LOOKING INWARD: REGIONAL PARALLEL TRADE AS A MEANS OF BRINGING AFFORDABLE DRUGS TO AFRICA

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I. INTRODUCTION

Suffering from persistent headaches and finding no relief from aspirin, Simon traveled from his village in Kenya to Nairobi, Kenya's capital, to see a doctor.[1] The doctor ran some tests, which confirmed his worse fears: Simon had cryptococcal meningitis, an HIV-related fungal infection that can be fatal if not treated quickly.[2] Not only did the doctor inform Simon that he was HIV-positive, he also explained that the cost of the lifetime treatment for the infection was ten dollars per pill.[3] At that price, Simon would use up his entire salary in two weeks.[4] Although the same drug sold in Thailand as a generic for ten cents per pill, that version was not available to Simon in Kenya.[5] The doctor advised Simon to return to his village without treatment, as the cost of transporting a live body home from Nairobi would be far less expensive than transporting a corpse.[6] If the affordable generic drug sold in Thailand had been available in Kenya, Simon may not have had to face such a desperate situation.

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[1] Rachel Cohen, Advocacy Liaison for the Médecins Sans Frontières [Doctors Without Borders] Access to Essential Medicines Campaign, Congressional Briefing: Solving the HIV/AIDS Drug Access Crisis in Africa: Meeting the Challenge to Save Millions of Lives and to Mitigate the Orphan Crisis (July 16, 2001), *available at* http://doctorswithoutborders.org/publications/article.cfm?id=1348.

[2] *Id.*

[3] *Id.*

[4] *Id.*

[5] *Id.*

[6] *Id.*

Although the United States prohibits the importation of cheaper drugs from other countries,[7] the search for low-priced drugs in other areas of the world is increasingly extending beyond a country's geographical borders. Because a drug may sell at a higher price in Country A than in Country B, a trader in Country A will purchase the drug from Country B at a lower price and then sell the drug in Country A. The goal of this parallel-trading system is to make drugs more affordable for consumers in Country A while generating a profit for the trader. Kenya, in fact, permitted parallel trading beginning in 2001[8]—likely too late to help Simon, but improving the situation for other patients.

The scenario described above outlines the contours of parallel trade. Parallel trade is premised on the economic principle of the free movement of goods and incorporates the patent-law concept of the exhaustion of intellectual property rights.[9] A key feature of an intellectual property system is the exclusive rights given to an inventor to prevent others from producing, selling, or distributing his invention for a specified period of time.[10] Exhaustion occurs when an intellectual property right holder's control over his invention ceases.[11] This cessation of intellectual property rights can happen in different ways depending on the type of exhaustion doctrine the country of importation has adopted.[12]

The choice of an exhaustion doctrine correlates to the prevalence of parallel trade in a country. For example, the United States follows the doctrine of national exhaustion, which means that an intellectual property right holder's rights do not end until after the first

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[7] *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 381(d)(1) (2006) ("[N]o drug . . . which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug.").

[8] Ben Shianya, *Patents, Parallel Importation and Compulsory Licensing of HIV/AIDS Drugs: The Experience of Kenya*, *in* MANAGING THE CHALLENGES OF WTO PARTICIPATION CASE STUDY 19 (Peter Gallagher et al. eds., 2005), *available at* http://www.wto.org/english/res_e/booksp_e/casestudies_e/case19_e.htm.

[9] *See Commission Communication on Parallel Imports of Proprietary Medicinal Products for Which Marketing Authorisations Have Already Been Granted*, at 6, 10, COM (2003) 839 final (Dec. 30, 2003) [hereinafter *Parallel Imports of Proprietary Medicinal Products*].

[10] JACOB ARFWEDSON, INST. FOR POL'Y INNOVATION, RE-IMPORTATION (PARALLEL TRADE) IN PHARMACEUTICALS 1 (2004).

[11] Duncan Matthews & Viviana Munoz-Tellez, *Parallel Trade: A User's Guide*, *in* INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 1429, 1432 (A. Krattiger et al. eds., 2007).

[12] *International Exhaustion and Parallel Importation*, WORLD INTELL. PROP. ORG., http://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htm (last visited Nov. 4, 2010).

sale of the protected product in the United States.[13] Hence, according to the national exhaustion doctrine, a right holder cannot limit the commercial exploitation of the product within the domestic country, but it can still refuse to allow importation of the product from other countries into the domestic market.[14] Conversely, under the doctrine of international exhaustion, an intellectual property right holder's exclusive rights cease after the first sale of the product in any market in the world, and a right holder can no longer exclude the product from entering the local market from other countries.[15] Thus, the type of exhaustion doctrine selected by a country will either promote or restrict the parallel trade of goods because the doctrine determines whether the right holder can prevent parallel imports of the patented product from entering the domestic market.[16]

Once the intellectual property rights protecting a product are exhausted, the inventor can no longer dictate the terms governing the sale of his product, and the notion of the free movement of goods applies.[17] The concept of the free movement of goods means that a product may be sold in other countries without restrictions and the right holder cannot prevent the product from entering new markets.[18] The product sold in a new market is called a parallel import.[19] Parallel trade is driven by price differences for similar products between countries.[20] Importantly, parallel trade does not refer to illegal activities, nor should it involve the trade of counterfeit goods.[21]

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[13] Matthews & Munoz-Tellez, *supra* note 11, at 1432.

[14] *International Exhaustion and Parallel Importation*, *supra* note 12.

[15] Matthews & Munoz-Tellez, *supra* note 11, at 1432.

[16] *Id.*

[17] *See generally* LENNART RITTER, EUROPEAN COMPETITION LAW: A PRACTITIONER'S GUIDE 745–47 (3d ed. 2004) (explaining that intellectual property rights are subject to the rules of the free movement of goods in the EU).

[18] *See* RITTER, *supra* note 17, at 747 (noting that once patent rights are exhausted, the patentee cannot prevent the importation of the goods); David R. Bumbak, *Industrial Property Rights and the Free Movement of Goods in the European Communities*, 16 CASE W. RES. J. INT'L L. 381, 381 (1984) (describing the inherent tension between exclusive intellectual property rights and the free movement of goods); David T. Keeling, *The Free Movement of Goods in EEC Law: Basic Principles and Recent Developments in the Case Law of the Court of Justice of the European Communities*, 26 INT'L LAW. 467, 467 (1992) (explaining that the principle of the free movement of goods means that goods placed on a market can be freely traded throughout, for example, Europe, and that such goods cannot be subject to any restrictions).

[19] Parallel imports are also referred to as "grey market goods." *International Exhaustion and Parallel Importation*, *supra* note 12. This Comment, however, will use the former term.

[20] Thomas N. Bart, *Parallel Trade of Pharmaceuticals: A Review of Legal, Economic, and Political Aspects*, 11 VALUE IN HEALTH 996, 997 (2008); Press Release, Eur.

Although parallel trade applies to all types of goods, the trade mechanism is particularly relevant in the public health sector because of conflicts over pharmaceutical drug pricing and patent rights.[22] An inherent tension exists between the exclusive protection granted by patents and the cost of and access to drugs by consumers.[23] This tension is apparent in the public health crisis facing places like Africa, where the cost of drugs is high, and therefore, drugs are inaccessible to much of the population. Importantly, although focus has primarily been on the lack of affordable drugs in developing African countries as compared to the United States and Europe, drug prices within Africa vary widely. For example, a study found that the price of a drug sold in Uganda was 124% higher than the price of the same drug sold in Ethiopia.[24]

Even though parallel trade has the potential to cut drug costs for consumers,[25] the system is not without its critics. A common argument against parallel trade is that it hurts innovation because pharmaceutical companies are less likely to invest in research and development of new drugs if their profits decrease because of the availability of cheaper drugs from other sources.[26] Pharmaceutical companies have actively attempted to fight parallel imports. For example, in 2007, Pfizer brought a suit against the Philippines for importing a cheaper version of its patented hypertension drug from India.[27] Parallel trade, therefore, is as controversial as it is critical.

