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ARTICLES

Expanding Access to Medicines and Promoting Innovation: A Practical Approach

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I. INTRODUCTION

Stark disparities in health outcomes around the world highlight the consequences of unequal access to drugs, diagnostics, and vaccines. When comparing outcomes among populations both in and between countries, alarming evidence of that disparity emerges: for instance, a child born in Cambodia is over eighteen times more likely to die by the age of five than a child born in Iceland; among those in the lowest wealth quintile, that same risk is forty-three times greater.[1]

While advances in science have led to treatments, and even cures, for a number of health conditions, the poor all too often lack access to these innovations. For example, antiretroviral drugs (ARVs), which are used to control HIV infection by preventing the virus from multiplying, have shown impressive efficacy in suppressing and stopping the progression of HIV. However, 22 million (60%) of the 36.9 million people living with HIV globally did not have access to treatment in 2014.[2] In some cases, treatments are sold at prices that are out of reach for those living in poverty. For example, in Kuwait, the lowest-paid government employee must work eleven days to afford a seven-day course of treatment with the lowest-priced generic ciprofloxacin for a respiratory infection.[3] And while price can be a major obstacle limiting efforts to get lifesaving medicines to those who need them most, it is not the only one. In some markets, particularly in poor countries, drugs, diagnostics, and vaccines that are readily available in other parts of the world are not available at any price. Newer, targeted cancer treatments, for example, are often unavailable in low-income countries.[4] As barriers to access can result in death or diminished quality of life for patients, policy efforts must be aimed at addressing them.

Against that backdrop, I seek to explore two strategies with the potential to increase the availability of lifesaving medicines for the world's poorest

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1. For 2013, the under-five mortality rate in Cambodia was estimated to be 37.9 deaths per 1,000 live births, compared to the estimate of 2.1 deaths per 1,000 live births in Iceland. WORLD HEALTH ORG., WORLD HEALTH STATISTICS 2015 45, 47 (2015), http://apps.who.int/iris/bitstream/10665/170250/1/9789240694439_eng.pdf. For Cambodia's lowest and highest wealth quintiles, the under-five mortality rates were estimated at 91 and 30, respectively. *Id.* at 139.

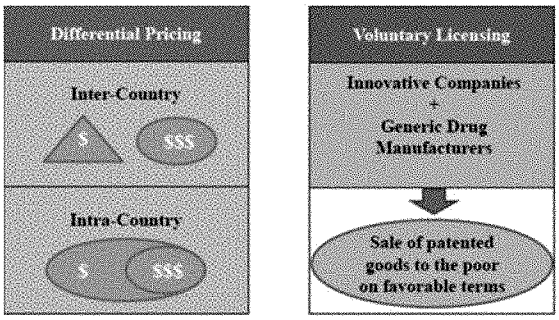
2. *See* UNAIDS, AIDS BY THE NUMBERS 2015 3, 5 (2015), http://www.unaids.org/sites/default/files/media_asset/AIDS_by_the_numbers_2015_en.pdf.

3. *See* ALEXANDRA CAMERON ET AL., WORLD HEALTH ORG., THE WORLD MEDICINES SITUATION 2011: MEDICINES PRICES, AVAILABILITY AND AFFORDABILITY 8–9 & fig. 1.4 (2011), http://apps.who.int/medicinedocs/documents/s20054en/s20054en.pdf.

4. *See* Lawrence N. Shulman et al., *Bringing Cancer Care to the Poor: Experiences from Rwanda*, 14 NATURE 815 (2014), http://www.nature.com/nrc/journal/v14/n12/full/nrc3848.html (noting the challenge in bringing targeted treatments to Rwanda).

populations: differential pricing and voluntary licensing (Figure 1). Differential pricing involves charging different prices to different people, for example by charging more for the same product in wealthier countries than is charged in poorer countries (*inter*-country differential pricing) or selling effectively the same product at two different prices in the same country (*intra*-country differential pricing). Voluntary licensing involves partnership agreements between innovative companies and generic manufacturers that allow the sale of patented goods to poor populations on favorable terms.

Figure 1. Schematic of Strategies to Increase Access: Differential Pricing and Voluntary Licensing



These two strategies are notably pragmatic; neither would require any modification of the complex web of national laws and international agreements that govern the production and distribution of pharmaceutical products, and both could be employed with greater frequency by pharmaceutical firms.

Before turning to these strategies, Section II offers a brief overview of the problem of access to medicines for the world's poorest populations, as well as a discussion of some of the goals and assumptions that guide the Global Access in Action (GAiA) project,[5] of which this Article is a part.

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5. Global Access in Action is a project of the Berkman Klein Center for Internet & Society at Harvard University that conducts action-oriented research into access to lifesaving medicines and alternative incentives for the development of medical treatments for underserved populations. *See Global Access in Action*, BERKMAN KLEIN CTR. FOR INTERNET & SOC'Y AT HARV. U., https://cyber.law.harvard.edu/research/globalaccessinaction (last updated July 5, 2016); *see also Access to Medicines*, GLOBAL ACCESS IN ACTION (2017), http://www.globalaccessinaction.org/access-to-medicines/. "On June 13, 2016, The Harvard Global Health Institute and the Berkman Center for Internet & Society brought together more than sixty leaders from the pharmaceutical industry, foundations, civil society, academia, and government for a conference to develop actionable solutions for increasing access to medicines and promoting innovation to help the world's poor." Molly McDonough & Ebba Mark, GLOB. ACCESS IN ACTION, WORKSHOP REPORT: INSIGHTS INTO ACTION: PRACTICAL STRATEGIES TO EXPAND ACCESS TO MEDICINE AND PROMOTE INNOVATION 1 (2016), http://www.globalaccessinaction.org/files/2016/07/FinalWorkshopReport.pdf. There were both public and private sessions at the workshop that fostered candid discussion of ongoing and new concerns, the

Section III explores differential pricing, a strategy commonly found in many categories of products, from books and airline tickets to soft drinks.[6] When applied to pharmaceuticals, charging different prices to different groups poses some practical challenges. This Article focuses on two of them: physical arbitrage and information arbitrage. Arbitrage is defined as the practice of both buying and selling a product to benefit from a difference in price. Physical arbitrage occurs when middlemen purchase lower-priced goods in bulk and resell them to the target market for the higher-priced goods, thereby eroding the market for higher-priced goods. Information arbitrage occurs when insurance companies or bulk purchasers such as governments, non-governmental organizations (NGOs), or large health care providers refuse to pay a price that is higher than the lowest known price of a comparable product. Reference pricing, which can be influenced by information arbitrage, refers to national programs that set reimbursement ceilings on classes of medicines sharing a therapeutic equivalence or chemical entity, based on a schema such as average prices of medicines or generics, lowest-priced medicines, averages of the lowest price medicines, or other weighting mechanisms based on costs within the class.[7]

Strategies for overcoming these challenges are explored, suggesting that intra-country differential pricing is underutilized and could lead to some win-win scenarios, particularly in middle-income countries (such as India, Brazil, Thailand, and the Philippines) where both poor and wealthy populations live side-by-side. Building on the experiences of several pharmaceutical companies that have experimented with this approach, I suggest ways in which physical arbitrage challenges can be mitigated or overcome with thoughtful program design.

Section IV explores a second strategy, which I refer to as voluntary licensing, in which patent owners permit others to sell their patented products—under favorable terms and subject to certain conditions—to facilitate distribution to impoverished populations. Consider, for example, Gilead Sciences, a pharmaceutical company that owns patents on certain ARVs for

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findings of cutting-edge experiments to increase access, and raised open questions. Key ideas and messages are summarized in the workshop summary now available freely online. *See id.*

6. *See* William W. Fisher III & Talha Syed, *Chapter 3: Differential Pricing*, *in* INFECTION: THE HEALTH CRISIS IN THE DEVELOPING WORLD AND WHAT WE SHOULD DO ABOUT IT (forthcoming 2017), http://cyber.law.harvard.edu/people/tfisher/Infection_Differential_Pricing.pdf; C.C., *Why Books Come out in Hardback Before Paperback*, ECONOMIST (Oct. 15, 2014), http://www.economist.com/blogs/economist-explains/2014/10/economist-explains-15; Allen Tran, *Introducing Premise's Coca-Cola Index*, PREMISE (Sept. 26, 2014), http://blog.premise.com/data/science/2014/09/26/introducing-premise-coca-cola-index/.

7. While a discussion of the existing mechanisms to assure bioequivalence and adequate manufacturing quality of brand name and generic drugs are outside the scope of this paper, it is worth noting these processes are neither universally implemented nor enforced. The implication is that substandard and counterfeit drugs, including antimicrobials, continue to be a significant global concern affecting access to medications with serious public health consequences including antimicrobial resistance. *See* Theodoros Kelesidis & Matthew E. Falagas, *Substandard/Counterfeit Antimicrobial Drugs*, 28 CLINICAL MICROBIOLOGY REVS. 443 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4402958/pdf/zcm443.pdf.

treating HIV/AIDS. Gilead has been commercially successful in selling its drugs in affluent countries. However, there are a number of countries in which Gilead is unlikely to make a profit from selling its drugs despite a large number of potential customers, because of the extreme poverty those potential customers face. These markets are often heavily dependent on donor programs. After several years of trial and error, Gilead developed a model of interaction with certain partners with capabilities to produce generic drugs that led to a win-win-win scenario for Gilead, the generic partners, and HIV/AIDS patients in some of the world's poorest countries: entering into geographically specific non-exclusive licensing deals with generic partners that allowed for the sale of Gilead's patented products in markets where Gilead was not likely to make money on its own. Where the generic partners succeeded in making a profit, Gilead received a small percentage of the earnings. From Gilead's perspective, this partnership program created at least the possibility of turning a profit in markets where the company had not planned to market its drugs. Even if the profit was negligible, the program allowed Gilead to run a highly-effective and much-praised corporate social responsibility program[8]—a program undertaken in order to promote social and environmental concerns—that essentially broke even. From the perspective of the generic manufacturers, it allowed for the marketing of patented drugs much earlier than would otherwise have been possible. Most importantly, from the perspective of HIV/AIDS patients in the world's poorest countries, this partnership program provided low-cost drugs that saved lives.

Gilead's model of non-exclusive voluntary licensing offers considerable promise for replication by other pharmaceutical companies seeking to run more sustainable and cost-effective corporate social responsibility programs that are similarly impactful in terms of increasing access to medicines.[9] This Article explores the circumstances under which voluntary licensing is likely to be an effective strategy and suggests that it is likely to work best (1) in the world's poorest countries, where there is not likely to be a significant market for the

8. *See Patents for Humanity Awards 2013—Medicines & Vaccines*, U.S. PAT. & TRADEMARK OFF. (Aug. 7, 2014), http://www.uspto.gov/page/patents-humanity-awards-2013-medicine.

9. This statement does not imply that drug donation programs ought to be discouraged, as there have been examples of laudable, sustainable, and successful drug donation programs, such as the notable example of the Mectizan Donation Program: "Merck and the Task Force for Child Survival and Development created value, commitment, and shared purpose through the use of common objects, people, and ideas. . . . These commonalities (which they constructed and then maintained) allowed the partners to create a successful collaboration—to span diverse social worlds and pursue the shared objective of treating onchocerciasis (river blindness) in poor countries with donations of ivermectin." LAURA J. FROST & MICHAEL R. REICH, ACCESS: HOW DO GOOD HEALTH TECHNOLOGIES GET TO POOR PEOPLE IN POOR COUNTRIES? 22 (2008), http://www.accessbook.org/downloads/AccessBook.pdf. One of the keys to the success of this Program was the establishment of long-term partnerships to ensure the stable supply, wide distribution, and administration of the drug. *See* CTR. FOR GLOBAL DEV., CASE 7: CONTROLLING ONCHOCERCIASIS IN SUB-SAHARAN AFRICA 1 (2007), https://www.cgdev.org/doc/millions/MS_case_7.pdf. The Mectizan Donation Program partnership has expanded to also provide albendazole for lymphatic filariasis. *See* MECTIZAN DONATION PROGRAM, http://www.mectizan.org/.

drug or vaccine in the near future, and (2) for disease categories in which there is considerable donor funding.

As an alternative to licensing arrangements, I suggest that pharmaceutical companies can also have a profound impact on humanitarian outcomes without undermining profitability by contributing unprofitable patents to patent pools—agreements between patent owners to license their patents to each other or to third parties—and to international humanitarian research efforts. Sometimes, a research path that does not lead to desired outcomes in one area can lay the groundwork for a breakthrough in another area. The research that led to the development of the "Post-It Note" initially sought to develop a strong adhesive, but it turned out that there were valuable commercial applications for a weak adhesive.[10] Likewise, the research that led to Viagra initially sought a treatment for cardiovascular disease.[11]

In this spirit, allowing researchers seeking cures for diseases that primarily affect the poor to access previously unavailable proprietary research materials (subject to confidentiality protections or non-disclosure agreements) may be a low-cost, high-reward method to confront problems of access. In cases without commercial justifications for maintaining secrecy around research that did not pan out, donating research to solve problems that disproportionately affect poor communities—and for which there are insufficient commercial incentives for optimal levels of research and development (R&D)—can be done without undermining competitiveness in commercial areas. This can be an extremely effective way for pharmaceutical companies to create positive impact.

Section V provides a summary of the Article's conclusions, as well as recommendations regarding further research to adapt the discussed strategies in different contexts, improve access to lifesaving medicines, and increase incentives for investment in R&D.

II. PATENTS, ACCESS, AND INCENTIVES

In seeking to develop policy recommendations for increasing access to medicines, a fundamental challenge is figuring out how to allow companies that develop medicines and vaccines to recoup the cost of R&D. Although the precise cost of undertaking R&D is widely debated, the amount is undeniably substantial.[12] Under most circumstances, the patent system creates incentives by allowing inventors who discover new and useful medicines to exclude

10. *See* Nick Glass & Tim Hume, *The 'Hallelujah Moment' Behind the Invention of the Post-It Note*, CNN (Apr. 4, 2013), http://www.cnn.com/2013/04/04/tech/post-it-note-history/index.html.

11. *See Discovered by Accident, Viagra Still Popular 10 Years Later*, FOX NEWS (Mar. 24, 2008), http://www.foxnews.com/story/2008/03/24/discovered-by-accident-viagra-still-popular-10-years-later.html.

