no substitute for competition in the long run for innovation and access, especially in light of the fundamental differences between what firms are prone to engage in, and what society actually

115 United Nations Secretary-General 2008, paragraph 5; and United Nations Secretary-General 2009, paragraph 41.
needs. It would therefore be logical to conclude that tiered pricing might only work effectively in a regulated environment, in the presence of competition and other regulatory mechanisms that discipline the behavior of the firms in the interest of welfare gains to all.

National intra-country tiered pricing strategies should focus on those categories where sufficient market competition is yet to develop - as monitored by a national agency (such as the drug regulatory authority, or the national competition agency). Tiered pricing should be time limited and accompanied by all other efforts to enhance competition including a regular review of the patents issued. Ideally, such tiered pricing strategies also need to be supplemented with increased competition coordination and surveillance between governments.

Principle 2: Tiered prices should be set on the basis of competitive or ‘pseudo’ competitive bids

It is highly relevant not just to enable firms to price discriminate, but to in fact ascertain and negotiate that these price discounts are aligned with social objectives. This necessitates that tiered prices should ideally be negotiated by national agencies tasked with these objectives in a fair and free manner. Where firms do not have sufficient incentives to come forward, the following two incentives can be considered:

(a) a demand pooling giving the originator firm/s incentives to engage;
(b) an assurance of the purchase commitment duration;

Providing these two assurances upfront is essential signalling the expansion of market and assurance of profits for the pharmaceutical sector. In order to be able to set the right price for tiered pricing, the central authority requires to start off from a competitive producer’s price (or a ‘pseudo’ competitor price, if a generic firm to produce the said product is unavailable) and work to include some sort of an additional premium on the originator firm’s investment costs, thus making it lucrative for the company to engage in the said exercise, while respecting its original investments. There is also a need for oversight in this instance on whether the said product has already benefited from patent protection and market exclusivity and is under a secondary patent protection, or whether there are other extenuating factors that should affect the pricing process.

Principle 3: Creating fair pricing outcomes

The notion of a fair price has a moral underpinning, which is not just about the end price but also about how the industry should be organized in a way that addresses access. Resting on the premise that both the innovators of health technologies and the patients who need them most should be treated ethically, a fair price is one that is at once affordable and able to provide the required market incentives for innovators to recover their R&D investments. In this context, there are real difficulties posed by information asymmetries to determine what a fair price for any product could be. Solutions proposed to address this question up until now include separating R&D from pricing, and value-based pricing. Value based pricing is based on the logic that instead of prices being set by the pharmaceutical firms on the basis of their R&D costs, they should instead be determined on the basis of their expected benefit to the consumers. This process shifts the pricing power from the firms to the regulators who specifies the maximum willingness to pay for a unit of any particular drug based on its effectiveness. But it may pose issues of incentives for future incentives for R&D by firms especially since regulators tend to have little information on the nature of science. There are also other suggestions to delink R&D from pricing, and while the suitability of these proposals is still contested, it appears that designing effective intra-country tiered pricing in an effective way will be sufficient to preserve enough space for profits given the rising middle class in the emerging economies, and the converging disease profiles across all countries, which will all contribute to expansion of markets to pharmaceutical companies.