Comm'n, MEMO/04/7 Commission Communications on Parallel Imports of Proprietary Medicinal Products—Frequently Asked Questions (Jan. 19, 2004), *available at* http://europa.eu/rapid/searchAction.do (select "Search Complete Database" under "Date Range"; then enter "MEMO/04/7" in "Reference" field).

[21] Matthews & Munoz-Tellez, *supra* note 11, at 1429.

[22] *Id.* at 1432–33.

[23] *See generally* David Henry & Joel Lexchin, *The Pharmaceutical Industry as a Medicines Provider*, 360 LANCET 1590, 1590–93 (2002) (describing the lack of affordable drugs in developing countries and the use and abuse of patents by pharmaceutical companies).

[24] KRISTEN MYHR, MÉDECINS SAN FRONTIÈRES, COMPARING PRICES OF ESSENTIAL DRUGS BETWEEN FOUR COUNTRIES IN EAST AFRICA AND WITH INTERNATIONAL PRICES (2000) (manuscript at 18) (on file with author). The generic name of the drug is ceftriaxone. *Ceftriaxone Injection*, MEDLINEPLUS, http://www.nlm.nih.gov/medlineplus/druginfo/meds/a685032.html (last updated Dec. 21, 2010). Ceftriaxone sold under the branded name Rocephin by Roche and is commonly used to treat infections. *Id.*

[25] *Parallel Trade in Medicines*, EURACTIV (Aug. 3, 2007), http://www.euractiv.com/en/health/parallel-trade-medicines/article-117528 [hereinafter EURACTIV].

[26] *Id.*

[27] Elmira Bacatan, Access to Medicine: Drama Unfolding, OXFAM EAST ASIA BLOG (May 13, 2008), http://www.oxfamblogs.org/eastasia/?p=80.

Despite criticisms, the parallel trade of pharmaceutical drugs will not likely disappear any time soon and, if anything, it will become more prevalent for several reasons. First, under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement[28] and the Declaration on the TRIPS Agreement and Public Health (Doha Declaration),[29] World Trade Organization (WTO) countries may select the intellectual property right exhaustion doctrine that best suits their domestic policy goals.[30] The least-developed countries have until 2016 to comply with the TRIPS Agreement, which requires that they provide patent, trademark, and copyright protection.[31] The TRIPS agreement calls for WTO member states to grant patents for any invention in all technological fields, which covers pharmaceutical drugs.[32] As the least-developed countries implement patent-law regimes, they may choose to allow parallel trade. For example, a draft patent law in Bangladesh permits parallel trade.[33] India's revised patent law contains a liberal parallel-importing provision.[34] And South Africa, recognizing the potential cost-saving effects of parallel trade, authorized the parallel importation of drugs under the Medicines and Related Substances Control Amendment Act of 1997.[35]

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[28] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1, Legal Instruments—Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement]. The TRIPS Agreement is a multilateral agreement on intellectual property. *Overview: The TRIPS Agreement*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Nov. 4, 2010).

[29] WORLD TRADE ORG., Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration].

[30] *Id.* para. 5(d); TRIPS Agreement, *supra* note 28, art. 6; *Fact Sheet: TRIPS and Pharmaceutical Patents, Obligations and Exceptions*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#dohadecl 5d (last visited Nov. 3, 2010).

[31] Press Release, World Trade Org., Poorest Countries Given More Time to Apply Intellectual Property Rules (Nov. 29, 2005), *available at* http://www.wto.org/english/news_e/pres05_e/pr424_e.htm.

[32] TRIPS Agreement, *supra* note 28, arts. 27:1, 70:8.

[33] WORLD BANK, BANGLADESH DEVELOPMENT SERIES PAPER NO. 23, PUBLIC AND PRIVATE SECTOR APPROACHES TO IMPROVING PHARMACEUTICAL QUALITY IN BANGLADESH 18 (2008), *available at* http://siteresources.worldbank.org/INTBANGLADESH/Resources/pharmaceutical.pdf.

[34] The Patents (Amendment) Act, 2005, No. 15, section 58, Acts of Parliament, 2005 (India), *available at* http://www.patentoffice.nic.in/ipr/patent/patent_2005.pdf; Shamnad Basheer & Mrinalini Kochupillai, *'Exhausting' Patent Rights in India: Parallel Imports and TRIPS Compliance*, 13 J. INTELL. PROP. RIGHTS 486, 490 (2008).

[35] *See* Medicines and Related Substances Control Amendment Act 90 of 1997 § 10 (S. Afr.), *available at* http://www.info.gov.za/view/DownloadFileAction?id=70836.

Developing countries would not be alone if they chose to open their markets to parallel trade. Europe has a parallel trade system for pharmaceutical drugs that continues to grow in response to price differences for drugs between European countries. The Treaty Establishing the European Economic Community[36] authorized the free movement of goods between European member countries and thereby established a European parallel trade system based on regional exhaustion.[37] The EU has integrated new country members into the existing parallel trade system. For example, Sweden allowed parallel imports of pharmaceuticals when it joined the EU in 1995 so as to comply with EU regulations.[38] Parallel imports are now included as acceptable drug substitutes under a generic substitution policy that mandates Swedish physicians to prescribe the lowest-priced generic substitute for a drug.[39] Poland, which joined the EU in 2004, doubled the number of drugs authorized for parallel importation in 2008; sales of parallel imports increased eighty-nine percent in 2008.[40] The parallel trade system in the EU is established and growing, and it illustrates the use of parallel imports as a means of cutting health-care costs.

This Comment will argue that the African Union (AU) should consider a parallel trade system based on regional exhaustion as a means of addressing the pharmaceutical drug crisis. Parallel trade is not going away given its strong foundation in the EU and the flexibility available to developing countries in selecting intellectual property right exhaustion doctrines under the TRIPS Agreement. Although much focus is on the lack of affordable drugs in Africa as compared to North America or Europe, drug prices also differ between African countries. These price differentials are a motivation for parallel trade. Such price differentials between African countries strengthen

[36] Consolidated Version of the Treaty Establishing the European Community arts. 28–30, Dec. 24, 2002, 2002 O.J. (C 325) 33, *available at* http://eur-lex.europa.eu/en/treaties/dat/12002E/pdf/12002E_EN.pdf [hereinafter EEC Treaty].

[37] Under the doctrine of regional exhaustion, the intellectual property rights for a patent cease upon the first sale of a product in a regional market. Matthews & Munoz-Tellez, *supra* note 11, at 1432.

[38] PIERRE MOÏSE & ELIZABETH DOCTEUR, ORG. FOR ECON. CO-OPERATION AND DEV. (OCED), OCED HEALTH WORKING PAPERS NO. 28, PHARMACEUTICAL PRICING AND REIMBURSEMENT POLICIES IN SWEDEN 38 (2007), *available at* http://www.oecd.org/dataoecd/63/17/40699881.pdf.

[39] *Id.* at 22, 38.

[40] IHS GLOBAL INSIGHT, POLAND'S PARALLEL IMPORTS MARKET GROWS RAPIDLY IN 2008 (2009), *available at* http://www.globalinsight.com/SDA/SDADetail16048.htm.

the idea that the AU should explore a regional exhaustion system modeled after the EU system.

Part II of this Comment will introduce the relevant principles of parallel trade in the context of pharmaceutical drugs. It will review the EU's approach to parallel trade and focus on the applicable patent-law principles, the regulations that govern the EU system, case law, and the benefits of and concerns about the system.[41] Part III will examine Africa's current approach to free trade and intellectual property rights and will review the current drug crisis in Africa. In particular, this Comment will highlight South Africa's experience with the parallel trade of drugs. Part IV will argue that a parallel trade system based on regional exhaustion has the potential to increase access to pharmaceutical drugs in the AU. This Part will review the motivations for implementing such a system in Africa and discuss the required support structure, drawing on the EU's experience.