12. One frequently cited study estimated the average cost in 2014 of developing a prescription drug that wins market approval was over $2.5 billion. HENRY G. GRABOWSKI & RONALD W. HANSEN, TUFTS CTR. FOR THE STUDY OF DRUG DEV., COST OF DEVELOPING A NEW DRUG (Nov. 18, 2014), http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf.

competitors from the market for a period of time, thus allowing them to charge higher prices than would be possible under competitive conditions. If the populations afflicted by a disease are willing and able to pay for the patented medicine, the inventor can recoup the costs of R&D during this period of exclusivity, providing an incentive to engage in research in the future.

This system works well in the context of diseases that afflict wealthy populations, in which willingness and ability to pay are adequate proxies for the societal value of the innovation. But the patent system (and the associated system of data exclusivity) does a poor job of incentivizing R&D of inventions that primarily afflict the global poor, as the end users lack the financial wherewithal to pay a "patent premium"—i.e., the difference between what the price would be in a competitive market and what it would be if the owner of the patent can exclude competitors for a period of time.

This creates two barriers to providing lifesaving medicines to those who need them most. First, prices that reflect a "patent premium" can be unaffordable even to those who desperately need medicine; "priced out of the market," many face stark choices between medicine and other necessities, sometimes with devastating results.[13] Second, unsolved research problems that primarily affect the global poor tend to receive suboptimal levels of R&D relative to problems that affect affluent populations; when there is not a pot of gold at the end of the rainbow, there tends to be less commercial investment in finding cures (e.g., Ebola, Zika, tuberculosis, malaria). Humanitarian activity can fill this gap to some degree, and a wide range of actors including pharmaceutical companies, philanthropies, NGOs, intergovernmental organizations (IGOs), and governments invest significant resources into these efforts, despite little hope of commercial profit. But the resources devoted to humanitarian R&D pale in comparison to the resources devoted to more lucrative areas of research—and they fall far short of what is needed to combat these problems on a global scale.[14]

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13. Research has highlighted the fact that out-of-pocket health care payments push households into financial catastrophe or extreme poverty, particularly in low- and middle-income countries. In 2005, the WHO estimated that 150 million individuals face catastrophic expenditures and 100 million individuals are pushed into poverty each year due to health care costs, impeding on ability to pay for education, food and clothing. *See* KE XU ET AL., WORLD BANK, DESIGNING HEALTH FINANCING SYSTEMS TO REDUCE CATASTROPHIC HEALTH EXPENDITURES 2 (2005), http://apps.who.int/iris/bitstream/10665/70005/1/WHO_EIP_HSF_PB_05.02_eng.pdf?ua=1. In India, researchers estimated that 70% of out-of-pocket health care expenditure is spent on drugs and medicines. *See* Charu C Garg et al., *Reducing Out-of-Pocket Expenditures to Reduce Poverty: A Disaggregated Analysis at Rural-Urban and State Level in India*, 24 HEALTH POL'Y & PLANNING 116 (2009), http://heapol.oxfordjournals.org/content/24/2/116.full. A study in the Philippines found that pharmaceuticals were found to comprise 64% of out-of-pocket health care costs. *See* Valerie Gilbert T. Ulep & Nina Ashley O. Dela Cruz, *Analysis of Out-of-Pocket Expenditures in the Philippines*, 40 PHILIPPINE J. OF DEV. 93, 99 (2013), http://dirp3.pids.gov.ph/webportal/CDN/PUBLICATIONS/pidspjd13-oop%20expenditures.pdf.

14. A recent example of an alternative funding mechanism designed to address investment shortages in diseases afflicting the poorest countries is the "Pandemic Emergency Financing Facility (PEF), an innovative, fast-disbursing global financing mechanism designed to protect the world against deadly pandemics." *See* Press Release, World Bank Grp., World Bank Group Launches

With the dual challenge of access and incentives in mind, I begin this Article with several assumptions:

(1) Important work is already being done. One of the most promising opportunities for policy interventions is to improve the effectiveness of existing humanitarian efforts by pharmaceutical companies (under either their corporate social responsibility programs or their business units), NGOs, philanthropic entities, governments, and IGOs.

(2) Innovation is a long-term investment. Efforts to increase the availability and affordability of lifesaving medicines should be structured to maintain or increase incentives to invest in the next wave of innovation—particularly regarding disease categories for which there are insufficient commercial incentives to invest in R&D because they disproportionately affect the global poor. Developing medicines and increasing access is a long-term challenge, and it is necessary to develop strategies that advance both goals in the short-term and the long-term.

(3) One size does not fit all. Strategies that offer promise in the world's poorest countries with respect to disease categories for which there is abundant donor financing (for example, combating HIV/AIDS in Sub-Saharan Africa) will not necessarily work equally well in countries where poor populations live side-by-side with more affluent populations or for disease categories for which there is a lack of donor funding. Thus, this Article begins to explore the circumstances under which particular approaches are more or less plausible.

(4) The private sector can and must be involved. We should seek strategies for increasing the availability and affordability of lifesaving medicines that are replicable, sustainable, and scalable. Instead of models that require the sustained coercion of commercial actors, we should explore both business models agreeable to for-profit companies that must answer to a board of directors and profit-seeking investors, as well as structures that rely on traditional humanitarian responses by NGOs, IGOs, and governments.

(5) Pragmatism is essential. While worthy of exploration, proposals that face significant practical challenges in this political environment—including dramatic legal changes and massive infusions of new resources—are beyond the scope of this Article.

Groundbreaking Financing Facility to Protect Poorest Countries against Pandemics (May 21, 2016), http://www.worldbank.org/en/news/press-release/2016/05/21/world-bank-group-launches-groundbreaking-financing-facility-to-protect-poorest-countries-against-pandemics.

III. DIFFERENTIAL PRICING

Differential pricing is the practice of setting different prices for different groups of potential buyers of the same product.[15] The ambition of this practice is to increase revenues—and reach more consumers—by adapting the prices of products to the purchasing power of buyers. Economists sometimes use the term "price discrimination" to refer to this phenomenon. While the term "discrimination" often has a pejorative connotation in other contexts, that is not intended here.

Charging different prices in different countries is commonly known as "inter-country differential pricing" or "inter-country price discrimination." Charging different prices to different populations within the same country is called "intra-country price discrimination."

Inter-country differential pricing is a common practice for many categories of products. A Coca-Cola is twice as expensive in Brazil as it is in China.[16] Intra-country differential pricing is also common. A hardcover book released in January costs about twice as much as paperback version with identical content released in June.[17] Similarly, passengers in first-class or business-class airplane seats pay much more than passengers who fly coach, and indeed, the difference in price far exceeds the monetary value of the additional benefits.[18] Moreover, passengers sometimes pay much more or much less for a seat than the passenger sitting next to them paid, depending solely on when, where, and from whom they bought their tickets.[19]

This section will first briefly discuss inter-country differential pricing in the context of pharmaceuticals before turning to a more in-depth discussion of intra-country differential pricing.

A. Inter-Country Differential Pricing

Many pharmaceutical companies charge different prices for the same products in different countries, most notably drugs for treating HIV/AIDS. Generally, these companies divide countries into a small number of "tiers" and then charge a single price per unit within that tier.

There are several methodologies for determining which countries fall into which tier. The prosperity of a country's population, as measured by the country's Gross National Income (GNI)—the total income earned by a country's population including both gross domestic product (GDP) and net

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15. *See* Rachel Sachs, Differential Pricing and Access to Medicines: Striving for an Ideal Solution, Harvard Law School Seminar in Law & Economics 3 (Mar. 7, 2013), http://isites.harvard.edu/fs/docs/icb.topic1133008.files/Sachs_Differential%20Pricing%20and%20Access%20to%20Medicines_2-24-13.pdf.

16. Tran, *supra* note 6.

17. *See* C.C., *supra* note 6.

18. Fisher & Syed, *supra* note 6.

19. *Id.*

income received from overseas—generally plays a key role; for example, a pharmaceutical firm may have one tier of pricing for the world's poorest countries, another for lower middle-income countries, and another for the rest of the world. Some companies also take into account the prevalence of the relevant disease category.[20] Consider, for example, Kaletra, an ARV for treating HIV that is marketed by Abbott Pharmaceuticals. At first, Abbott offered one price for African countries and sixteen other lower-income countries and another price for the rest of the world.[21] Starting in 2006, Abbott also introduced a second tier for forty lower middle-income countries.[22]

The use of tiers can indeed increase the accessibility of medicines by charging lower prices in poorer countries than the prices charged in wealthy countries. Novartis, for example, charges $40 per treatment for the antimalarial drug Riatem in wealthy countries, while charging under $2 for the same formulation, known as Coartem, in poorer, malaria-endemic countries.[23]

Defining appropriate tiers, however, can be difficult. Within each tier, some countries are wealthier than others, and deciding which countries fall within which tier can have dramatic consequences. For example, residents of Burundi (with a 2011 per capita GNI of $250) and residents of Equatorial Guinea (with a 2011 per capita GNI of $15,670) paid the same price for the HIV/AIDS drugs Viread and Truvada.[24] Residents of countries with GNIs that fall just outside of a particular tier often pay dramatically higher prices. For example, the 2006 price in Honduras for the ARV Kaletra was $7,775, compared to $500 in Sub-Saharan Africa.[25] Even when tiers can be defined that promote access to medicines in the short-term, inter-country differential pricing tiers are generally inferior to competition in attaining the lowest drug prices in the long-term.[26]

These and other challenges have led some scholars to conclude that inter-country differential pricing is an imperfect strategy for improving global access to medicines and achieving the lowest sustainable prices.[27]

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20. When this practice is used, a firm might offer heavily discounted prices in a country with a high prevalence of HIV/AIDS (for example), even if the county has a GNI that is slightly higher than that of other countries in the same price tier.

21. *See* SUERIE MOON ET AL., BIOMED CTR., A WIN-WIN SOLUTION?: A CRITICAL ANALYSIS OF TIERED PRICING TO IMPROVE ACCESS TO MEDICINES IN DEVELOPING COUNTRIES 4 (2011), http://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-7-39 (citing CARMEN PEREZ-CASAS ET AL., MSF ACCESS CAMPAIGN, ACCESSING ARVS: UNTANGLING THE WEB OF PRICE REDUCTIONS FOR DEVELOPING COUNTRIES (1st ed. 2001)).

22. *Id.*

23. *See* Cheri Grace, World Health Org., Equitable Pricing of Newer Essential Medicines for Developing Countries 34 (2003) (prepublication draft), http://apps.who.int/medicinedocs/documents/s18815en/s18815en.pdf.

24. Sachs, *supra* note 15, at 11.

25. MOON ET AL., *supra* note 21, at 4.

26. *Id.*

27. *Id.*

B. Intra-Country Differential Pricing

While most examples of differential pricing schemes have involved price differences between countries (particularly in the case of vaccines), there are also several examples of efforts to market drugs and vaccines at different prices to different populations within the same country.[28] Although the proprietary nature of research conducted by companies can make it difficult to assess the effectiveness of these strategies, several pharmaceutical companies have publicly experimented with intra-country differential pricing as a sustainable strategy for expanding access to medicines.[29] For example, the pharmaceutical company GlaxoSmithKline (GSK) has offered its vaccine for Hepatitis B, at different prices to the public and private sectors in low- and middle-income countries.[30] In India, GSK offered the vaccine to NGOs at around $1 per dose and to the private sector at around $2 per dose.[31] In Brazil, the public sector price was $0.58 per dose while the private sector price was $5 per dose, with several other price levels in between.[32]

Intra-country differential pricing is an especially promising option for middle-income countries that have both affluent and poor populations (such as India, Brazil, Thailand, and the Philippines).[33] Setting a single socially-responsible price in a country of this sort is especially difficult. On the one hand, the pervasive poverty and widespread disease burdens in such countries give credence to arguments that a lower price point would be appropriate. On the other hand, emerging markets also have affluent populations that are critical to the business plans of pharmaceutical companies. Unlike the world's poorest countries, where branded pharmaceutical companies have little hope of making significant profits in the near term, middle-income countries are essential to firms' long-term profitability.[34] Intra-country differential pricing provides a way of avoiding this dilemma; a firm can both preserve its profits and expand access by charging affluent consumers a high price and poor consumers a much lower price.

Intra-country differential pricing is a strategy worthy of greater attention and replication because a well-crafted program holds great promise for providing win-win outcomes for both the poorest populations and for commercial firms. Moreover, if implemented effectively, this strategy could

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28. *See* PRASHANT YADAV, DIFFERENTIAL PRICING FOR PHARMACEUTICALS: REVIEW OF CURRENT KNOWLEDGE, NEW FINDINGS AND IDEAS FOR ACTION (2010), http://apps.who.int/medicinedocs/documents/s18390en/s18390en.pdf.

29. *Id.*

30. *Id.* at 30.

31. *Id.*

32. *Id.*

33. YADAV, *supra* note 28, at 23–25.

34. *See, e.g.*, Patrick Hillmann & Meagan Bates, *The Future of the Pharmaceutical Industry is in Emerging Markets*, PHARMACEUTICAL COMPLIANCE MONITOR (Mar. 13, 2015), http://www.pharmacompliancemonitor.com/the-future-of-the-pharmaceutical-industry-is-in-emerging-markets/8719/.

also maintain or enhance the incentives for further research and development into disease categories that primarily affect the global poor.[35]

C. Challenges to Effective Intra-Country Differential Pricing

Two main challenges can impede implementation of an intra-country differential pricing approach: physical arbitrage and information arbitrage. This section considers each of these challenges in turn, as well as strategies that pharmaceutical companies have used, or could use, to overcome them.

1. Physical Arbitrage

The first challenge to effective intra-country differential pricing, known as "physical arbitrage," refers to a particular challenge faced when selling a high-priced product alongside a lower-priced product that is nearly identical: middlemen will purchase the lower-cost product in bulk and resell it to more affluent customers, thus undercutting the market for the higher-priced product.[36]

Governments can play a role in combating arbitrage by regulating distribution systems and strengthening border controls. For example, one reason that the volume of inter-country physical arbitrage—the diversion of drugs from countries with lower prices to countries with higher prices—is fairly low despite significant differences in prices between countries,[37] is that higher-income countries generally have strong border controls that prevent the illegal resale of drugs from other markets.[38] With respect to intra-country differential pricing, the absence of this crucial barrier—the border—makes arbitrage a more serious hazard.