II. KEY PRINCIPLES OF PARALLEL TRADE IN THE PHARMACEUTICAL CONTEXT: AN ILLUSTRATION IN THE EUROPEAN APPROACH

Parallel trade is the mechanism by which products protected by intellectual property rights—from a patent, trademark, or copyright—are placed into circulation in one market and then exported to a second market and sold without the authorization of the intellectual property right holder.[42] The consequence of parallel trade is that a protected product is available from multiple sources: the right holder and traders or dealers.[43] The main motivation for parallel trade is price differences between countries for goods.[44] But the extent to which parallel trade is established in a country or region depends on the exhaustion doctrine that has been implemented by the local or regional government.[45] Because of the research-based, patent-protected nature of the pharmaceutical industry, parallel trade is particularly relevant in the context of prescription drugs.[46] Yet it is

[41] This Comment does not focus extensively on economic principles. Instead, this Comment will examine parallel trade primarily from the perspective of intellectual property law.

[42] ARFWEDSON, *supra* note 10, at 1. This Comment focuses on patents, specifically of pharmaceutical drugs.

[43] *Id.*; *see* Press Release, Eur. Comm'n, *supra* note 20 ("[P]arallel imports play an important role in preventing compartmentalisation of national markets.").

[44] EURACTIV, *supra* note 25.

[45] Matthews & Munoz-Tellez, *supra* note 11, at 1432.

[46] ARFWEDSON, *supra* note 10, at 6.

precisely because the stakes are so high and because so many players are involved in the pharmaceutical industry that parallel trade of drugs is controversial. The current parallel trade system for drugs in the EU illustrates the potential benefits of and issues surrounding this trade mechanism.

A. Price Differences Between Countries Drive Parallel Trade Systems

Parallel trade is motivated by price differences between countries for similar products.[47] A wholesaler in the country where the product is available at a low price can make a profit by selling the product in a country where it is currently sold at a higher price.[48] The main contributors to price differentials between countries include variations in intellectual property right protection, consumer purchasing power, government price regulation, inflation, tax rates, and marketing strategies.[49] Thus, these factors indirectly fuel parallel trade.

Many players operate within an economic market, and, as such, parallel trade affects several parties. The obvious example is consumers, who benefit from lower-priced products, although the exact amount of resultant savings to the consumer is uncertain.[50] Another group affected by parallel trade is the patent owners and local licensees. Patent right holders oppose parallel trade because they receive direct benefits from exclusively importing their protected product.[51] Patent right holders often set the selling price and parallel trade undermines the ability to control price by introducing competition.[52] Conversely, the presence of competition allows retailers, wholesalers, and traders to make a profit on the sale of parallel imports.[53] Finally, governments play a role in parallel trade systems because they may set price controls, which contribute to price differentials between countries.[54] Parallel imports may result in savings for governments that, for example, reimburse patient health-care costs.[55] Additionally, gov-

[47] Bart, *supra* note 20, at 997; EURACTIV, *supra* note 25.

[48] ARFWEDSON, *supra* note 10, at 6.

[49] *Id.*

[50] Matthews & Munoz-Tellez, *supra* note 11, at 1430; EURACTIV, *supra* note 25; *see also Parallel Distributions in Medicines—FAQs*, EUR. ASSOC. OF EURO-PHARMACEUTICAL COS., http://www.eaepc.org/faq/index.php?n=6 (last visited Nov. 4, 2010) (noting that another effect of parallel trade is the creation of additional jobs).

[51] Matthews & Munoz-Tellez, *supra* note 11, at 1431.

[52] *Id.*

[53] Press Release, Eur. Comm'n, *supra* note 20.

[54] *Parallel Imports of Proprietary Medicinal Products*, *supra* note 9, at 6.

[55] Matthews & Munoz-Tellez, *supra* note 11, at 1430.

ernments may select or promote parallel trade as a public policy mechanism to ensure consumer access to certain goods, such as drugs.[56] As such, a variety of economic factors contribute to the price differences for goods between countries that drive parallel trade systems. But it is local and regional governments, with the power to select an exhaustion doctrine, that determine whether a functioning parallel trade system is launched in the first place.

B. The Correlation Between the Selection of an Exhaustion Doctrine and the Existence of a Parallel Trade System

The concept of exhaustion emerges at the crossroad of intellectual property rights and economics. Patents give inventors the rights to exclude competitors from producing, selling, and distributing their invention for a specified period of time, typically twenty years from the filing date of the patent application.[57] Accordingly, the legal question regarding parallel trade is as follows: "To what extent should countries allow or limit the ability of [intellectual property] right holders within particular national/regional territories to control the movement of products across different markets on the basis of local ownership of [intellectual property] rights?"[58] This question is answered in part by the exhaustion doctrine implemented by a country or group of countries, which outlines the interaction between intellectual property rights and market forces.

The three types of exhaustion doctrines are national exhaustion, regional exhaustion, and international exhaustion. Under national exhaustion, the exclusive rights of a patent holder over his protected product cease after the first sale of the product within national borders.[59] Therefore, although patent holders cannot block sales within the country, they can prevent parallel imports from outside the country's borders.[60] The second type of exhaustion is regional exhaustion. Here, the exclusive rights of a patent holder end after the first sale of the patented product in a regional market.[61] The EU follows regional exhaustion, which means that parallel imports are allowed between member countries but are blocked from countries outside the EU.[62] The third type is international exhaustion, which is the exhaustion

[56] *Id.*
[57] ARFWEDSON, *supra* note 10, at 1.
[58] Matthews & Munoz-Tellez, *supra* note 11, at 1432.
[59] *Id.*
[60] *Id.*
[61] *Id.*
[62] *Id.*

doctrine with the widest scope. Under this approach, the patent rights granted to an inventor cease after the first sale of the patented product in any market in the world.[63] India, Malaysia, Taiwan, Israel, and Argentina are examples of countries that adopted international exhaustion.[64] In these countries, patent holders cannot prevent parallel imports from entering the local market by relying on intellectual property rights alone.[65]

No legally binding global agreement governs the exhaustion of patent rights.[66] Under the TRIPS Agreement and the Doha Declaration, WTO member countries can select the exhaustion doctrine that best fits their individual domestic policy goals.[67] This essentially means that parallel trade is a matter of national interest. A variety of factors can impact the choice of exhaustion doctrine and, in the context of parallel trade of pharmaceutical drugs, may include the presence of a local or regional pharmaceutical industry.[68]

C. Parallel Trade in the Pharmaceutical Industry: The Role of Patents and Profits

The pharmaceutical industry has been particularly susceptible to parallel trade. Parallel trade is driven by price differences between goods, and several internal and external characteristics of the pharmaceutical industry, ranging from strong patent rights over drugs to government regulations, impact the price of drugs. First, the pharmaceutical industry is an industry protected by patents,[69] which means pharmaceutical companies have the exclusive rights to make and sell a patented drug. Governments grant patents in reward for the significant research and development efforts required to develop new drugs.[70] Pharmaceutical companies hope to recoup research costs

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[63] *Id.*

[64] Bart, *supra* note 20, at 998.

[65] *Id.*

[66] ARFWEDSON, *supra* note 10, at 4.

[67] Doha Declaration, *supra* note 29, para. 5(d) ("The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN [most favored nation] and national treatment provisions of Articles 3 and 4."); TRIPS Agreement, *supra* note 28, art. 6 ("For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.").

[68] Bart, *supra* note 20, at 998.

[69] ARFWEDSON, *supra* note 10, at 6.

[70] *Id.*

from patented drug-sale profits.[71] Second, the research-based nature of the pharmaceutical industry results in a policy of active price discrimination on the part of pharmaceutical companies in an attempt to earn revenue.[72] Third, the pharmaceutical industry is a highly regulated industry and strict governmental drug-approval rules increase research costs, which in turn raise drug prices.[73] Finally, outside factors such as government-enforced price controls, exchange rates, consumer demand, and different intellectual property regimes also impact drug prices.[74] The combination of internal and external influences on the pharmaceutical industry contributes to the varying drug costs incurred by consumers.