Besides border controls, several strategies are available for combating physical arbitrage both within and between countries. One method implemented by several pharmaceutical companies is the use of different branding and packaging for drugs offered to different pricing tiers.[39] These changes alert distributors, consumers, and enforcers to the possibility of physical arbitrage.[40] For example, GSK has achieved success by changing the packaging and color of its tablets for differentially priced products.[41] Similarly, Bayer created four different brands of its contraceptive Microgynon.[42]

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35. The Appendix explores several examples of how intra-country differential pricing has been implemented in the past. *See infra* pp. 198–203.

36. *See, e.g.*, YADAV, *supra* note 28, at 39.

37. *See* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drugs Markets*, 5 YALE J. OF HEALTH POL'Y, L., & ETHICS 193, 262 (2005), http://digitalcommons.law.yale.edu/yjhple/vol5/iss1/4/ (noting that observed volumes of inter-country physical arbitrage are low, despite many years of differential pricing to large markets like India).

38. *Id.* at 265, 267.

39. *See* YADAV, *supra* note 28, at 27, 31, 40, 47–48.

40. *Id.*

41. *Id.* at 40, 47–48.

42. *See The Access to Medicines Index 2012: Bayer AG Company Profile*, ACCESS TO MEDICINE FOUND. 10 (Nov. 2012),

When more steps in the supply chain exist, pharmaceutical companies may have a more difficult time enforcing prohibitions against diversion.[43] Preventing product leakage—i.e., products exiting the supply chain into the hands of unauthorized middlemen—requires extensive efforts to strengthen all components of the supply chain.[44] Working with a group purchaser that has control of the distribution system can enhance the visibility of the supply chain and reduce risk.[45] International organizations can sometimes act as important partners in this respect. The WHO's support for Novartis's Malaria Initiative included monitoring leakage through a pharmacy survey.[46]

Another key factor is the choice of appropriate distributors. One possibility is to license particular distributors and terminate their licenses if they cannot prevent arbitrage. Some initiatives have used community health workers as distributors,[47] which can be especially effective in rural areas.[48] In Madagascar, for example, Population Services International (PSI) began distributing an antimalarial drug for children, ACTipal, via community health workers.[49] PSI would make the drug available to community health workers at a lower price, using different packaging than the ACTipal provided through private pharmacies.[50] These ACTipal blister packs were distributed first to specific intermediaries, including NGO offices, shops, and private individuals' offices, with the recommended price printed directly on the packaging to deter mark-ups.[51] Community health workers could then purchase the drug for distribution

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http://2012.atmindex.org/sites/www.accesstomedicineindex.org/files/company/downloads/company_profile_access_to_medicine_index_2012_27nov12_final_bayer.pdf [hereinafter Bayer Company Profile].

43. YADAV, *supra* note 28, at 39-40.

44. A related challenge for differential pricing schemes is the potential for the diversion of *customers* from the more profitable markets—i.e., situations in which a more affluent customer is able to take advantage of the lower price offered to the poor. Though not discussed at length here, a key strategy for overcoming this challenge is the selection of appropriate distribution channels. *See* YADAV, *supra* note 28, at 42–44. For example, using government-run pharmacies for distributing lower-priced drugs may be unlikely to attract higher-income consumers who are unwilling to wait in line or shift their business from the private pharmacies they generally use.

45. YADAV, *supra* note 28, at 47–48.

46. Grace, *supra* note 23, at 33.

47. Community health workers are frontline public health personnel who are members of the communities they serve. With a close understanding of their own communities, such workers are in a position to improve quality and cultural competence in health care delivery. *See* NAT'L CTR. FOR CHRONIC DISEASE PREVENTION & HEALTH PROMOTION, CTRS. FOR DISEASE CONTROL, POLICY EVIDENCE ASSESSMENT REPORT: COMMUNITY HEALTH WORKER POLICY COMPONENTS (2014), https://www.cdc.gov/dhdsp/pubs/docs/chw_evidence_assessment_report.pdf.

48. *See* Yasmin Chandani et al., *Making Products Available Among Community Health Workers: Evidence for Improving Community Health Supply Chains from Ethiopia, Malawi, and Rwanda*, 4 J. GLOBAL HEALTH 96, 97 (2014).

49. *See* SERGIO TORRES RUEDA ET AL., ACTWATCH, THE PRIVATE COMMERCIAL SECTOR DISTRIBUTION CHAIN FOR ANTIMALARIAL DRUGS IN MADAGASCAR: FINDINGS FROM A RAPID ASSESSMENT 10–11 (2012), http://www.actwatch.info/sites/default/files/content/publications/attachments/ACTwatch%20Mada%20report%20FINAL-SCR.pdf.

50. *Id.*

51. *Id.* at 11.

to the community.[52] This method of distribution can reduce the risk of arbitrage by giving community health workers a strong incentive to protect their supply of medicines.

Technological improvements in the supply chain can help mitigate arbitrage risks as well. For example, MPedigree and Sproxil sell software that allows firms to label individual packages of drugs with a scratch-off code.[53] The patient can then text the code to the company and receive a reply as to whether the product is genuine.[54] Sproxil has also developed software that allows companies to monitor products along each step in the supply chain by requiring each manufacturer and distributor to scan a barcode.[55] Though primarily employed as a means of combating counterfeit drugs, tools such as scratch-off codes and barcodes could serve to protect supply chain integrity in ways that would help firms, regulators, and other stakeholders prevent and detect diversion and physical arbitrage of legitimate products targeted towards lower-income tiers in an intra-country differential pricing regime. Cost remains an obstacle to widespread adoption of this approach, though it is possible that these technologies may become more affordable over time.

In addition, certain products are, by nature, less susceptible to arbitrage. GSK's success in implementing a tiered pricing scheme for its Hepatitis B vaccine is partially due to the special characteristics shared by many vaccines.[56] Requiring a continuous cold chain, vaccines are difficult to transport and sell outside of controlled environments.[57] Additionally, they are often administered through injection, requiring a health care provider's involvement.[58] These features render physical arbitrage more conspicuous and technologically challenging.[59] Intra-country differential pricing is thus particularly suited to vaccines and other injectable medicines.

In keeping with this observation, some companies have either changed the delivery method of a drug—for example, from a prepackaged syringe to a vial[60]—or packaged the drug with point-of-delivery services in order to reduce

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52. *Id.*

53. *See* Yepoka Yeebo, *The African Startup Using Phones to Spot Counterfeit Drugs*, BLOOMBERG (July 31, 2015), http://www.bloomberg.com/news/features/2015-07-31/the-african-startup-using-phones-to-spot-counterfeit-drugs; *see also About Us*, SPROXIL, https://www.sproxil.com/defender (last visited Feb. 24, 2017).

54. *See* Yeebo, *supra* note 53; *About Us*, *supra* note 53.

55. *See Sproxil Informer™*, SPROXIL, http://sproxil.com/track-trace.html (last visited Feb. 24, 2017).

56. *See* YADAV, *supra* note 28, at 30.

57. *Id.*

58. *Id.*

59. *Id.*

60. In its intra-country differential pricing model in Egypt, Roche shifted the delivery of Peginterferon from a pre-packaged syringe, which could be more conveniently administered by patients or transported, to vials, which were administered within the clinic. *See Improving Access to Hepatitis Treatment,* DEVEX IMPACT, https://www.devex.com/impact/partnerships/improving-access-to-hepatitis-treatment-552 (last visited Feb. 24, 2017).

its portability and thereby deter arbitrage.[61] These options, however, have the more obvious downside of creating additional hurdles to access in countries with shortages of health workers and resources.[62] Finally, creating several price tiers for a range of markets can reduce the price difference between adjacent markets, decreasing the incentives for physical arbitrage.[63] This strategy, however, can increase administrative complexity and costs.

2. Information Arbitrage

The second challenge faced by pharmaceutical firms seeking to engage in differential pricing is sometimes known as "information arbitrage," the concern that insurance companies or bulk purchasers such as governments, NGOs, or large health care providers will not be willing to pay a price that is higher than the lowest known price of a comparable product.[64] For example, if an insurance company knows that a drug company is charging some consumers within a certain jurisdiction $10 per month for a medication, $10 per month will become the ceiling on the amount the insurance company is willing to pay to reimburse for that medication.

This hazard is especially salient for pharmaceutical firms that must bargain with entities that engage in "reference pricing," tying the price a purchaser is willing to pay to the prices that others pay.[65] Many countries—including Canada, France, and Spain—use reference pricing to determine the prices they will pay for drugs.[66] At the most basic level, this means that they look to a set of other countries, determine what prices those countries pay for drugs, and use that information to negotiate with pharmaceutical companies.[67] Countries across the income spectrum use reference pricing, but generally refer to countries in their own income range.[68]

A variety of approaches to reference pricing have been adopted. In terms of setting prices, there are a number of different formulas on which countries rely.[69] Most countries using international reference pricing generally rely on the

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61. As discussed above, Novartis combines a monthly treatment for leprosy with a clinic visit to ensure compliance and reduce the risk of diversion. *See* YADAV, *supra* note 28, at 30–31.

62. *See* Shehla Zaidi et al., *Access to Essential Medicines in Pakistan: Policy and Health Systems Research Concerns*, 8 PLOS ONE 6–7 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3661571/pdf/pone.0063515.pdf.

63. Novartis used five different price tiers in its Coartem pricing model. *See* Adriana Benedict & William Fisher, Novartis's Coartem & the Malaria Initiative: Intra-Country Differential Pricing through Partnerships for Global Access 11 (July 28, 2014) (unpublished manuscript) (on file with author).

64. *See* YADAV, *supra* note 28, at 40–41.

65. *See* KAI RUGGERI & ELLEN NOLTE, RAND CORP., PHARMACEUTICAL PRICING: THE USE OF EXTERNAL REFERENCE PRICING 16 (2013), http://www.rand.org/pubs/research_reports/RR240.html.

66. *Id.* at xii.

67. *Id.*

68. *Id.*

69. Reference pricing that incorporates *international* price differences is known as external reference pricing (ERP), and it has been adopted by approximately thirty countries worldwide. *See* Cécile Rémuzat et al., *Overview of External Reference Pricing Systems in Europe*, J. MKT. ACCESS & HEALTH POL'Y 2 (2015), http://www.jmahp.net/index.php/jmahp/article/view/27675.

manufacturer's posted price of a drug, *not* the price at which it was ultimately sold.[70]

The most serious threats to differential pricing (both inter- and intra-) posed by reference pricing arise when a high-income country includes one or more lower-income countries in the "basket" of jurisdictions that are employed to set the price ceiling.[71] When that occurs, pharmaceutical firms are highly reluctant to reduce prices in the lower-income countries because they will be thereby forced to lower prices in the far more lucrative high-income country market.[72]

The hazard posed to differential pricing by reference pricing is entangled in a complex way with the question of the appropriate degree of transparency in pharmaceutical pricing. Recently, demands for greater transparency have been made with increasing urgency in many fora: in international organizations such as the World Health Assembly, which recently passed a resolution about transparency in vaccine prices;[73] in national governments around the world, which have generated legal mandates for price transparency; [74] in state legislatures, many of which are in the process of drafting legislation on the subject (e.g., New York's Pharmaceutical Cost Transparency Act); [75] in international trade agreements such as the Trans-Pacific Partnership Agreement;[76] and from individuals within the health care system, such as the 118 leading cancer experts who recently included measures to increase

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70. *See* David Henry & Andrew Searles, *Pharmaceutical Pricing Policy, in* MDS-3: MANAGING ACCESS TO MEDICINES AND HEALTH TECHNOLOGIES 9.18 (2012), http://apps.who.int/medicinedocs/documents/s19577en/s19577en.pdf.

71. *See* YADAV, *supra* note 28, at 40–41.

72. *Id.*

73. *See* Press Release, Médicins Sans Frontières, Governments Take Decisive Step Over Vaccine Prices (May 26, 2015), https://www.msfaccess.org/our-work/vaccines/article/2419; *cf.* David Ridley, *Price Differentiation and Transparency in the Global Pharmaceutical Marketplace*, 23 PHARMACOECONOMICS 651 (2005) (describing WHO efforts to promote price transparency for pharmaceuticals).

74. *See, e.g.*, Jillian Clare Kohler et al., *Does Pharmaceutical Pricing Transparency Matter? Examining Brazil's Public Procurement System*, 11 GLOBALIZATION & HEALTH 34 (2015); M.P. Stander et al., *A First Step Towards Transparency in Pricing of Medicines and Scheduled Substances*, 104 S. AFR. MED. J. 10 (2014).

75. *See* S. Res. 5338, 2015–2016 Leg., Reg. Sess. (N.Y. 2015), http://www.nysenate.gov/legislation/bills/2015/s5338. The New York legislation would require that companies provide "information regarding the total costs for each drug for: production; research and development; clinical trials and other regulatory costs; materials, manufacturing and administration; costs paid by other entities, including federal, state or other governmental programs; other costs to acquire the drug; total marketing and advertising costs; a cumulative annual history of the average wholesale price; total profits derived from the sale of the drug; and the total amount of financial assistance provided by the manufacturer, if available." *Id.; see also* S. Res. 1048, 189th Cong. (Mass. 2016); Andrew Pollack, *Drug Prices Soar, Prompting Calls for Justification*, N.Y. TIMES (July 23, 2015), http://www.nytimes.com/2015/07/23/business/drug-companies-pushed-from-far-and-wide-to-explain-high-prices.html.

76. *See* Andrew Mitchell et al., *Public Health and the Trans-Pacific Partnership Agreement*, 5 ASIAN J. INT'L L. 279 (2015); Deborah Gleeson et al., *How the Trans Pacific Partnership Agreement Could Undermine PHARMAC and Threaten Access to Affordable Medicines and Health Equity in New Zealand*, 112 HEALTH POL'Y 227 (2013).

transparency in a list of proposals to improve the U.S. health care system.[77] Transparency, advocates assert, would address the high cost of drugs and other problems, strengthening the position of consumers, generating price uniformity, and uncovering corruption and other bottlenecks in the market.[78]

While price transparency efforts can have a salutary effect in reducing opportunities for graft and corruption, some argue that heightened transparency may not be the best way to address concerns about drug prices, and that it may, in fact, prove detrimental to beneficial schemes.[79] Transparency reform could exacerbate problems of pricing by expanding price uniformity to the detriment of the poor,[80] weakening the incentives to develop medicines for illnesses experienced disproportionately in low- and middle-income countries,[81] and facilitating seller collusion.[82] The latter has been a particular concern in the antitrust field; the easier it is to obtain data on prices, economists have found, the easier it is for firms to determine and enforce a monopoly price.[83]

In theory, confidentiality can encourage competition and drive down prices by removing opportunities for collusion or parallelism among suppliers that may accompany published bid prices.[84] Just as competition and antitrust laws prohibit trade associations from serving as mechanisms for otherwise competitive entities to share contemporaneous and granular pricing data (for fear that it will limit competition and drive prices up),[85] there is a danger that well-meaning efforts to promote price transparency will have the perverse effect of driving prices up rather than down.