The prevalence of parallel trade in the pharmaceutical industry has generated arguments for and against allowing parallel imports of drugs. Supporters point to the fact that in countries where drug costs are high, parallel trade may help lower costs because parallel trade increases the supply of drugs, and therefore, increases price competition.[75] But opponents of parallel trade argue that pharmaceutical companies will be less likely to invest in research and development because their profits will decrease due to the existence of lower-priced parallel imports.[76] The exclusive right of a pharmaceutical

[71] A. Bryan Baer, Note, *Price Controls Through the Back Door: The Parallel Importation of Pharmaceuticals*, 9 J. INTELL. PROP. L. 109, 126 (2001).

[72] *See generally id.* at 127 ("[P]harmaceutical companies segment the world market into discrete geographic regions adjusting price accordingly to maximize their recovery of capital." This approach incentivizes the development of new products.); Press Release, Eur. Comm'n, *supra* note 20 (noting price discrimination by drug manufacturers as a basis for parallel trade).

[73] ARFWEDSON, *supra* note 10, at 6.

[74] Matthews & Munoz-Tellez, *supra* note 11, at 1430; Baer, *supra* note 71, 126–27; *see also* Panos Kanavos & Sotiris Vandoros, *Competition in Prescription Drug Markets: Is Parallel Trade the Answer?*, 31 MANAGERIAL DECISION ECON. 325, 336 (2010) (finding that drug prices are determined by regulation, the presence of generic drugs in the market, and the number of competitors in the wholesale market).

[75] *See* Matthews & Munoz-Tellez, *supra* note 11, at 1430 ("By increasing the options for alternative supplies of products, parallel imports can allow consumers to gain access to the products they need from another market at lower prices than are being charged in their own market."); Joan Costa-Font & Aaron Burakoff, Comment, *An Overview of Progress in the International Regulation of the Pharmaceutical Industry*, 1 PIERCE L. REV. 103, 106–07 (2002) (noting that parallel importing "increase[s] both supply and price competition . . . ."); EURACTIV, *supra* note 25 (noting that parallel imports may help cut pharmaceutical costs for governments).

[76] *See* Claude E. Barfield & Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consume Welfare, and Health Policy*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 185, 187 (1999) (characterizing the pharmaceutical industry as a high-technology industry "where parallel imports will inhibit the ability of firms to recoup R&D [(research and development)] and other fixed costs and ultimately reduce their ability to innovate."); Costa-Font & Burakoff, *supra* note 75, at

company to market a drug allows it to charge super-competitive prices to recover research-and-development expenses for drugs that went to market and for unmarketable drugs.[77] Without the market protection that stems from a patent, pharmaceutical companies would not have an incentive to develop new drugs.[78] In rebuttal, supporters of parallel trade point to the lack of evidence that parallel trade has caused pharmaceutical companies to cut back on research.[79]

Supporters also argue that implementing a global international exhaustion system—that is, a system in which all countries would adopt the international exhaustion doctrine—would allow consumers worldwide to take advantage of lower prices.[80] Supporters say that international exhaustion of patent rights is consistent with the liberal trade policy promoted by the WTO and that the WTO should favor open trade over territorial-based restrictions that hinder free trade.[81] Opponents, however, respond that price discrimination is a good thing.[82] Besides noting that research and development requires that pharmaceutical companies are able to sell their drugs at a profit, those against parallel trade argue that price discrimination allows companies to offer lower prices in some countries and higher prices

107 ("Since parallel trade erodes the price differences, it undermines the price mechanism that pays for research and development."); EURACTIV, supra note 25 ("Big pharmaceutical companies say that, as their profits decrease due to parallel imports, they are obliged to invest less in R&D.").

[77] Baer, *supra* note 71, at 126.

[78] *Id.*

[79] *See* Donald Macarthur, *Parallel Trading of Medicines: The Case for a Fair Deal*, 11 CONSUMER POL'Y REV. 6, 9 (2001) ("Diversion of sales from one European country to another has not led to the research-based industry cutting back on research and development. According to the manufacturers' body, [European Federation of Pharmaceutical Industries and Associations], spend on pharmaceutical R&D in Europe grew more than three-fold from 1985 to 1999. There is no evidence that capital investment is affected either."). For an argument that parallel trade may increase incentives for drug manufacturers to develop innovative drugs by reducing the attractiveness of drugs that imitate already existing drugs, see Alain Schlaepfer, Innovation, Imitation and Parallel Trade in the Pharmaceutical Industry 1–2 (Aug. 2008) (unpublished manuscript) (presented at the 10th Annual European Trade Study Group Conference, 2008), *available at* http://www.etsg.org/ETSG2008/Papers/Schlaepfer.pdf.

[80] ARFWEDSON, *supra* note 10, at 2.

[81] Joan A. Harrelson, Note, *TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion*, 7 WIDENER L. SYMP. J. 175, 195 (2001).

[82] *See* ARFWEDSON, *supra* note 10, at 2–4 (reviewing a discussion that price discrimination promotes economic development through research while providing for low priced essential medicines); Barfield & Groombridge, *supra* note 76, at 187. ("[P]rice discrimination . . . will enhance welfare by facilitating entry into new, low-priced markets and thus expanding output.").

in others.[83] If a pharmaceutical company had to set only one price, it would likely set a price higher than many people could afford.[84] The argument follows that a global system of international exhaustion would actually raise prices for consumers in poor countries and shut them out of access to affordable medicines.[85]

In addition to the debate over drugs profits and pharmaceutical research, other arguments against parallel trade are also common. The amount of direct savings by consumers is uncertain.[86] Additionally, safety is a concern because faulty repackaging of drugs places consumers at risk.[87] The risk that counterfeit drugs will replace imported drugs is also a fear.[88] Finally, opponents look to the integrity of the patent-law system and note that restrictions on parallel trade are a "normal competitive restraint" that is "consistent with the purpose of patent protection."[89] But in the face of the arguments offered

[83] *See* ARFWEDSON, *supra* note 10, at 2 (noting the argument that if a company cannot price discriminate, it will only set one price, and that price would likely be higher than many consumers would be willing to pay).

[84] *Id.*

[85] *See id.* (noting the argument that a global regime of international exhaustion may hurt the welfare of individuals in poor countries because it would raise prices in those markets higher than the average international price); David W. Opderbeck, *Patents, Essential Medicines, and the Innovation Game*, 58 VAND. L. REV. 501, 554 (2005) ("The high demand elasticity in developing country markets makes R&D investment too great a gamble for developed country manufacturers if the developed country market cannot support monopoly prices."); Alan O. Skyes, *Public Health and International Law: TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution,"* 3 CHI. J. INT'L L. 47, 64 (2002) ("When parallel imports are possible, by contrast, [pharmaceutical companies] will likely become unwilling to sell at low prices in markets where demand is weak. Poorer countries may then find themselves largely priced out of the market for particular medications."); *cf.* Barfield & Groombridge, *supra* note 76, at 260 ("[P]rice differentials of pharmaceuticals across markets often have little to do with the pricing strategies of pharmaceutical firms; rather, it is based on government intervention."). Barfield and Groombridge stated this proposition in support of the argument that parallel trade may do little to create the uniform market that supporters of international exhaustion desire. *Id.* at 260. Yet this point also weakens the argument that price differentials are required to promote drug research and development.

[86] EURACTIV, *supra* note 25.

[87] Barfield & Groombridge, *supra* note 76, at 260.

[88] Bryan A. Liang, *Parallel Trade in Pharmaceuticals: Injecting the Counterfeit Element into Public Health*, 31 N.C. J. INT'L L. & COM. REG. 847, 852–53 (2006). The risk that drugs with "fake, tainted, different, expired, concentrated, or diluted drug forms and/or ineffective materials" could replace legitimate drugs en route to another market is a concern. *Id.* at 852. The risk that counterfeits may mix with legitimate drugs also exists; this is referred to as "salting." *Id.* at 853.

[89] Patricia M. Danzon, *The Economics of Parallel Trade*, 13 PHARMAECONOMICS 293, 301 (1998); *see also* Barfield & Groombridge, *supra* note 76, at 215 (arguing that patent protection is necessary to the pharmaceutical industry because other companies

by opponents of parallel trade, parallel trade has managed to take hold in the pharmaceutical industry and is most firmly established in the EU.

D. Strong Support for a Single Market and the Endurance of the European Parallel Trade System for Pharmaceutical Drugs

Parallel trade has a strong foundation in the EU. The Treaty Establishing the European Economic Community (EEC Treaty) permitted parallel trade in Europe. Articles 28 and 30 of the EEC Treaty prohibit national laws that restrict the free flow of goods between member countries,[90] and Article 81 prohibits agreements that attempt to restrict the common market with limitations, such as restrictions on production and development.[91] The EU's desire for a single market facilitated the implementation and acceptance of parallel trade.[92] Parallel trade contributes to the development of such a market by allowing products sold at different prices to move between the national markets of EU members and thereby increasing the availability of products to the consumer.[93]

The free movement of goods in the EU means that no member country can place legal, legislative, or other barriers between the

or individuals can easily copy drug compounds). Economists find that, especially in the pharmaceutical industry, "the symbiotic relationship between property rights granted through patents and the simultaneous increment to the nation's 'knowledge base' through publication of the patent, contributes strongly to technological advancement and higher economic growth." *Id.* at 259.

[90] EEC Treaty, *supra* note 36, arts. 28, 30. Article 28 of the EEC Treaty prohibits "quantitative restrictions on imports and all measures having equivalent effect." *Id.* art. 28. Article 30 of the EEC Treaty recognizes that restrictions may be necessary in some cases as long as the restrictions do not constitute arbitrary discrimination or disguised restrictions on trade between member countries. *Id.* art. 30.

[91] *Id.* art. 81. Article 81 of the EEC Treaty forbids "all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market . . . ." *Id.*

[92] *See, e.g.*, Case C-44/01, Pippig Augenoptik v. Hartlauer Handelsgesellschaft, 2003 E.C.R. I-3095, 1 C.M.L.R. 39, 1278 (2004) ("[I]n completing the internal market as an area without internal frontiers in which free competition is to be ensured, parallel imports play an important role in preventing the compartmentalisation of national markets.").

[93] Press Release, Eur. Comm'n, *supra* note 20; *see also Commission Communication on the Single Market in Pharmaceuticals*, at 1, COM (1998) 588 final (Nov. 25, 1998) ("The purpose of the completion of the Single Market in Pharmaceuticals is not just to provide an environment which is favorable for pharmaceutical innovation and industrial development, it is also to improve consumer choices in pharmaceuticals of the required quality, safety and efficacy, at an affordable cost.").

trading members.[94] In accordance with this approach, the EU follows the doctrine of regional exhaustion.[95] This means that within the EU, parallel trade is not restricted between member countries absent a private contract provision.[96] In some cases, a member country can stop or restrict parallel imports if the country shows that restrictive measures are necessary to protect human health and life or to protect industrial and commercial property.[97] Parallel imports from countries outside the EU follow the intellectual property laws of the territories from which they originated, and consequently, right holders in European member countries can ban parallel imports from outside the EU based on the principles of regional exhaustion.[98]

A review of the pharmaceutical parallel-import process in the EU provides insight into the mechanics of parallel trade. First, the parallel importer chooses an EU source country where the product is sold at a lower price than in another EU country.[99] The trader purchases the product from a retail vendor in the low-price country who originally purchased the drug directly from the manufacturer or a licensed reseller.[100] The parallel importer then repackages the product so the drug is labeled and contains instructions in the language of the receiving country.[101] To ensure that no alteration of the drug occurred during the repackaging process, the importer must identify who repackaged and manufactured the product, the repackaging must not damage the reputation of the trademark or its owner, and the trademark owner must receive notice before the repackaged product goes on sale.[102] A parallel trader must obtain a Parallel Im-

[94] Liang, *supra* note 88, at 852.

[95] Bart, *supra* note 20, at 998.

[96] Barfield & Groombridge, *supra* note 76, at 199.

[97] Press Release, Eur. Comm'n, *supra* note 20.

[98] Case C-355/96, Silhouette Int'l Schmied v. Harlauer Handelsgesellschaft, 1998 E.C.R. I-4799, 2 C.M.L.R. 953 (1998). The European Court of Justice (ECJ) in *Silhouette* held that a European Commission directive on trademarks only implemented an intra-community exhaustion rule: "[T]he Directive cannot be interpreted as leaving it open to the Member States to provide in their domestic law for exhaustion of the rights conferred by a trade mark in respect of products put on the market in non-member countries." *Id.* at 977. This means that EU countries "are required to uphold the right of trademark owners to restrict parallel imports" from outside the EU. Barfield & Groombridge, *supra* note 76, at 199. The case is assumed to apply to patents as well. *Id.* at 200; *see also* Matthews & Munoz-Tellez, *supra* note 11, at 1432 (noting that an implication of regional exhaustion is the ability of right holders to ban parallel imports from outside the region).

[99] ARFWEDSON, *supra* note 10, at 8.

[100] *Id.*

[101] *Id.*

[102] Press Release, Eur. Comm'n, *supra* note 20.

port Product License issued by a national agency or the European Medicines Agency.[103] Prior to placing the imported drug on the market, the trader must demonstrate that the imported drug is identical to the drug currently available on the importing country's market.[104] "Sufficiently similar" products—drugs "manufactured according to the same formulation, [use] the same active ingredients, and . . . have the same therapeutic effects"—are acceptable.[105] The policies behind the EU parallel trade system aim to further the goal of improving the quality, safety, and efficacy of health care for EU citizens.[106]

Parallel trade is attractive in Europe because the governments of EU member countries fix drug prices—drug prices are not controlled by free competition laws, as they are in the United States.[107] EU countries with socialized medicine favor parallel trade as a way to obtain cheaper drugs and reduce government health-care spending.[108] European case law reflects this preference, as cases starting from the 1970s onward have upheld the concept of regional exhaustion and have given priority to free trade throughout Europe.[109] Notably, the European Court of Justice (ECJ) held that a pharmaceutical company

[103] ARFWEDSON, *supra* note 10, at 10. In accordance with the concept of the free movement of goods, the European Medicines Agency has recently made parallel trade of pharmaceutical drugs in the EU easier by permitting a drug to go through a single registration process for safety, efficacy, and labeling review. Lana Kraus, Note, *Medication Misadventures: The Interaction of International Reference Pricing and Parallel Trade in the Pharmaceutical Industry*, 37 VAND. J. TRANSNAT'L L. 527, 545 (2004). Once approved, the drug may be placed on the market in all European countries with standardized labeling and dosage. *Id.* at 545.

[104] ARFWEDSON, *supra* note 10, at 8.

[105] Press Release, Eur. Comm'n, *supra* note 20.

[106] *Commission Communication on the Single Market in Pharmaceuticals*, *supra* note 93, at 1–2.

[107] EURACTIV, *supra* note 25.

[108] Julia A. Moore, *Parallel Trade, Unparallel Laws: An Examination of the Pharmaceutical Parallel Trade Law of the United States, the European Union and the World Trade Organization*, 6 RICH. J. GLOBAL L. & BUS. 77, 83 (2006); *cf.* Kanavos & Vandoros, *supra* note 74, at 336 (finding that parallel trade does not lead to price competition and characterizing the effect of parallel trade on the pharmaceutical budgets of European countries as "at best ambiguous").