Transparency can pose a challenge to initiatives that rely to some extent on the lack of readily available pricing information, such as differential pricing.

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77. *See* Julie Steenhuysen, *Experts Support Call for Lower Cancer Drug Prices*, REUTERS (July 23, 2015), http://www.reuters.com/article/us-cancer-costs-protest-idUSKCN0PX0A220150723?.

78. *See* Margaret K. Kyle & David B. Ridley, *Would Greater Transparency and Uniformity of Health Care Prices Benefit Poor Patients*? 26 HEALTH AFF. 1384, 1385 (2007), http://content.healthaffairs.org/content/26/5/1384.full.

79. *See, e.g.*, KEVIN OUTTERSON, INT'L TRADE ADMIN., THE TRANSPARENCY REVOLUTION IN PHRMA PRICING 6-7 http://www.ita.doc.gov/td/health/phRMA/Outterson%20Response4.pdf.

80. Kyle & Ridley, *supra* note 78, at 1385.

81. *Id.*

82. *See id.* (citing George J. Stigler, *A Theory of Oligopoly*, 72 J. POL. ECON. 44 (1964)).

83. *See* MARC IVALDI ET AL., EUROPEAN COMM'N, THE ECONOMICS OF TACIT COLLUSION 26 (2003), http://ec.europa.eu/competition/mergers/studies_reports/the_economics_of_tacit_collusion_en.pdf; *see also* Edward J. Green & Robert H. Porter, *Non-Cooperative Collusion under Imperfect Price Information*, 52 ECONOMETRICA 87, 90 (1984); George J. Stigler, *A Theory of Oligopoly*, 72 J. POL. ECON. 44, 47–48 (1984).

84. *See Spotlight on Trade Associations*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/dealings-competitors/spotlight-trade (last visited Feb. 24, 2017) (noting that sharing historical rather than current data is less likely to raise antitrust concerns); *see also* Tara Isa Koslov & Elizabeth Jex, *Price Transparency or TMI?*, FED. TRADE COMM'N (July 2, 2015), https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi (describing FTC's position that full price transparency in health care context "might harm competition by enabling competing providers to coordinate or collude on price").

85. *Spotlight on Trade Associations*, *supra* note 84.

The efforts described above, as well as the increased availability of information via the Internet,[86] threaten the ability of pharmaceutical companies to offset the costs of providing products to low- and middle-income countries or lower-income communities by placing a heavier burden on other populations.[87] When products are comparable and the prices charged to poorer patients are easily ascertainable—when consumers become more aware that they are paying significantly more for medicines than others in their country or in neighboring countries—companies face downward pricing pressure in affluent markets and differential pricing schemes may no longer be feasible.[88] Thus price transparency efforts must be implemented carefully to avoid unintended consequences.

One way to maintain differential pricing while accommodating calls for greater transparency might be to promote "reasonable transparency"—that is, a system "establishing clear and consistent processes for negotiating contracts with relatively simple rebate structures and transparency to the public about the existence, purpose, and type of reimbursement contracts in place."[89] This approach maintains some level of opacity that may be helpful in the implementation of differential pricing schemes. Transparency measures that avoid mandating contemporaneous and granular pricing information are most likely to avoid unintended consequences.

Rebates, rather than discounts, provide another promising means of alleviating this tension. Confidential rebates to poor populations make it harder for other purchasers to observe the low prices granted to certain purchasers.[90] Discounts to lower-income countries or market segments can be structured as confidential rebates paid directly to ultimate purchasers. At the same time, wholesalers can be charged a common price or can act as distributors who do not own the product. In this way, pharmaceutical firms can make it harder for other purchasers to demand similar rebates.[91] This approach also prevents wholesalers or parallel traders from purchasing the product at the low price intended for lower-income countries and then exporting it to higher-price countries. Likewise, it prevents leakage of products between market segments within countries, confining discounts to the intended beneficiaries.

Another variant of this approach is to link discounts to a specific volume of use. If rebates are calculated and paid retrospectively (or via a fixed volume contract), it is difficult for other purchasers to take advantage of the lower price

86. *See* OUTTERSON, *supra* note 79, at 8.

87. *See* Kyle & Ridley, *supra* note 78.

88. *Id.*

89. Steven Morgan et al., *International Best Practices for Negotiating 'Reimbursement Contracts' with Price Rebates from Pharmaceutical Companies*, 32 HEALTH AFF. 771 (2013), http://content.healthaffairs.org/content/32/4/771.long.

90. *See id.*

91. *See* Patricia M. Danzon & Adrian Towse, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*, 3 INT'L J. HEALTH CARE FIN. & ECON. 183, 194 (2003).

offered for sale into poor communities as a means of negotiating lower prices in more affluent segments.[92]

Negotiated, confidential price discounts may provide the most efficient approach to achieving appropriate price differences, as long as bargaining is conducted by procurement agencies that can make price-volume commitments. Auditing could discourage corruption, assuring that some details are in the public domain without compromising the confidentiality of negotiations.[93]

This approach might be particularly successful if firms are willing to offer rebates or discounts to impoverished residents of wealthy countries as well. For example, because new drugs are so costly in high-income countries, pharmaceutical firms risk negative social pressure from patient groups in wealthier countries that cannot access the drugs.[94] The United Kingdom's National Institute for Health and Care Excellence (NICE), for instance, declined to approve Halaven due to its cost ineffectiveness, arguing that its ability to extend life for 2.7 months could not justify its cost.[95] Similar social pressure has surrounded Gilead's pricing of Hepatitis C drug Sovaldi at $84,000 for a full course in the U.S. as compared to $900 for a full course in India and Egypt.[96] In a recent breakthrough, the Medicaid program of Massachusetts, MassHealth, negotiated new rebates with Gilead and Bristol-Meyers Squibb to significantly lower the price of three Hepatitis C therapies.[97]

Where countries largely use the initial prices set by the manufacturer—not including rebates or discounts—to determine the reference price, structuring differential pricing through rebates or discounts can significantly mitigate the risk of information arbitrage.

Another way to decrease the risk of reference pricing undermining differential pricing efforts is to bundle medicines and the provision of services together.[98] For example, Novartis' rifampicin is used to treat leprosy on a monthly basis in combination with a daily dose of clofazimine and dapsone.[99] Rifampicin has a number of other indications more relevant than leprosy to higher-income markets—such as treatment of prosthetic joint infections,

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92. *Id.* at 194–95.

93. *Id.* at 196.

94. *See, e.g.*, Avik Roy, *The Sovaldi Tax: Gilead Can't Justify the Price It's Asking for Hepatitis C Therapy*, FORBES (June 17, 2014), http://www.forbes.com/sites/theapothecary/2014/06/17/the-sovaldi-tax-gilead-cant-justify-the-price-its-asking-americans-to-pay/.

95. Haalven is the brand name for eribulin, a drug used to treat breast cancer. *See* Janette Greenhalgh et al., *Eribulin for the Treatment of Advanced or Metastatic Breast Cancer: A NICE Single Technology Appraisal*, 33 PHARMACOECON. 137, 145, 147 (2015).

96. *See, e.g.*, Roy, *supra* note 94; *see also* Donald G. McNeil, *Curing Hepatitis C, in an Experiment the Size of Egypt*, N.Y. TIMES (Dec. 15, 2015), http://www.nytimes.com/2015/12/16/health/hepatitis-c-treatment-egypt.html.

97. *See MassHealth Implements New Drug Rebate Program, Expands Access to Hep C Treatment*, EXEC. OFFICE OF HEALTH & HUMAN SERVS., MASS.GOV (June 30, 2016), http://www.mass.gov/eohhs/gov/newsroom/press-releases/eohhs/masshealth-implements-new-drug-rebate-program.html.

98. YADAV, *supra* note 28, at 30–31.

99. *Id.*

osteomyletis, and tick-borne pathogens—but clofazimine and dapsone do not.[100] As a result, the risk of arbitrage is higher with respect to rifampicin than it is with respect to the other two drugs. To mitigate this risk, Novartis developed a system of service bundling; patients are given monthly supplies of clofazimine and dapsone and then return to the clinic once a month for their dose of rifampicin.[101] By offering the products and services as a package, the prices for each component remain hidden. As Prashant Yadav explains, this scheme "minimizes the risks of diversion of the rifampicin to higher priced markets and also ensures better clinical compliance."[102] Although effective in the leprosy context, this strategy is feasible only with regard to certain diseases and requires complex negotiations among a number of parties.[103]

A further serious challenge to intra-country differential pricing is that the elites of lower-income countries may resist efforts to segment the marketplace, as they would pay higher prices under a segmented approach than they would in a less differentiated pricing scheme. Unfortunately, this is a group that may also have disproportionate control over the legislative and regulatory processes that may need to be adjusted in order to make an intra-country differential pricing scheme work. For this reason, pharmaceutical firms that seek to engage in intra-country differential pricing may want to develop an affirmative strategy for early engagement with these elites.

3. 3D Printing: A Potential Game-Changer?

Finally, it is worth considering which disruptive technologies might alter the landscape of future price discrimination efforts. As mentioned previously, technological measures developed by MPedigree and Sproxil could be very useful in improving the integrity of supply chains, but truly disruptive advances may also be right around the corner.[104]

A notable example is that of 3D printing, a rapidly developing technology that could help improve access to medicine and alleviate price discrimination issues. In August 2015, the FDA approved the first 3D-printed drug, an epilepsy pill specially designed using 3D printing to ameliorate the process of oral drug administration.[105] Aprecia Pharmaceuticals, a company at the vanguard of 3D-printed pills, has received fifty patents for pharmaceutical applications related to

100. *Id.*
101. *Id.*
102. *Id.*
103. *See* ADRIAN TOWSE ET AL., OFFICE OF HEALTH ECON., DRUGS AND VACCINES FOR DEVELOPING COUNTRIES 15 (2011), https://faculty.fuqua.duke.edu/~dbr1/research/developing-Oxford.pdf.
104. *See supra* text accompanying notes 53–55.
105. *See* Hope King, *First 3D-printed Drug Approved by FDA*, CNN MONEY (Aug. 4, 2015), http://money.cnn.com/2015/08/04/technology/fda-3d-printed-drug-epilepsy/.

3D printing.[106] Others will likely follow. Although medical applications of 3D printing are still in their nascent stages, it is estimated that by 2020 they will comprise a $2.13 billion dollar industry.[107]

Researchers in the UK have ventured into what may be the future of pharmaceutical manufacturing with a "chemputer"—containing both laboratory equipment and chemical components—that can be programmed to produce individualized medications on demand.[108] If this technology becomes commonplace, doctors or pharmacists will provide individuals with algorithms that can be submitted into a 3D printer in order to produce medication.[109] These algorithms would contain information related both to the chemical inks necessary to produce the medication, as well as its molecular blueprints.[110] Of course, the existence of advanced technologies will not necessarily translate to their rapid or widespread dissemination in low-resource environments.[111] In many low- and middle-income countries, costs may remain prohibitive, along with other barriers such as health worker shortages or inadequate training.

If 3D printing of medicines does become widespread,[112] it could transform the distribution mechanisms of lifesaving medicines for better or for worse. On the one hand, it could help control the differential prices charged to different audiences, just as online purchasing of airplane tickets facilitated differential pricing in that market.[113] In particular, 3D printing could be a way to differentiate the price of a medicine among even more nuanced categories of people, as it could be possible to customize formulations and doses that might not otherwise be commercially viable. It could also facilitate the transmission of pharmaceuticals to remote areas; rather than requiring complex and costly shipments, drugs could be produced in comparably close proximity to these populations,[114] provided that raw materials and 3D printers were effectively distributed, operated, and maintained.

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106. *See ZipDose® Technology: A Revolution in Formulations*, APRECIA PHARMACEUTICALS, https://www.aprecia.com/zipdose-platform/zipdose-technology.php.

107. *See* Press Release, Markets and Markets, 3D Printing Medical Devices Market worth 2.13 Billion USD by 2020. (Sept. 2015), http://www.marketsandmarkets.com/PressReleases/3d-printing-medical-devices.asp.

108. *See* Oliver Wainwright, *The First 3D-Printed Pill Opens Up a World of Downloadable Medicine*, GUARDIAN (Aug. 5, 2015), http://www.theguardian.com/artanddesign/architecture-design-blog/2015/aug/05/the-first-3d-printed-pill-opens-up-a-world-of-downloadable-medicine.

109. *See* Emily Matchar, *The Future of 3D-printed Pills*, SMITHSONIAN (Aug. 20, 2015), http://www.smithsonianmag.com/innovation/future-3d-printed-pills-180956292/?no-ist.

110. *See, e.g.*, Dominic Basulto, *Why it Matters that the FDA Just Approved the First 3D-printed Drug*, WASH. POST (Aug. 11, 2015), https://www.washingtonpost.com/news/innovations/wp/2015/08/11/why-it-matters-that-the-fda-just-approved-the-first-3d-printed-drug/.

111. *See* Trudie Lang, *Advancing Global Health Research Through Digital Technology and Sharing Data,* 331 SCI. 714 (2011).

112. *See, e.g.*, Basulto, *supra* note 110.

113. Eric K. Clemons et al., *Price Dispersion and Differentiation in Online Travel: An Empirical Investigation,* 534 MANAGEMENT SCI. 535 (2002).

114. Timothy M. Rankin et al., *Three-dimensional Printing Surgical Instruments: Are We There Yet?*, 189 J. SURGICAL RES. 193 (2014).

On the other hand, there is a danger that new technologies could empower counterfeiters and unauthorized producers, or otherwise cause disruptions to the supply chain in ways that might undermine efforts to increase the poor's access to lifesaving medicines. For instance, hacking of 3D printers to acquire trade secrets could be a legitimate concern, which might limit settings in which they are used and the potential for more widespread use. Stability and cost of manufacturing ingredients and hardware might also be a concern that could limit adoption.