[109] *See* Case 15/74, Centrafarm B.V. v. Sterling Drug Inc., 1974 E.C.R. 1147, 2 C.M.L.R. 480 (1974). The European Court of Justice (ECJ) in *Centrafarm* gave priority to free trade by holding that once a patent holder places a product on the market or consents to placing the product on the market, then his intellectual property rights are exhausted and such rights cannot prevent parallel imports. *Id.* at 503–04; *see also* Case 104/75, Officier van Justitie v. De Peijper, 1976 E.C.R. 613, 2 C.M.L.R. 271 (1976). In *De Peijper*, the ECJ held that consumers can import cheaper drugs from a pharmacy in another member country if the drug was for sale in the consumer's own country and interpreted Articles 30 to 36 (now Article 28 and 30) of the EEC Treaty as establishing the legality of parallel imports. 2 C.M.L.R. at 303–06.

exhausted its patent rights even if the company placed its product on the market in a country that did not offer patent protection for pharmaceutical drugs, as long as the company consented to placing its drug on that market.[110] In an unusual move in 2004, however, the ECJ in *Bundesverband der Arneimittel-Importeure eV v. Bayer AG* reversed the European Commission's decision that Bayer violated Article 81 of the EEC Treaty when Bayer penalized wholesalers in Spain and France with excise duties for exporting a drug to the United Kingdom, where it was forty percent more expensive.[111] Article 81 prohibits agreements that attempt to restrict the common European market.[112] But in *Bayer*, the ECJ held that Bayer could independently restrict parallel trade of its products.[113] Despite this holding, which appears to curb parallel trade, the European Commission has distinguished *Bayer* as concerning "competition issues (private sector practices regarding supplies) and does not alter the [ECJ's] case law on free movement of goods or state measures regarding parallel imports."[114] The relatively consistent commitment to the free movement

[110] Case 187/80, Merck & Co. Inc. v. Stephar B.V., 1981 E.C.R. 2063, 3 C.M.L.R. 463 (1981). Merck sold its drug in Italy, where, at the time, there were no patent protections for pharmaceutical drugs and prices were low. *Id.* at 467–68. Stephar imported the drug from Italy into the Netherlands. *Id.* The ECJ held that since Merck consented to putting its drug on the Italian market, it exhausted its patent rights, despite the absence of Italian patent protection. *Id.* at 471–72; *see also* Case C-267/95, Merck & Co. Inc. v. Primecrown Ltd., 1996 E.C.R. I-6285, 1 C.M.L.R. 83 (1997). The ECJ in *Primecrown* affirmed the principles in *Stephar*—namely, that the patentee consented to market the product in Spain and Portugal (where there were no pharmaceutical patent rights at the time) and, therefore, its rights were exhausted and traders could import the products into the United Kingdom. 1 C.M.L.R. at 172–74, 176; *cf.* Case 19/84, Pharmon B.V. v. Hoechst AG, 1985 E.C.R. 2281, 3 C.M.L.R. 775 (1985). In *Pharmon*, the issue was whether the ECJ should apply the exhaustion principle to drugs sold under a compulsory license. 3 C.M.L.R. at 781; *see infra* Part III.C (defining compulsory licensing). According to the ECJ, the patent rights were not exhausted because the patentee did not consent to the compulsory license. 3 C.M.L.R. at 791.

[111] Case C-2/01, 2004 E.C.R. I-23. 4 C.M.L.R. 692, 698 (2004). Article 81 was previously Article 85 of the EEC Treaty. 4 C.M.L.R. at 693.

[112] EEC Treaty, *supra* note 36, art. 81.

[113] *Bayer*, 4 C.M.L.R. at 713–14 ("The mere fact that the unilateral policy of quotas implemented by Bayer . . . produces the same effect as an export ban does not mean either that the manufacturer imposed such a ban or that there was an agreement prohibited by Art. 85(1) of the Treaty."); *id.* at 718 ("[T]he mere fact that there is a hindrance to parallel imports is not sufficient to demonstrate the existence of an agreement prohibited by Art. 85(1) of the Treaty.").

[114] Press Release, Eur. Comm'n, *supra* note 20. For an argument that the *Bayer* decision weakens the EU's economic solidarity and cohesiveness and that because the EU favors parallel trade, authorities will continue to encourage parallel trade, see generally Luke W. Reynolds, Note & Comment, *ECJ in* Bayer *Allows Pharmaceutical*

of goods by the ECJ likely correlates to the enduring EU parallel trade system.[115]

Empirical data shows that parallel imports account for a significant portion of the pharmaceutical markets in EU countries. Denmark and Sweden lead the way, with parallel imports making up 15.2% and 13.9%, respectively, of their pharmaceutical markets in 2007.[116] In Germany, the market share of re-imported drugs was 5.8% in 2002[117] and it reached 8.9% in 2007.[118] The increase is likely because of the continued effect of a 2001 German law that makes it mandatory for pharmacists to supply low-priced alternative drugs, namely, generics or parallel imports, when possible.[119] An estimated 90% of pharmacists supply parallel imports in the United Kingdom.[120] In 2007, parallel imports made up 12.4% of the United Kingdom market.[121] Parallel trade in the EU is expected to gradually increase as a result of the enlargement of the EU in 2004.[122]

Companies to Increase Profits by Breaking Down European Union Cohesion—With Just One Pill, 28 LOY. L.A. INT'L & COMP. L. REV. 379 (2006).

[115] As evidence of its continued commitment to promoting single EU market, the ECJ recently reiterated that agreements between producers and distributors defined in terms of national divisions in trade between member states may violate the EEC Treaty's goal of achieving a single market. Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, GlaxoSmithKline Services Unlimited v. Commission, 2009 ECJ EUR-Lex LEXIS 1330, ¶ 61 (3d Chamber Oct. 6, 2009). Evidence that consumers have been deprived of the benefits of effective competition in terms of supply or price is not required to find that an agreement is anti-competitive, as Article 81 of the treaty protects the overall structure of the market and not just the interests of competitors or consumers. *Id.* at ¶ 63. As such, an agreement between a drug manufacturer and Spanish wholesalers that distinguished between prices charged for domestic retail and prices charged for drug exports to other EU countries violated Article 81. *Id.* at ¶¶ 7, 66–67.

[116] EUR. FED'N OF PHARM. INDUS. & ASS'NS, THE PHARMACEUTICAL INDUSTRY IN FIGURES, KEY DATA, 2009 UPDATE 3 (2009), *available at* http://www.interfarma.org.br/site2/images/Site%20Interfarma/Informacoesdosetor/Publicacoes/EFPIA2009.pdf [hereinafter EFPIA].

[117] ARFWEDSON, *supra* note 10, at 11–12.

[118] EFPIA, *supra* note 116, at 3.

[119] ARFWEDSON, *supra* note 42, at 11.

[120] *Id.* at 13.

[121] EFPIA, *supra* note 116, at 3.

[122] EURACTIV, *supra* note 25. For example, Romania, which ascended to the EU in 2007, has become a "hotspot" for exporting drugs to other EU countries via parallel trade. *Parallel Trade Continues to Drive Pharma Exports*, BUS. MONITOR ONLINE (May 11, 2010), http://www.allbusiness.com/pharmaceuticals-biotechnology/pharmaceuticals-industry/14431230-1.html. Applications to the European Medicines Agency for parallel trade licenses for drugs originating in Romania jumped from 11 in 2007 to 191 in 2009. *Id.* Membership in the EU is largely attributed as the driving force behind Romania's growing pharmaceutical export industry, as "improved trade

Despite the establishment of parallel trade in the EU and its continued growth, criticisms of the system persist and mirror the general concerns of parallel trade described above.[123] Opposing parallel trade, the Association of the British Pharmaceutical Industry alleges that it caused a £1.3 billion loss in sales revenue for the United Kingdom–based pharmaceutical industry in 2005.[124] The European Federation of Pharmaceutical Industries and Associations agrees that the desire to create a single market for pharmaceuticals is contributing to significant losses for the research-driven pharmaceutical industry and believes that importers, not patients, are receiving benefits to the detriment of the intellectual property system.[125] Additionally, critics question whether parallel trade has really promoted a single market because differences between European national markets still exist.[126] Instead of facilitating a common market, parallel trade may highlight competing goals of the EU—namely, the ability of each member country to set its own drug prices versus the principle of free trade that allows traders to profit at the expense of pharmaceutical companies.[127] In addition, pharmaceutical companies may be responding to reduced profits by setting a uniform price that is higher than most consumers are willing to pay. For example, in 2003, Roche announced that it was setting a European drug price of fifty-two euros per day for its new AIDS drug, an amount higher than other AIDS drugs, which may symbolize an attempt to stop parallel trade from inhibiting research cost recovery.[128] Finally, the complexities of the European supply chain may create opportunities for counterfeit

conditions inherent in EU membership meant there was greater potential for sales of Romanian products abroad." *Id.*

[123] *See supra* Part II.C (describing the arguments against parallel trade).

[124] EURACTIV, *supra* note 25.

[125] ARFWEDSON, *supra* note 10, at 10; EURACTIV, *supra* note 25; *see also* Danzon, *supra* note 89, at 303–04 ("[I]f the free movement of goods is defined to permit parallel trade, this undermines the ability of pharmaceutical companies to maintain price differentials between countries. This reduces revenues which in turn has adverse long run effects on the level of R&D, particularly R&D investments in the EU . . . .").

[126] *Commission Communication on the Single Market in Pharmaceuticals*, *supra* note 93, at 3 ("The continued differences between European markets lead to excess costs (such as higher marketing costs, higher distribution and administrative costs) and, in some cases, to excess production capacity, that could be off-set by a better operating (single) market."). *But cf.* Moore, *supra* note 108, at 82 ("In the EU, the drive towards the single market outweighs the negative effects of parallel trade within the Community.").

[127] Costa-Font & Burakoff, *supra* note 75, at 107.

[128] Kraus, *supra* note 103, at 550.

pharmaceutical drugs to enter into the market,[129] another common argument offered by those who oppose parallel trade.

Supporters of the EU parallel trade system do exist. For example, the European Association of Euro-Pharmaceutical Companies notes reduced consumer spending as a result of parallel trade and also points to the benefits of competition and free movement of medicines.[130] This association also questions whether parallel imports really hurt drug companies' sales volume, given that parallel imports are still the original products produced by the industry.[131] Such support, coupled with the priority given to parallel trade by EU entities like the European Commission and the ECJ, suggests that the EU parallel trade system will continue to grow. Countries looking to adopt parallel trade would be well served by reviewing the EU's experience in establishing and maintaining parallel trade on a regional basis.

III. THE PUBLIC HEALTH CRISIS AND THE DESIRE FOR A SINGLE MARKET: A DISCUSSION OF PARALLEL TRADE IN THE AFRICAN UNION

The urgency of the public health crisis in the AU demands a thorough evaluation of the roles of intellectual property law and economics in addressing the crisis. Understanding the magnitude of the drug problem in the AU and the current state of African intellectual property regimes will provide a foundation from which to develop and refine solutions to improve access to affordable drugs. Importantly, the long-term vision of the AU—namely, to create a single African market[132]—must be considered in order to ensure that any solutions proffered accord with the goals and functions of the AU governing entities. Finally, a review of previous attempts to address the African public health crisis by international bodies, African countries, and other organizations highlights the ongoing search to find the optimal balance between intellectual property rights, market forces, and health care. Notably, parallel trade has been considered a means of increasing the availability of affordable drugs and has been adopted in South Africa. Parallel trade is relevant because the public health crisis in the AU creates strong motives to incorporate intellectual

[129] *See* Liang, *supra* note 88, at 854–56. Drugs may change hands more than twenty times before reaching their final destination. *Id.* A drug is manufactured in one country, shipped to the country with the intended market, sold by wholesalers in that country, and then moved to a more expensive market. *Id.* The World Health Organization (WHO) estimates that counterfeit drugs comprise eight to ten percent of the European pharmaceutical market. *Id.*

[130] ARFWEDSON, *supra* note 10, at 10; EURACTIV, *supra* note 25.

[131] EURACTIV, *supra* note 25.

[132] *See infra* Part III.B (describing the AU's goal of a common market).

property rights with the AU's goal of a common market in order to increase access to drugs.

A. Persistent Limited Access to HIV/AIDS Medication in Africa Despite Limited Patent Protection

The HIV/AIDS crisis and lack of affordable antiretroviral treatments in Africa is well documented. Sub-Saharan Africa continues to be the epicenter of the AIDS epidemic.[133] More than two out of three adults and nearly 90% of children living in the region are infected with HIV, resulting in a total of 22.5 million people living with HIV in Sub-Saharan Africa.[134] Almost three out of four AIDS deaths globally occurred in the region in 2007.[135] Approximately 17% of people in sub-Saharan Africa received HIV/AIDS medications in 2005.[136] South Africans account for 25% of those receiving antiretroviral treatment.[137] Countries like Botswana and Uganda have drug coverage of up to 50%, while the percentage of people receiving medication in other African countries remains below 10%.[138] Although the price of first line HIV/AIDS treatment has dropped, the price of second-line treatments remains very high, with significant price differences between African countries.[139]

Although the devastating effects of the drug crisis in Africa on HIV/AIDS patients are obvious, the exact reason why essential drugs are so inaccessible is not as readily evident. Patents, however, are not the main barrier preventing access to HIV/AIDS treatment in Africa. Although drugs may be patented in Africa under national patent law or through regional intellectual property groups, many antiretroviral drugs are not patented in Africa.[140] Despite this fact, the price for the drugs remains "unacceptably high" in some countries,[141] which weakens the argument that patents are the reason for lack of access to

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[133] JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS &WORLD HEALTH ORG., AIDS EPIDEMIC UPDATE 4 (Dec. 2007), *available at* http://data.unaids.org/pub/EPISlides/2007/2007_epiupdate_en.pdf.

[134] *Id.* at 7.

[135] *Id.*

[136] WORLD HEALTH ORG., PROGRESS ON GLOBAL ACCESS TO HIV ANTIRETROVIRAL THERAPY: A REPORT ON "3 BY 5" AND BEYOND 7 (March 2006), *available at* http://www.who.int/hiv/fullreport_en_highres.pdf.

[137] *Id.*

[138] *Id.*

[139] *Id.* at 29–30.

[140] Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?* 286 JAMA 1886, 1889 (2001).

[141] WORLD HEALTH ORG., *supra* note 136, at 29.

drugs. Other factors besides the exclusive rights granted by patents are likely responsible, such as the high cost of treatments, poverty, national regulatory requirements for medicines, tariffs and sales tax, and insufficient international aid.[142] Furthermore, whether patent protection in Africa is truly an incentive for pharmaceutical companies to develop and provide drugs for African consumers is debatable.[143] Given the variety of factors suggested as contributors to the drug crisis, a deeper look at the current market situation and intellectual property law in the AU is worthwhile.

B. Intellectual Property in the African Union Reflects the Goal of a Single Market

Unlike the EU, with its established parallel trade system, countries that make up the AU are still in the infant stages of working towards a single market.[144] But recent activities within the AU reflect the goal of building a common market. In 2002, to promote peace, security, and stability, the AU succeeded the Organization for African Unity.[145] The AU Constitution incorporates the Treaty Establishing the African Economic Community (Treaty of Abuja) which envisions a common African market.[146] The Treaty of Abuja calls for the creation and expansion of regional economic communities (RECs) to promote and strengthen trade between groups of African countries, with the goal of integrating the RECs into a single market based on free trade by 2023.[147] The AU Commission functions as the day-to-day manager of the AU and "elaborates, promotes, coordinates and har-

[142] Attaran & Gillespie-White, *supra* note 140, at 1886, 1890–91.

[143] *Id.* at 1890 ("[I]t is doubtful that pharmaceutical research and development will always require the incentive of patentability in poor countries, since the option to patent antiretroviral drugs in African has frequently gone unexercised."); *see also* Opderbeck, *supra* note 85, at 554 ("[N]o matter what level of patent protection is afforded in developing countries, it is unlikely that developed country manufacturers will devote significant R&D resources to such [essential medicine] vaccines or treatments.").