IV. VOLUNTARY LICENSING

Voluntary licensing—which authorizes a generic manufacturer to distribute a patented medicine in certain countries—is another strategy with underutilized potential to increase access to medicines for the world's poor in a replicable and sustainable way, by facilitating low-cost production of medicines for low-income populations. Licenses may be offered to generic manufacturers royalty-free or for small royalties, as has been done for several ARVs.[115]

This type of licensing can lead to win-win-win scenarios in which more poor people with serious diseases can afford lifesaving medicines, philanthropic funders can have a greater impact with their limited procurement budgets, and pharmaceutical companies can run corporate social responsibility programs that cost less—and potentially break even or make a modest profit—while dramatically increasing impact.[116]

Gilead Sciences' partnership-based model of voluntary licensing for its HIV/AIDS drugs offers an illustration of how this strategy can work. Gilead is structured somewhat differently from other pharmaceutical firms in that it has few employees and no manufacturing facilities in low- and middle-income countries.[117] In the early 2000s, the company sought to develop a distribution mechanism for its HIV/AIDS drugs.[118] Since the vast majority of the people living with HIV/AIDS live in low- and middle-income countries, affected individuals and local governments are not the primary purchasers of these drugs; rather, the primary purchasers tend to be philanthropic organizations, such as the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the Clinton HIV/AIDS Initiative (CHAI), the Global Fund, and UNITAID.[119]

Most of the pharmaceutical companies marketing HIV/AIDS drugs responded to this situation by offering tiered prices.[120] In the poorest countries with a high prevalence of HIV/AIDS, they typically charged no-profit, no-loss

115. *See* TAHIR AMIN, VOLUNTARY LICENSING PRACTICES IN THE PHARMACEUTICAL SECTOR: AN ACCEPTABLE SOLUTION TO IMPROVING ACCESS TO AFFORDABLE MEDICINES? 4 (2007), http://apps.who.int/medicinedocs/documents/s19793en/s19793en.pdf.

116. *See* V. KASTURI RANGAN & KATHARINE LEE, HARV. BUS. SCH. PUB. 9-510-029, GILEAD SCIENCES, INC.: ACCESS PROGRAM (2013), http://www.hbs.edu/faculty/Pages/item.aspx?num=37998.

117. *Id.* at 10.

118. *Id.* at 5.

119. *Id.*

120. *Id.*

prices.[121] In lower middle-income countries, these companies offered discounted prices that were slightly higher than the no-profit, no-loss prices offered in the world's poorest countries but that were below what they charged in affluent countries.[122]

Gilead experimented with a number of different models in addition to tiered pricing before settling on an unconventional structure that essentially involved dual distribution channels.[123] The first channel was a group of eleven distributors who sold Gilead's branded products in 130 low- and lower middle-income countries.[124] Gilead allowed this group to mark the drugs up 10% to 15% to cover costs.[125] The second channel involved non-exclusive partnerships with generic manufacturers, in which the generic companies paid Gilead a 5% royalty on sales.[126] Gilead offered non-exclusive licenses to these generic manufacturers that were geographically limited to low-income countries with high HIV/AIDS rates.[127]

Between 2006 and 2007, Gilead entered into thirteen non-exclusive license agreements with Indian generic firms to manufacture and distribute tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) in the form of active pharmaceutical ingredients, generic versions of Viread and Truvada, and other fixed-dose combinations containing the two compounds.[128] Gilead also entered into a similar non-exclusive license agreement with Aspen, the company's own branded distributor for Africa.[129]

Under this structure, licensees could sell their generic versions at prices of their own choosing in ninety-four countries, including India, South Africa, and Thailand.[130] In exchange, they paid royalties to Gilead equal to 5% on all sales.[131] Licensees could purchase the active pharmaceutical ingredients from either Gilead or one another and could therefore also sell them to other licensees.[132] To ensure quality, licensees were required to seek FDA tentative approval or WHO prequalification.[133] Gilead has recently launched a modified version of this program with respect to Hepatitis C drugs.[134]

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121. *Id.*

122. *See* RANGAN & LEE, *supra* note 116, at 5.

123. *Id.* at 7.

124. *Id.* at 2.

125. *Id.* at 2, 9.

126. *Id.* at 11.

127. *Id.* at 2.

128. *See* INT'L FED'N OF PHARMACEUTICAL MFRS. & ASS'NS, POLICY POSITION: VOLUNTARY LICENSES AND NON-ASSERT DECLARATIONS (2016), http://www.ifpma.org/wp-content/uploads/2016/03/IFPMA-Position-on-VL-and-Non-Assert-Declarations-18FEB2015.pdf.

129. *See* RANGAN & LEE, *supra* note 116, at 11.

130. *Id.* at 2, 11.

131. *Id.*

132. *Id.* at 11.

133. *Id.*

134. Most recently, Gilead has experimented with licensing products while they are still in the development pipeline in order to reduce delays in bringing products to lower-income countries. In 2014, Gilead entered into generic licensing agreements for the production of sofosbuvir and

The rationale for this program, now part of Gilead's "Access Partnerships" portfolio, was simple—provide the maximum amount of access without costing the company money.[135] From Gilead's perspective, this structure had several advantages: (1) Unlike its branded competitors who were engaged in more traditional tiered pricing, Gilead bore much less risk in connection with the distribution of its medicines in the poorest countries via its generic partnerships program—with the possible exception of some risk of physical arbitrage, which could be managed by contract (these licenses typically include terms that, for example, prohibit the manufacturers from exporting goods to middle-income countries, including China and Brazil[136]). (2) Unlike traditional corporate social responsibility programs that involve the donation of below-marginal-cost drugs under some circumstances,[137] the costs of Gilead's model were limited to administrative overhead.[138] (3) By contractually obligating its generic partners to pay 5% royalties on sales, the licensing strategy retained some limited revenue potential. Even if this revenue would never amount to much, Gilead

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ledipasvir/sofosbuvir for Hepatitis C to be sold in low-income countries for about $900 for a twelve-week treatment (as opposed to $84,000 in the United States). In 2015, Gilead expanded its Hepatitis C licensing agreements with Indian generic manufacturers to include an investigational compound (GS–5816) being evaluated as part of a single-tablet regimen with sofosbuvir for Hepatitis C. Once approved, the generic distribution will be available in 91 low- and middle-income countries that account for 54% of the global incidence of Hepatitis C. *See* Press Release, Gilead, Gilead Expands Hepatitis C Generic Licensing Agreements to Include Investigational Pan-Genotypic Agent (Jan. 26, 2015), http://www.gilead.com/news/press-releases/2015/1/gilead-expands-hepatitis-c-generic-licensing-agreements-to-include-investigational-pangenotypic-agent.

135. *See* RANGAN & LEE, *supra* note 116, at 13.

136. *See* Nathan Ford et al., *Tough Choices: Tenofovir, Tenders and Treatment*, S. AFRICAN J. HIV MED. 8, 9 (2008), https://www.msfaccess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/AIDS_article_TDFtenders Tx_ENG_2008.pdf; CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES, MEDICINS SANS FRONTIÈRES, UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS (2010), http://d2pd3b5abq75bb.cloudfront.net/2012/07/16/14/39/31/171/UTW_13_ENG_Jul2010.pdf.

137. On one hand, drug donation programs can suffer from two weaknesses: they will only continue for as long as the company is willing to continue donating the medicines free of charge, and they may be more likely to crowd out generic competitors that could further increase access and possibly offer a longer-term supply of the medication. Thus, compared to Gilead's voluntary licensing scheme, traditional donation programs can be more expensive and less sustainable for pharmaceutical companies seeking to expand access to medicines. For example, in 2011, Merck donated two million doses of its HPV vaccine to Rwanda over a three-year period. *See Financing HPV Vaccination in Developing Countries,* 377 LANCET 1554 (2011), http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(11)60622-3.pdf. Similarly, AstraZeneca will deliver up to a 90-day supply of medicine free of charge to qualified patients. *See Breast Cancer Action*, ASTRAZENECA DRUGS, http://archive.bcaction.org/index.php?page=astrazeneca (last updated Jan. 22, 2008) (discussing AstraZeneca's Patient Assistance Program); TOWSE ET AL., *supra* note 103. On the other hand, a strong argument in favor of drug donation programs is the idea that cost-sharing (even if considered minimal by some standards) could still be unaffordable to many populations and lead to difficulties with medication adherence and worse health outcomes. *See, e.g.*, Michael T. Eaddy et al., *How Patient Cost-Sharing Trends Affect Adherence and Outcomes: A Literature Review*, 37 PHARMACY & THERAPEUTICS 45 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/pdf/ptj3701045.pdf.

138. Hypothetically, the non-exclusive licensing of its patents in certain countries for a period of time is another cost, but as a practical matter, these were countries where Gilead had no realistic prospect of profitability in the near-to-middle term.

could hope eventually to cover the cost of administering the program, making the generic partnership program sustainable as a non-charitable endeavor. (4) Gilead's generic partnership program took advantage of the generic companies' comparative advantages in bulk production at a low cost.[139] In many cases, generic companies could produce so-called "small-molecule" drugs at considerably lower costs than U.S.-based multinationals.[140] (5) By providing licenses to multiple generic companies at once, Gilead created price competition that drove down prices over time.[141] The generic partnership model therefore avoids one of the major shortcomings of traditional tiered pricing models: the "stickiness" of set prices, which may continue without renegotiation even after market forces would otherwise naturally drive down prices and allow philanthropic purchasers greater purchasing power over time.[142] In combination, these advantages are substantial, suggesting that other firms should strongly consider greater use of this strategy.

A. Design Choices and Other Variants of Voluntary Licensing

Voluntary licenses vary widely, but can be roughly described along three dimensions: (1) whether the license is for a single drug or a "patent pool" of related medications; (2) how broad the scope of the market for the license is; and (3) how collaborative the relationship between the brand-name pharmaceutical company and the generic manufacturer is. Some of these design choices are dictated by the necessities of the drug, disease condition, or market.[143] Others can be selected to maximize the benefit or minimize the risk of the project.

1. Scope of License

The first defining feature of a voluntary license model is what product or products the license covers. Voluntary licenses applicable to a single drug can be helpful in many contexts, but there are shortcomings with regard to certain drugs—such as ARVs—that are usually combined with other drugs.

A patent pool is an agreement between different patent owners to pool their patents and license them, collectively, to each other or to third parties.[144] These pools can be an important form of voluntary licensing, offering the benefits of scale and uniformity for generic companies seeking voluntary licenses for

139. *See* RANGAN & LEE, *supra* note 116, at 11.

140. *Id.* at 12.

141. *Id.*

142. *See* MOON ET AL., *supra* note 21, at 2.

143. *See* AMIN, *supra* note 115.

144. *See* WORLD INTELLECTUAL PROP. ORG., PATENT POOLS & ANTITRUST: A COMPARATIVE ANALYSIS 3 (Mar. 2014), http://www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf.

multiple compounds.[145] They can help facilitate the development of combination and second-line treatments by making multiple patents available to generic firms through a single license, thereby minimizing transaction costs.[146] They also encourage collaboration in the development of combination products by making all the patents in the pool available to any contributing firm.[147] As a result, patent pools can be particularly effective in addressing the need for pediatric and heat-stable formulations of HIV/AIDS medications.

Vitamin A-enriched "Golden Rice" provides a relevant example of a patent pool in the agricultural context. This genetically engineered variety offers biosynthetic beta-carotene to be grown and eaten in areas where vitamin A deficiency—which kills approximately 2.7 million children under the age of five every year—is prevalent.[148] Although developed in part with public funding, about thirty companies had owned around forty-five patents in connection with Golden Rice.[149] Private patent holders licensed their patents to Syngenta, which in turn licensed the patents royalty-free to research organizations in low- and middle-income countries.[150] Farmers who earn less than $10,000 per year from their Golden Rice sales do not need to pay royalty; those with higher sales must obtain a commercial license from Syngenta.[151]

In 2010, UNITAID founded the Medicines Patent Pool to facilitate the creation of fixed-dose combinations for ARVs.[152] The organization invited patent owners to contribute their patents to encourage the development of new treatments for HIV, Hepatitis C, and tuberculosis.[153] To date, seven different patent owners have licensed twelve ARVs and one Hepatitis C antiviral to the patent pool.[154] The Medicines Patent Pool has, in turn, sublicensed the patents to fourteen generic manufacturers, enabling the production of a variety of combination and pediatric formulations.[155] Along with other ventures, the pool has given rise to the Pediatric HIV Treatment Initiative for the development of

145. *Id.* at 13.

146. *Id.* at 9.

147. *See id.* at 17 n. 71.

148. *See Vitamin A Deficiency-Related Disorders (VADD)*, GOLDEN RICE PROJECT, http://www.goldenrice.org/Content3-Why/why1_vad.php (last visited Feb. 25, 2017).

149. Amanda L. Brewster et al., *Facilitating Humanitarian Access to Pharmaceutical & Agricultural Innovation*, *in* CONCEPT FOUND., IPHANDBOOK OF BEST PRACTICES 47, 48 (2007), http://www.iphandbook.org/handbook/chPDFs/ch02/ipHandbook-Ch%2002%2002%20Brewster-Hansen-Chapman%20Humanitarian%20licensing.pdf.

150. *Id.*

151. *Id.*

152. *See* MEDICINES PATENT POOL, PROGRESS AND ACHIEVEMENTS OF THE MEDICINES PATENT POOL 2010–2015, 1 (2015), http://www.medicinespatentpool.org/wp-content/uploads/WEB_Progress_Report_2015_EN.pdf.

153. *See About the MPP*, MEDICINES PATENT POOL, http://www.medicinespatentpool.org/about/ (last visited Feb. 25, 2017).

154. *Id.*

155. *Our Work: Sub-Licensees*, MEDICINES PATENT POOL, http://www.medicinespatentpool.org/ourwork/current-sub-licensees/ (last visited Feb. 25, 2017).

pediatric fixed-dose combinations needed in low- and middle-income countries.[156]

The BIO Ventures for Global Health (BVGH) patent pool was also founded in 2010 with molecular compounds and process patents contributed by GSK and RNAi patents as well as technology contributed by Alnylam Pharmaceuticals.[157] The BVGH patent pool offers royalty-free, non-exclusive licenses to qualified participants for "research, development, manufacture and export of therapeutics for the sixteen major [neglected tropical diseases] as identified by the US FDA for sales into [least developed countries] as defined by the United Nations."[158]

In 2009, GSK and Pfizer established a specialized HIV company, ViiV Healthcare, in an effort to increase access to ARVs in low- and middle-income countries.[159] Shionogi later became a shareholder as well.[160] At the time of ViiV's creation, GSK transferred to the organization eight licenses for ARV production that it had previously issued to Indian, Kenyan, and South African generic firms.[161] Today, ViiV functions as a kind of patent pool with access to the HIV research and expertise of all three of its shareholder firms, allowing it to coordinate the development of more effective HIV treatments.[162]

As these examples demonstrate, patent pools can be preferable to a series of bilateral voluntary licensing arrangements in the context of combination therapies or where the relevant intellectual property is owned by multiple entities. Patent pools may also be more attractive to generic licensees, offering more potential revenue and incentives to invest in manufacturing and distribution infrastructure, which may be particularly valuable for newer players.[163] However, patent pools can be challenging to organize because they involve multiple stakeholders.[164]

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156. *See* MEDICINES PATENT POOL, *supra* note 152, at 1.

157. *See* Press Release, Alnylam Pharm., Inc., BIO Ventures for Global Health Chosen as Administrator of Intellectual Property Pool Involving GSK and Alnylam as Participants (Jan. 20, 2010), http://files.shareholder.com/downloads/ABEA-430HSO/3846655684x0x358426/3D2787C4-97DC-4D95-A542-78A2E19C9974/ALNY_News_2010_1_20_General_Releases.pdf.

158. *See* Esther van Zimmeren et al., *Patent Pools and Clearinghouses in the Life Sciences*, 29 TRENDS IN BIOTECHNOLOGY 569, 571 (2011).

159. *See* Press Release, ViiV Healthcare, ViiV Healthcare Announces a Voluntary License Agreement with the Medicines Patent Pool to Increase Access to HIV Medicines for Children (Feb. 27, 2013), http://www.viivhealthcare.com/media/press-releases/2013/february/viiv-healthcare-announces-a-voluntary-licence-agreement-with-the-medicines-patent-pool-to-increase-access-to-hiv-medicines-for-children.aspx.

160. *See* Press Release, ViiV Healthcare, Shionogi and ViiV Healthcare Announce New Agreement to Commercialise and Develop Integrase Inhibitor Portfolio (Oct. 28, 2012), https://www.viivhealthcare.com/media/press-releases/2012/october/shionogi-and-viiv-healthcare-announce-new-agreement-to-commercialise-and-develop-integrase-inhibitor-portfolio.aspx.

161. *See* INT'L FED'N OF PHARMACEUTICAL MFRS. & ASS'NS, *supra* note 128.

162. *See Who We Are*, ViiV HEALTHCARE, https://www.viivhealthcare.com/about-us/who-we-are.aspx (last visited Feb. 25, 2017).

163. *See* WORLD INTELLECTUAL PROP. ORG., *supra* note 144.

164. *Id.*

2. Market Definition

The second design choice in creating a voluntary license model is the identification of the market covered by the license. Most include a geographic scope defined by national boundaries.[165] Pharmaceutical companies may be inclined to target lower-income countries for voluntary licenses because those markets represent areas where the companies are unlikely to sell products themselves in the near future.[166] However, this approach is controversial because middle-income countries also have large poor populations that do not have access to essential medications, and those countries may protest their exclusion from voluntary licenses.[167] Médecins Sans Frontières criticized Johnson & Johnson for some of its market definition choices, arguing that the company left too many impoverished people outside of the program's scope.[168] At the same time, a generic licensing program that includes commercially viable markets runs the risk of cannibalizing a commercial firm's markets in low- and middle-income countries and undermining that firm's business models.[169]

To address this challenge, intra-country differential pricing may offer a better solution than voluntary licensing in lower middle-income countries where affluent populations and impoverished populations live side by side. Another possibility is to experiment with intra-country segmentation of voluntary licensing, restricting generic partners from marketing their products in certain geographic areas within a country to certain populations or to certain distribution channels (e.g., via public health workers). To my knowledge, no such experiment has been attempted to date.

It is also important to emphasize the dynamic nature of these markets. The affluent populations within poor and middle-income countries may grow over time, making it possible to sell non-subsidized drugs in countries that previously would not have been commercially viable. The hope that this will occur could act as an obstacle to voluntary licensing, if pharmaceutical firms are reluctant to surrender patent rights to generic partners in markets that are not commercially viable but may become so in the future. One possible strategy is to allow licenses to phase out or be reconsidered at intervals set in advance, or to include in the license agreements certain triggers relating to the economic growth of the target market.

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165. *See* AMIN, *supra* note 115, at 3, 14.

166. For example, the BIO Ventures for Global Health patent pool is restricted to least-developed countries, as defined by the United Nations. *See* Zimmeren et al., *supra* note 158, at 571.

167. *See* AMIN, *supra* note 115, at 14, 18; *see The Medicines Patent Pool/Gilead Licences: Questions and Answers*, MEDICINES PATENT POOL, http://www.medicinespatentpool.org/current-licences/the-medicines-patent-poolgilead-licences-questions-and-answers/ (last visited Feb. 25, 2017).

168. *See* Press Release, Access Campaign, Médicins Sans Frontières, Johnson & Johnson / Tibotec AIDS Drug Licenses Leave Out Too Many Patients (Jan. 28, 2011), www.msfaccess.org/about-us/media-room/press-releases/johnson-johnson-tibotec-aids-drug-licenses-leave-out-too-many.

169. *See* AMIN, *supra* note 115.

3. Relationship Between Licensor and Licensee

A third key task in designing a voluntary license is to define the relationship between the patent holder and the generic licensee. In its simplest form, a voluntary license can declare a patent holder's intention not to assert its patent rights under certain conditions.[170] For example, patent holders pledging patents to the Eco-Patent Commons essentially declared that the public at large could use their innovations without restriction.[171] Once pledged, the patents were made available to the public at large through the online Patent Database.[172]

Many voluntary licenses will, however, include various restrictions on the use of the patent. These might consist of provisions for the maintenance of quality and safety standards for any manufacturer using the intellectual property.[173] Often, conditions related to geographic scope, quality standards, and qualifications for generic manufacturers are included.[174] Another possibly useful provision for the patent-holder is a guarantee regarding the maintenance of supply chains and/or efforts to combat arbitrage.

Bristol-Myers Squibb is an example of a company that has engaged in more in-depth licensing agreements. In 2006, the company entered into a deal with generic companies in South Africa and India regarding the production of atazanavir (Reyataz), an ARV.[175] Bristol-Myers Squibb provided not only a royalty-free license, but also a full transfer of the technology required to manufacture and test the drug, including personnel training.[176] One of the generic companies, Emcure, obtained tentative approval from the FDA for its version of atazanavir by 2008 and for its own co-formulation of atazanavir and a boosting agent in 2014.[177] In 2011, Bristol-Myers Squibb entered into a similar agreement with the Brazilian government to transfer atazanavir manufacturing and distribution capabilities to a public pharmaceutical laboratory and a local manufacturer.[178] This license enabled the Brazilian

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170. *About the Eco-Patent Commons*, ECO-PATENT COMMONS, https://ecopatentcommons.org/about-eco-patent-commons [https://perma.cc/Y73F-7TWV] (last visited Feb. 26, 2017).

171. *Id.*

172. *Id.*

173. *See Intellectual Property and Patient Access,* GILEAD SCI. INC. (Oct. 2014), https://www.gilead.com/~/media/files/pdfs/policyperspectives/intellectual%20property%20and%20patient%20access%20%201022141.pdf?la=en.

174. *Id.*

175. *See Patents, Licensing and Technology Transfer: Working with Generic Companies and Other Partners*, BRISTOL-MYERS SQUIBB, http://www.bms.com/responsibility/access-to-medicines/Pages/patents-licensing-technology.aspx (last visited Feb. 25, 2017).

176. *Id.*

177. *Id.*

178. *Id.*

government to build the capacity necessary to become the sole supplier of atazanavir in Brazil.[179]

Another design choice related to the licensor/licensee relationship is whether the license should be exclusive or non-exclusive. In 2011, Johnson & Johnson's Tibotec Pharmaceuticals granted several non-exclusive licenses to Indian and South African generic manufacturers to market and distribute rilpivirine hydrochloride both as a single agent and as part of a fixed-dose combination.[180] The Indian firms were given rights to market in Sub-Saharan Africa, in the lowest income countries and in India, whereas the South African firm was only given rights to market in Sub-Saharan Africa.[181]

This approach—offering multiple non-exclusive licenses to a group of generic manufacturers—can have the benefit of promoting competition and bringing down prices.[182] There may, however, be some practical limitations to its use. It shows greatest promise where there is an established market for the drug at issue: In the case of HIV/AIDS drugs, this successful approach was facilitated by the presence of significant donor funding from PEPFAR, UNITAID, CHAI, and the Global Fund, among others.[183] Outside the context of disease categories for which there is significant donor funding, non-exclusive licenses to multiple generic manufacturers may be more difficult to implement.[184] Additionally, some licensing arrangements may require a high degree of technology transfer to—and capacity building for—the generic licensee.[185] Some brand-name pharmaceutical firms may be reluctant to make such an investment in multiple generic manufacturers.[186]

Pharmaceutical companies that traditionally manufacture and distribute medicines in-house may be particularly reluctant to enter into multiple non-exclusive licensing arrangements with generic manufacturers for cultural or practical reasons. Gilead is unusual in that it has a relatively small personnel headcount and few manufacturing facilities abroad.[187] For this reason, voluntary licensing is not a fundamental shift in its business model. Patent holders with more traditional manufacturing and distribution structures may be more hesitant

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179. *Id.*

180. *See* Press Release, Johnson & Johnson, Tibotec Signs Multiple Agreements with Generic Manufacturers to Provide New HIV Treatment (Jan. 27, 2011), http://www.investor.jnj.com/releasedetail.cfm?releaseid=545920.

181. *Id.*

182. *See The Impact of Patents on Access to Medicines*, ACCESS CAMPAIGN, MEDICINS SANS FRONTIÈRES, http://www.msfaccess.org/our-work/overcoming-barriers-access/article/1360 (last visited Feb. 25, 2017).

183. *See* Lara Stabinski, Off. of the U.S. Global AIDS Coordinator, *Financial Resources for HIV: PEPFAR's Contributions to the Global Scale-up of Treatment*, WORLD HEALTH ORG. (Nov. 5, 2012), http://www.who.int/hiv/amds/1-PP12.pdf?ua=1.

184. See Brewster et al., *supra* note 149, at 53.

185. See WORLD INTELLECTUAL PROP. ORG., *supra* note 144, at 13–14.

186. Relatedly, some generic manufacturers have complained that the technology transfer required by voluntary licenses is often insufficient, requiring them to undertake additional lab work to produce the drugs. *See* AMIN, *supra* note 115, at 13–14.

187. Rangan & Lee, *supra* note 116, at 6–7.

to give away the associated expertise and potential revenue to generic manufacturers in low- and middle-income countries. For these firms, choosing a single generic partner and even taking an ownership stake in that partner may be more in-line with their organizational dynamics and strategic priorities. On the other hand, this approach may exert less downward pressure on drug prices than multiple non-exclusive licenses.[188]

Because exclusive licenses carry a higher risk that the product will be priced out of reach for many consumers, brand-name companies entering into exclusive licenses may want to include provisions in license agreements guaranteeing a reasonable price. One challenge posed by this approach is that defining the appropriate price in advance will be difficult; it may also be necessary to incorporate a method of reevaluating price over time.

B. Non-Assert Declarations

As an alternative to voluntary licenses, several firms have also offered non-assert declarations: commitments not to enforce certain patents in a defined group of countries.[189] As with voluntary licenses, non-assert declarations may be accompanied by technology transfer agreements or require generic manufacturers to meet certain quality standards in order to be covered.[190] Some firms have taken these declarations a step further by halting all patent filing and enforcement in lower-income countries.[191]

For example, Boehringer Ingelheim has offered non-assert declarations to all WHO pre-qualified manufacturers for nevirapine in low-income countries and African countries.[192] Roche has issued non-assert declarations accompanied by technology transfer agreements allowing generic firms to manufacture its second-line ARVs, and it has halted patent filing for its ARVs in Sub-Saharan Africa.[193] Bristol-Myers Squibb has instituted twelve non-assert agreements with African and Indian generic companies for the production of stavudine and didanosine and four agreements for the production of atazanavir, as well as a general non-enforcement policy for its patents on ARVs in sub-Saharan

188. *Id.* at 14; *see also Boehringer Ingelheim Grants South African Generic Drug Company License to Produce Nevirapine,* KAISER HEALTH NEWS (Oct. 16, 2002), http://khn.org/morning-breakout/dr00014052/ (noting that advocates criticized the exclusive license "not go[ing] far enough" because the deal "[gave] Aspen a monopoly on the generic version of the drug," making it less likely to reduce prices).

189. *See* INT'L FED'N OF PHARMACEUTICAL MFRS. & ASS'NS, *supra* note 128.

190. *Id.*

191. *See* Liza P. Viana, *Big Pharmaceutical Firms Say MDGs Partnerships Are 'Best-Kept Secret,'* INTELL. PROP. WATCH (Sept. 27, 2013), http://www.ip-watch.org/2013/09/27/big-pharmaceutical-firms-say-mdgs-partnerships-are-best-kept-secret.

192. *See* Press Release, Boehringer Ingelheim, Boehringer Ingelheim Increases Access to the Medication for the Treatment of HIV/AIDS (May 26, 2016), https://www.boehringer-ingelheim.com/press-release/boehringer-ingelheim-increases-access-medication-treatment-hivaids.

193. *See* INT'L FED'N OF PHARMACEUTICAL MFRS. & ASS'NS, *supra* note 128.

Africa.[194] In 2011, the company entered into a non-assert agreement allowing Matrix Laboratories to manufacture pediatric formulations and obtain WHO prequalification for them, so that procurement organizations could purchase them with funding from UN agencies, PEPFAR and the Global Fund.[195] Novartis has an especially broad non-assert policy, pledging not to enforce the patents on any of its products in the lowest-income countries.[196]

C. Donation of Research, Patents, and Medicines

Pharmaceutical companies can also have a profound impact on humanitarian outcomes without undermining profitability by contributing unprofitable patents to patent pools and unsuccessful research data to international humanitarian research efforts. False starts or research paths that do not lead to desired outcomes in the intended area could lay the groundwork for a breakthrough in another area. Numerous inventions—including Viagra, Listerine, Propecia, Brandy, Coca-Cola, Play-Doh,[197] and Post-It Notes[198]—emerged from research intended to solve entirely different problems.

Allowing researchers seeking cures for diseases that primarily affect the poor to have access to previously unavailable proprietary research materials may be an effective but low-cost method for contributing to efforts to solve global health challenges. To the extent that this research material is still hypothetically commercially valuable, confidentiality protections or non-disclosure agreements could mitigate risk.

For example, Novartis received a 2015 Patents for Humanity Award recognizing its decision to license certain compounds discovered at the Novartis Institutes for Tropical Diseases to the Global Alliance for TB Drug Development.[199] The donated research included a class of drugs called indolcarboxamides that had shown impressive efficacy and safety profiles in fighting multidrug-resistant strains of tuberculosis.[200] More broadly, the WIPO Re:Search Program provides a searchable public database of available intellectual property assets and resources, allowing researchers seeking cures

194. *Patents, Licensing and Technology Transfer: Working with Generic Companies and Other Partners*, *supra* note 175.

195. *Id.*

196. *See Innovative Pricing*, NOVARTIS, https://www.novartis.com/about-us/corporate-responsibility/expanding-access-healthcare/innovative-pricing.

197. *See* Haley S. Edwards, *6 Hugely Successful Products Originally Invented for Something Else*, MENTAL FLOSS (Jan. 26, 2012), http://mentalfloss.com/article/29840/6-hugely-successful-products-originally-invented-something-else.

198. *See* Glass & Hume, *supra* note 10.

199. *See* Press Release, Novartis, Novartis Receives US Patent and Trademark Office 2015 'Patents for Humanity' Award (Apr. 14, 2015), http://3blmedia.com/News/Novartis-Receives-US-Patent-and-Trademark-Office-2015-Patents-Humanity-Award.

200. *Id.*

for neglected tropical diseases, tuberculosis, and malaria to access valuable research tools and patents that may support their work.[201]

These efforts are especially important when there are insufficient commercial incentives for pharmaceutical companies to engage in R&D. Pfizer, for example, has recognized the importance of research collaboration with respect to diseases that are rare in the general population.[202] In November 2012, the company announced collaboration with the Cystic Fibrosis Foundation Therapeutics Inc. to develop new drugs for patients with cystic fibrosis.[203] It has also worked with the CHDI Foundation to develop drugs that will slow the progression of Huntington's disease.[204]

Like rare diseases, diseases that affect the global poor are likely to be the subject of insufficient commercial R&D.[205] Supporting and facilitating research and collaboration efforts may be a high-value—yet fairly low-cost and low-risk—way for patent holders to contribute meaningfully to important, but under-resourced, research efforts.[206]

V. CONCLUSION AND RECOMMENDATIONS

The problem of access to medicines is pressing, but it is not new; worldwide efforts to expand access reach back decades. Tapping into the years of experience shared among pharmaceutical companies, international organizations, governments, and academics—as well as considerations of legal frameworks and anticipation of future outbreaks and technological innovations—provides enormous insight into what works and what does not. In this Article, I have focused on approaches to expand access to medicines that are demonstrated to be particularly replicable and sustainable: differential pricing and voluntary licensing. Broader implementation of these strategies

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201. *See About WIPO Re:Search*, WORLD INTELLECTUAL PROP. ORG., http://www.wipo.int/research/en/about/ (last visited Feb. 25, 2017).

202. Catherine Shaffer, *Pfizer Explores Rare Disease Path,* 28 NATURE BIOTECHNOLOGY 881, 881–82 (2010).

203. *See Cystic Fibrosis Foundation Therapies Announces $58 Million CF Drug Discovery Agreement with Pfizer,* CYSTIC FIBROSIS FOUND. (Dec. 21, 2012), https://www.cff.org/News/News-Archive/2012/Cystic-Fibrosis-Foundation-Therapeutics-Announces-$58-Million-CF-Drug-Discovery-Agreement-with-Pfizer.

204. *See Meet the Company: Pfizer,* HUNTINGTON STUDY GROUP, http://huntingtonstudygroup.org/hd-insights/meet-the-company-4 (last visited Feb. 25, 2017).

205. Peter von Philipsborn, et al., *Poverty-Related and Neglected Diseases—an Economic and Epidemiological Analysis of Poverty Relatedness and Neglect in Research and Development,* 8 GLOBAL HEALTH ACTION 1 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4306754/pdf/GHA-8-25818.pdf.

206. *Cf.* William Fisher & Quentin Palfrey, *Inside Views: Learning from Ebola*, INTELL. PROP. WATCH (July 14, 2015), http://www.ip-watch.org/2015/07/14/learning-from-ebola/ (arguing that "[g]reater attention should be paid to developing systematic incentives for investment in research and development into vaccines and medicines that treat diseases that disproportionately affect the global poor and for which there are not adequate commercial incentives for optimal levels of research and development").

could be possible in the short-term, having the potential to increase access to medicine and save lives.

Intra-country differential pricing offers greatest promise in the context of countries where there are both poor and wealthy residents living side-by-side. While risks of physical arbitrage persist, they can be mitigated through multiple strategies: (1) altering the branding and appearance of the product; (2) employing technical solutions and contractual provisions to ensure the integrity of supply chains; (3) improving border controls, particularly in conjunction with differential packaging; and (4) using distribution channels targeted to particular market segments such as government-run pharmacies, rural health centers, or community health workers dedicated to high-poverty areas. Vaccines and injectables may be particularly well-suited for intra-country differential pricing strategies because they require a cold storage supply chain and health provider administration. The risks of information arbitrage and reference pricing can be mitigated by rebates and confidential discounts. Important and well-intentioned efforts to promote price transparency should be structured carefully to avoid unintended consequences that could increase pricing obstacles for the poor. Retrospective, non-contemporaneous price transparency and auditing mechanisms may accomplish laudable anti-corruption and anti-gouging objectives without risking unintended consequences that may accompany granular and contemporaneous price transparency measures.

More widespread use of voluntary licensing—particularly non-exclusive partnerships between branded and generic pharmaceutical companies—offers great potential for dramatically increasing the efficacy of pharmaceutical companies' corporate social responsibility programs while decreasing their costs or even potentially turning a modest profit. Non-exclusive voluntary licenses granted to generic manufacturers may be a reasonable strategy in lower-income countries where there is not a large affluent population and where it is unlikely that a branded pharmaceutical company would otherwise be profitable in the near term. Such arrangements are most likely to be successful where there is already an established market for a class of drugs, particularly as a result of substantial donor funding. To facilitate the combination of therapies or technologies, patent pools may offer advantages in certain situations, despite typically being difficult to organize due to the involvement of multiple stakeholders. In cases where a firm's structure or culture renders multiple non-exclusive licenses undesirable or where the need for technology transfer and capability building in the generic partners makes it infeasible to enter into multiple partnerships, exclusive licensing arrangements with generic manufacturers may be an attractive alternative. However, these exclusive arrangements have certain drawbacks, as an appropriate initial price may be difficult to ascertain and there is no competition to drive down prices over time. As yet another option to consider related to voluntary licensing, donation of proprietary research to humanitarian research efforts (possibly subject to non-

disclosure agreements) can be a low-cost, high-benefit way for pharmaceutical companies to help alleviate the health crises confronting the global poor.

It is important to note that the ability to implement differential pricing and voluntary licensing strategies will depend on additional factors outside the scope of this Article, such as the particular features of the market for which the strategy is being contemplated. When analyzing or comparing markets within or between countries, factors such as the potential size of the market for a given product in a given economy, the income distribution within the country, and the level and source of foreign funding for access programs should be considered. Under real-world conditions, these and numerous other factors will influence which combinations of strategies will be most effective for researching, manufacturing, pricing, and distributing medicines to ensure that the needs of patients worldwide will be met regardless of their means. Along with continued experimentation and expansion of differential pricing and voluntary licensing schemes, further research and nuanced discussions of market dynamics and other key factors will be a critical part of the overall discourse concerning strategies to increase access to medicine.

GLOSSARY

Antiretroviral Drugs (ARVs) – Drugs used to control HIV infection. ARVs keep the total level of HIV in a patient's body low by preventing the HIV virus from multiplying. Although not a cure, ARVs have proven effective at suppressing the virus, especially when used in combination with one another.

Arbitrage – Generally, the practice of both buying and selling a product to benefit from a difference in the price. See "Information Arbitrage" and "Physical Arbitrage."

Corporate Social Responsibility (CSR) Programs – Programs undertaken by a corporation in order to promote social and environmental concerns.

Differential Pricing – The practice of setting different prices for different groups of potential buyers of the same product. Also referred to as price discrimination.

Gini Coefficient – "This is the most commonly used measure of inequality. The coefficient varies between 0, which reflects complete equality and 1, which indicates complete inequality (one person has all the income or consumption, all others have none)."[207]

Gross Domestic Product (GDP) – The standard measure of the value of final goods and services produced by a country during a period minus the value of imports.[208]

Gross National Income (GNI) – The total income earned by a country's population. Represents the sum of a nation's gross domestic product (GDP) and net income received from overseas.

Voluntary Licensing – A licensing scheme in which patent owners permit others to sell their patented products under favorable terms to facilitate distribution to impoverished populations subject to certain conditions.

Information Arbitrage – The practice in which insurance companies or bulk purchasers such as governments, NGOs, or large health care providers refuse to pay a price that is higher than the lowest known price of a comparable product.

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207. *See Measuring Inequality*, WORLD BANK, http://go.worldbank.org/3SLYUTVY00 (last visited Feb. 25, 2017).

208. *See Domestic Product*, ORG. FOR ECON. CO-OPERATION & DEV. DATA, https://data.oecd.org/gdp/gross-domestic-product-gdp.htm (last visited Feb. 25, 2017).

Inter-Country – Between countries. For example, inter-country differential pricing is the practice of charging different prices to different countries.

Intra-Country – Within a country. For example, intra-country differential pricing is the practice of charging different prices to different people within the same country.

Non-Assert Declarations – Commitments not to enforce certain patents in a defined group of countries.

Patent Pool – An agreement between patent owners to license their patents to each other or to third parties.

Physical Arbitrage – A phenomenon that can occur when a company sells an identical product at both a high price and a low price. Middlemen purchase the low-price product in bulk and seek to resell the product to more affluent customers, thus undercutting the market for the high-price product.

Price Discrimination – See "Differential Pricing."

Reference Pricing – The practice of setting the price a purchaser is willing to pay by reference to the price that others pay. In particular, the term often refers to capping the price a purchaser is willing to pay at the prices that others pay.

Voluntary Licenses – Arrangements between a patent holder and another party in a country, or serving the country's market.[209]

209. *See Voluntary Licensing*, WORLD HEALTH ORG. (2003), http://apps.who.int/medicinedocs/en/d/Js4907e/3.5.html#Js4907e.3.5.

APPENDIX

EXAMPLES OF INTRA-COUNTRY DIFFERENTIAL PRICING

1. Examples of Intra-Country Differential Pricing

In addition to GSK's hepatitis B vaccine, three examples illustrate how intra-country price discrimination can work: (a) Sanofi's Access Card Program; (b) Bayer's Contraceptive Security Initiative; and (c) Novartis's anti-malaria initiatives.

a. Sanofi's Access Card Program

In 2004, Sanofi launched its Access Card Program (CAP) to expand the availability of its antimalarial drug Arsucam, beginning in Cameroon, Gabon, and Madagascar.[210] Any family below the poverty level in the country qualified for an Impact Malaria Access Card.[211] The 226 participating pharmacies would offer the drug at one price for patients with sufficient income and a lower price for patients with an Access Card.[212] These pharmacies placed stickers on their windows advertising their participation in the program.[213]

Sanofi provided Arcusam to private pharmacies at two price tiers.[214] At the first tier, the drug was provided at a "no profit, no loss" price for patients with an Access Card.[215] This price was $1.35 for pediatric doses and $2.20 for adult doses.[216] The second tier reflected the market price—approximately 3.5 to 4.5 times the first tier price—for patients at or above the national poverty line.[217] CAP relied heavily on solidarity among all the links in the supply chain: wholesalers and pharmacists also agreed to import and distribute Arsucam without profit.[218] The CAP program reached 38,951 low-income patients in two years.[219]

Sanofi implemented a "one drug, two prices, three packages" arrangement for Arsucam's successor, a combination drug called ASAQ Winthrop in the

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210. Sanofi-Aventis, *Driving Back Disease Around the World* (Feb. 2006), http://siteresources.worldbank.org/INTHSD/Resources/376278-1114111154043/March1AccessSanofiAventis.ppt.

211. *Id.*

212. *Id.*

213. F. Bompart & M. Bernhardt, *Sanofi, Access to Antimalaria Medicines: The Impact Malaria Approach* (Nov. 16, 2011), http://www.inrud.org/icium/conferencematerials/634-bompart-_c.pdf [https://perma.cc/4LJC-GK37].

214. Sanofi-Aventis, *Driving Back Disease Around the World*, *supra* note 210.

215. Bompart & Bernhardt, *supra* note 213.

216. Sanofi-Aventis, *Driving Back Disease Around the World, supra* note 210.

217. *Id.*

218. *Id.*

219. *Id.*

public market and Coarsucam in the private market.[220] Sanofi sold boxes of ASAQ Winthrop to the public sector in bulk packaging at a "no profit, no loss" price of less than $1 for adults and less than $0.50 for children under five years old.[221] Purchasers included NGOs, religious charities, and national health services who made the treatment available to patients below the poverty line.[222] In the private sector, Coarsucam is sold through two distinct channels. Middle-income patients can purchase bulk packages of Coarsucam Impact Malaria at CAP pharmacies at the "no profit, no loss" price, while high-income patients purchase individual blisters of Coarsucam at the local market price (typically $2–3).[223] As a result of this "one drug, two prices, three packages" scheme, 95% of ASAQ units sold in 2012 were at the "no profit, no loss" level.[224]

A key feature of Sanofi's program is that the segmentation of the market occurs at the provider level, rather than through a particular distribution channel.[225] Health care providers—in this case, pharmacists—determine which drug to give each patient based on whether the patient presents an Access Card.[226] While this approach allows for greater flexibility, it also creates the potential for cannibalization of profits from the high cost version—patients may be able to purchase the lower-priced options even though they would be able to afford the higher-priced Coarsucam.[227]

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220 . GLOBAL FORUM FOR HEALTH RES., HEALTH PARTNERSHIPS REVIEW: FOCUSING COLLABORATIVE EFFORTS ON RESEARCH AND INNOVATION FOR THE HEALTH OF THE POOR 79 (Stephen Matlin et al., eds. 2008), http://www.innogen.ac.uk/downloads/HealthPartnershipsReview_Full.pdf. Sanofi developed the combination drug in partnership with the Drugs for Neglected Disease Initiative (DNDi) and chose not to pursue patent protection for ASAQ Winthrop—another factor that increased the availability and affordability of the drug. *See* Francois Bompart et al., *Innovative Public-Private Partnerships to Maximize the Delivery of Anti-Malarial Medicines: Lessons Learned from the ASAQ Winthrop Experience* 2, 10 MALARIA J. 1 (2011).

221 . DNDI & SANOFI-AVENTIS, PRESS PACK: ASAQ IN A FEW WORDS (Mar. 1, 2007), http://www.dndi.org/images/stories/pdf_products/ASAQ/ASAQ_presspack_final_reduced.pdf. Each box contains 25 blisters, which consist of three to six tablets each. *Id.*

222. GLOBAL FORUM FOR HEALTH RES., *supra* note 220, at 79.

223. DNDI & SANOFI-AVENTIS, *supra* note 221; Bompart & Bernhardt, *supra* note 213.

224. SANOFI, CORPORATE SOCIAL RESPONSIBILITY: 2012 REPORT 22 (2012), http://en.sanofi.com/ Images/32419_CSR_Report_2012.pdf.

225. *See id.*

226. A recent initiative in the Philippines, in the province of Palawan, involves a similar program design. Target patients are provided with cards and/or specialized prescriptions that cover certain medications, which they can present to local pharmacists in order to receive a lower price agreed to by pharmaceutical companies. *See* Anthony R.G. Faraon, Presentation: Improving Access to Medicines Project in the Philippines – The Palawan Pilot (2013), http://uhc-medicines.org/wp-content/uploads/2013/09/Faraon_Policy_Dialogue_-_Improving_Access_to_Medicines_Project_in_the_Philippines.pdf. Among the companies participating in this project are Novartis, Pfizer and Sanofi. *See Giving Palawan Communities Access to Medical Care*, MANILA TIMES (Aug. 16, 2014), http://www.manilatimes.net/giving-palawan-communities-access-medical-care/119417/.

227. *See* TOWSE ET AL., *supra* note 103.

b. Bayer-USAID Contraceptive Security Initiative

In several African countries, Bayer has implemented tiered pricing among four different market segments and distribution tiers for its contraceptive Microgynon Fe.[228] In the first tier, the contraceptive is provided at market price to upper-income women.[229] The second tier—Bayer's key innovation and the tier described in more detail below—consists of discounted commercial prices for middle-income women.[230] The third tier provides lower prices to a targeted "social market" of lower middle-income women, and is made possible by donor subsidies.[231] Finally, the fourth tier provides free or at-cost distribution to the public market.[232]

The second tier is meant to encourage women who can pay more for their medications to move to a higher price point at a private pharmacy instead of waiting in line for subsidized or free contraception.[233] For example, in Ethiopia, Microgynon Fe is sold at $0.61 at the second tier, while it is sold for $0.06–0.12 at the third tier.[234] The increased revenue improves the sustainability and self-sufficiency of the initiative.

Bayer has used different brand names and packaging for its different tiers in order to minimize the risk of diversion.[235] Microgynon is branded as Microgynon 21 in the first tier, Microgynon Fe in the second tier, Microgynon ED FE in the third tier, and Blue Lady Microgynon ED FE in the fourth tier.[236] The first-tier brand, Microgynon 21, differs from all other versions in that it does not include the added ferrous fumarate, which is included in the lower tiers to help supplement the iron in women's diets.[237] Each of the variations is available through a different distribution channel.[238] For example, the second-tier contraceptive, Microgynon Fe, is available through private local pharmacies.[239]

228. *See* Bayer Company Profile, *supra* note 42.

229. *See* ACCESS TO MED. FOUND., THE ACCESS TO MEDICINES INDEX 2012 53 (Nov. 2012), http://apps.who.int/medicinedocs/documents/s19987en/s19987en.pdf.

230. *Id.*

231. *Id.*

232. *See* ULRIKE VON GILARDI & KLAUS BRILL, BAYER HEALTHCARE PHARMACEUTICALS, PRESENTATION: 2ND TIER MARKETING PROJECT: ETHIOPIA 5 (June 24, 2011); *see* ACCESS TO MED. FOUND., *supra* note 229.

233. *See Interview with Ulrike von Gilardi and Ariane Püttcher*, BAYER HEALTHCARE, http://pharma.bayer.com/en/commitment-responsibility/family-planning/an-initiative-thats-right-on-target/ (last visited Feb. 25, 2017).

234. *See* VON GILARDI & BRILL, *supra* note 232, at 5.

235. See Bayer Company Profile, *supra* note 42.

236. *Id.*

237. *Id.*

238. *Id.*

239. *Id.*

c. Novartis's Anti-Malaria Initiatives

Novartis has implemented innovative intra-country differential pricing schemes for several key drugs.[240] In 2001, Novartis and the World Health Organization (WHO) signed a 10-year memorandum of understanding (MoU) whereby Novartis would supply its anti-malaria drug Coartem at cost to WHO.[241] The governments of malaria-endemic lower-income countries could then purchase Coartem from the WHO, often with financial assistance from the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund).[242] Novartis later agreed to provide the drug at cost to eighteen international agencies as well, including Médecins Sans Frontières and UNICEF.[243] The average public sector price per treatment was $1.57 in 2005, $1 in 2006, and $0.76 in 2009, compared to the private sector price of $7-10 per treatment.[244] For its part, the WHO agreed to work with countries to develop forecasts of demand for Coartem and to provide additional funding, technical assistance, and monitoring efforts to prevent arbitrage.[245] The WHO also approved Coartem for inclusion in its Model List of Essential Medicines in 2002, generating additional interest in the drug among low and middle-income countries.[246]

In 2010, Novartis began participating in an initiative designed to increase the affordability of Coartem in the private market as well.[247] The Global Fund's Affordable Medicines Facility - malaria (AMFm) program began heavily subsidizing purchases of Coartem for private sector buyers in African countries.[248] To keep retail prices of antimalarial combination therapies down,

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240. *See* YADAV, *supra* note 28, at 26–27, 30.

241. *See* WORLD HEALTH ORG., GLOBAL SUPPLY OF ARTEMETHER-LUMEFANTRINE BEFORE, DURING, AND AFTER THE MEMORANDUM OF UNDERSTANDING BETWEEN WHO AND NOVARTIS 1 (2011) [hereinafter GLOBAL SUPPLY], http://www.who.int/malaria/areas/treatment/MoU_termination_report_may2011.pdf?ua=1.

242. Hans Rietveld, Novartis Pharma AG, A New Class of Malaria Drugs: The Coartem Breakthrough from Novartis and Its Chinese Partners (May 26, 2008), http://www.vfa.de/download/new-class-malaria-drugs-novartis.pdf.

243. GLOBAL SUPPLY, *supra* note 241, at 3.

244. NOVARTIS, NOVARTIS GROUP ANNUAL REPORT 2009 71 (2009), http://www.novartis.co.za/downloads/Novartis_Annual_Report_2009_EN.pdf; PRASHANT YADAV ET AL., CENTER FOR GLOBAL DEV., MAPPING AND REALIGNING INCENTIVES IN THE GLOBAL HEALTH SUPPLY CHAIN: BASED ON THE SUPPLY CHAIN FOR ARTEMISININ COMBINATION TREATMENTS FOR MALARIA 11 (Dec. 2006), http://www.zlc.edu.es/projects/global/mapping-and-realigning-incentives-in-the-global-health-supply-chain-risk-and-incentive-study-of-global-health-supply-chains/.

245. Grace, *supra* note 23, at 34; GLOBAL SUPPLY, *supra* note 241, at 2; DEBORA L. SPAR & BRIAN J. DELACEY, HARV. BUS. SCH. PUB. 9-706-037, THE COARTEM CHALLENGE (A) 6 (2008), http://www.hbs.edu/faculty/Pages/item.aspx?num=33270.

246. Spar & Delacey, *supra* note 245, at 6–7.

247. *See Joining Forces to Advance Public Health*, NOVARTIS, https://www.novartis.com/about-us/corporate-responsibility/expanding-access-healthcare/malaria-initiative/joining-forces (last visited Feb. 25, 2017).

248. *See* ICF INT'L, INDEPENDENT EVALUATION OF PHASE 1 OF THE AFFORDABLE MEDICINES FACILITY—MALARIA (AMFM): MULTI-COUNTRY INDEPENDENT EVALUATION REPORT xxiv (2012),

AMFm paid very large co-payments (e.g., 91% of the sales price in Ghana) for buyers who agreed to provide the drugs for almost no cost in the public sector or sell at a reasonable margin (averaging 70%) in the private sector, not sell less effective antimalarial monotherapies, not divert products out-of-country, and participate in AMFm monitoring initiatives.[249]

The demand for Coartem generated by these partnerships significantly exceeded Novartis's forecasts.[250] Over time, the increased pressure of overhead costs made it difficult for Novartis to continue supplying Coartem at a "no profit" price.[251] In order to sustain the initiative, Novartis sought to increase margins by reaching two untapped markets.[252]

First, the non-premium private market was identified as a promising avenue for making the Malaria Initiative sustainable through a social business model.[253] In 2012, Novartis launched a new initiative to deliver more affordable Coartem to the non-premium private market sector in nine African countries,[254] with expansion to fourteen more African countries in 2013–2014.[255] Driving the initiative was the fact that antimalarials, even when provided for free at public facilities, remained inaccessible to the many poor communities who had to travel long distances or overcome other logistical barriers to reach those facilities, such that only one in three patients treated for malaria in sub-Saharan Africa received ACTs.[256] Second, to reach the premium private market composed of the middle and upper income sectors, Novartis introduced Coartem 80/480 in 2013, which conveniently reduced the number of tablets that had to be taken from twenty-four to six.[257] Including its two new markets, Novartis uses a five-point tiered pricing scheme for Coartem.[258] The first two pricing levels consist of treatments provided by Novartis at cost. Since 2001, over 400 million treatments of Coartem have been provided at cost in over sixty low and middle-income countries,[259] and the average at-cost price for Coartem has fallen by 50%.[260] The first tier consists of Novartis's at-cost sales to

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http://www.theglobalfund.org/documents/amfm/AMFm_2012IEPhase1FinalReportWithoutAppendices_Report_en/.

249. *See* Benedict & Fisher, *supra* note 63, at 8.

250. *See* MICHAEL CHU ET AL., HARV. BUS. SCH. PUB. 9-314-103, THE NOVARTIS MALARIA INITIATIVE 9 (July 14, 2014), http://www.hbs.edu/faculty/Pages/item.aspx?num=47229.

251. *Id.*

252. *Id.* at 9, 11.

253. *Id.* at 10.

254. *See* NOVARTIS, ANNUAL REPORT 2012, 68 (2012), https://www.novartis.com/sites/www.novartis.com/files/novartis-annual-report-2012-en.pdf.

255. CHU ET AL., *supra* note 250, at 13, 25.

256. *See* NOVARTIS, ANNUAL REPORT, *supra* note 254, at 68.

257. CHU ET AL., *supra* note 250, at 11, 13.

258. Benedict & Fisher, *supra* note 63.

259. *See* NOVARTIS, THE NOVARTIS MALARIA INITIATIVE: INNOVATING TO HELP ELIMINATE MALARIA 2, http://www.rollbackmalaria.org/files/files/news-and-events/press-releases/Novartis-en.pdf.

260. *See* NOVARTIS, CONNECTING WITH PATIENTS: PIONEERING INITIATIVES TO ENHANCE ACCESS TO HEALTHCARE (2010) 6, http://www.novartis.com/downloads/newsroom/product-related-info-center/connecting-with-patients.pdf [https://perma.cc/W3D9-VHRN].

governments (funded by donors such as the Global Fund, the President's Malaria Initiative, and USAID) through WHO until 2011 and afterwards through international procurement agencies that assist governments in supplying Coartem to patients at zero or almost-zero cost.[261] The second tier consists of Novartis's at-cost sales through donors, which are provided to patients at the lowest sustainable distributor price in each country.[262] Due in part to expanded production capacity, Novartis was able to lower the average price of Coartem.[263] The at-cost selling price for these treatments dropped from $2.40 to $1.80 after the first Global Fund-eligible generic was introduced and to $1.50 after an alternative artemisinin combination therapy (artesunate-amodiaquine) became available as a cheaper alternative in some countries.[264]

The third price level, for non-premium private markets in malaria-endemic countries, is targeted at emerging middle class and middle class patients whose personal disposable income approximates $20–22 per day.[265] On average, non-premium private market Coartem is expected to sell at $2.50.[266] The fourth price level, for premium markets in malaria-endemic countries, is targeted at upper-class individuals, whose personal disposable income is well above $20 per day.[267] For this market, Coartem 80/480 is more expensive than non-premium private market Coartem but cheaper than previous versions of Coartem available through private pharmacies serving the premium sector.[268]

Finally, at the top of the tiered pricing scheme is the price at which Coartem is sold in countries where malaria is not endemic, particularly for travelers who are going to—or have returned from—regions where malaria is endemic.[269]

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261. See GLOBAL SUPPLY, *supra* note 241; Edmund Rutta et al., *Increasing Access to Subsidized Artemisinin-based Combination Therapy through Accredited Drug Dispensing Outlets in Tanzania*, 9 HEALTH RES. POL'Y & SYS. 22 (2011), http://www.health-policy-systems.com/content/9/1/22.

262. Benedict & Fisher, *supra* note 63, at 12.

263. CHU ET AL., *supra* note 250, at 6.

264. ICF INT'L, *supra* note 248, at 214, 222, 232, 240–41, 252; Rutta et al., *supra* note 261; MOON ET AL., *supra* note 21.

265. Benedict & Fisher, *supra* note 63, at 13.

266. CHU ET AL., *supra* note 250, at 13

267. Benedict & Fisher, *supra* note 63, at 13.

268. CHU ET AL., *supra* note 250, at 13.

269. Benedict & Fisher, *supra* note 63, at 13.