[144] The AU consists of fifty-three member states; the only African state not in the AU is Morocco. *Member States*, AFRICAN UNION, http://www.africa-union.org/root/au/memberstates/map.htm (last visited Nov. 4, 2010).

[145] *African Union in a Nutshell*, AFRICAN UNION, http://www.africa-union.org/root/au/AboutAu/au_in_a_nutshell_en.htm (last visited Nov. 4, 2010).

[146] Treaty Establishing the African Economic Community art. 6, June 3, 1991, *available at* http://www.africa-union.org/root/au/Documents/Treaties/Text/AEC_Treaty_1991.pdf [hereinafter Treaty of Abuja].

[147] *Id.* Examples of RECs include the East African Community and the Economic Community of West African States. EAST AFRICAN COMMUNITY, http://www.eac.int/ (last visited Nov. 4, 2010); ECONOMIC COMMUNITY OF WEST AFRICAN STATES, http://www.ecowas.int/ (last visited Nov. 4, 2010).

monizes the programmes and policies of the Union with those of the RECs."[148] Unlike the European Commission, which has the power to draft new laws and implement the policies of the European Parliament and the European Council,[149] the AU Commission has no powers of its own.[150] Challenges to African integration and achievement of a common market include lack of financial resources and political will, poor infrastructure, and inadequate trade facilitation.[151] But in spite of these challenges, it is important to recognize the AU's desire for a single market and to view intellectual property law in the AU within that framework.

Most African countries have established patent regimes. For example, the earliest patent acts date in Rwanda to 1963, Liberia to 1972, Senegal to 1977, Democratic Republic of the Congo to 1982, and Ethiopia to 1995.[152] Additionally, regional-based intellectual property associations in Africa that are independent of the RECs aim to unify intellectual property regimes within Africa.[153] These associations are notable because they show a relative willingness by African

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[148] Constitutive Act of the African Union art. 20, July 11, 2000, *available at* http://www.africa-union.org/root/au/AboutAu/Constitutive_Act_en.htm; *African Union in a Nutshell*, *supra* note 145.

[149] EEC Treaty, *supra* note 36, art. 211 ("The Commission shall . . . have its own power of decision and participate in the shaping of measures taken by the Council and by the European Parliament in the manner provided for in this Treaty"); *The European Commission*, EUROPA, http://europa.eu/institutions/inst/comm/index_en.htm (last visited Nov. 4, 2010).

> [The European Commission] drafts proposals for new European laws, which it presents to the European Parliament and the Council. It is also the EU's executive arm—in other words, it is responsible for implementing the decisions of Parliament and the Council. That means managing the day-to-day business of the European Union: implementing its policies, running its programmes and spending its funds.

Id.

[150] Constitutive Act of the African Union, *supra* note 148, art. 20(3) ("The structure, functions and regulations of the Commission shall be determined by the Assembly."); Keith Gottschalk & Siegmar Schmidt, *The African Union and the New Partnership for Africa's Development: Strong Institutions for Weak States?* 4 INTERNATIONALE POLITIK UND GESELLSCHAFT [INT'L POL. & SOC'Y] 138, 141 (2004).

[151] *See* Gottschalk & Schmidt, *supra* note 150, at 142; Dejo Olowu, *Regional Integration, Development, and the African Union Agenda: Challenges, Gaps, and Opportunities*, 13 TRANSNAT'L L. & CONTEMP. PROBS. 211, 235–43 (2003).

[152] *Least Developed Countries—Country Profiles*, WORLD INTELL. PROP. ORG., http://www.wipo.int/ldcs/en/country (last visited Nov. 4, 2010).

[153] *See Africa Bureau—Cooperation and Partners*, WORLD INTELL. PROP. ORG., http://www.wipo.int/africa/en/partners_org/ (last visited Nov. 4, 2010). The two main regional intellectual property organizations in Africa are the African Regional Intellectual Property Organization and the African Intellectual Property Organization. *Id.*

countries to cooperate on a regional basis when it comes to trade-related issues.

Created in 1977, the African Intellectual Property Organization (OAPI) covers Francophone Africa and is regulated by the Revised Bangui Agreement.[154] The goals of the OAPI are to implement a common procedure for granting intellectual property rights, to promote economic development by effective protection of such rights, and to encourage creativity and technology transfer.[155] The Revised Bangui Agreement serves as the national patent law for all OAPI member countries.[156] The World Health Organization and Doctors Without Borders voiced concern over the Revised Bangui Agreement.[157] The organizations criticized the accord because it imposes strict conditions on the use of compulsory licenses and does not explicitly allow parallel imports from non-OAPI member countries.[158] The agreement, characterized as "TRIPS Plus," takes a stricter approach than the basic intellectual property protection requirements set out in the TRIPS Agreement.[159]

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[154] *See* Revised Bangui Agreement tit. 1, § 1, art. 2, Feb. 24, 1999, *available at* http://www.wipo.int/wipolex/en/other_treaties/details.jsp?group_id=21&treaty_id=227 (select "Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization"); *African Intellectual Property Organization*, WORLD INTELL. PROP. ORG., http://www.wipo.int/africa/en/partners_org/partners/oapi_bg.html (last visited Nov. 4, 2010).

[155] Revised Bangui Agreement, *supra* note 154, tit. 1, § 1, art. 2.

[156] INT'L INTELL. PROP. INST., PATENT PROTECTION AND ACCESS TO HIV/AIDS PHARMACEUTICALS IN SUB-SAHARAN AFRICA 39–41 (2000), *available at* http://www.wipo.int/about-ip/en/studies/pdf/iipi_hiv.pdf; *see* Enyinna S. Nwauche, A Development Oriented Intellectual Property Regime for Africa at Part V.I(a) (2005) (unpublished manuscript) (presented at 11th General Assembly of the Council for the Development of Social Science Research for Africa, 2005), *available at* http://www.codesria.org/IMG/pdf/nwauche.pdf ("[T]he OAPI states are closely integrated and could be considered a common intellectual property market.").

[157] *See* Press Release, Médecins San Frontières, New Agreement on Patents for Medicines in Francophone Africa Threatens Health of Populations (May 11, 2000), *available at* http://doctorswithoutborders.org/press/release.cfm?id=597&cat=press-release.

[158] COMM'N ON INTELL. PROP. RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 161 (Sept. 2002), *available at* http://www.iprcommission.org/graphic/documents/final_report.htm; World Health Org., *Fears Over New Regional Patent Agreement*, ESSENTIAL DRUGS MONITOR, No. 28/29, at 35 (2000), *available at* http://apps.who.int/medicinedocs/pdf/s2248e/s2248e.pdf; Press Release, Médecins San Frontières, *supra* note 157; *see infra* Part III.C (defining compulsory licensing).

[159] *See* Susan K. Sell, *The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive, and Institutional Dimensions*, 77 TEMP. L. REV. 363, 385–86 (2004).

Established in 1976 by the Agreement on the Creation of the African Regional Intellectual Property Organization, the African Regional Intellectual Property Organization (ARIPO) covers English-speaking Africa.[160] The sixteen member countries include Kenya, Ghana, Uganda, and Zimbabwe.[161] The goals of the ARIPO include harmonizing and developing intellectual property laws, promoting the exchange of ideas, and providing training.[162] Unlike the OAPI, which provides substantive national patent law for its members through the Revised Bangui Agreement, the ARIPO's activities are largely procedural. For example, under the Harare Protocol on Patents and Industrial Designs, the ARIPO has the power to grant patents on behalf of member countries.[163] But the laws of each ARIPO member country determine the substantive rights stemming from the patent.[164] Therefore, the ARIPO serves mainly as a facilitative body that enables faster registration for intellectual property rights.[165]

Information about African intellectual property law is difficult to obtain for several reasons. Most African countries have a small intellectual property law profession, communication is difficult, and intellectual property is often seen as an imported commodity that is unaffordable, as in the case of patented drugs.[166] Some countries, like South Africa and Nigeria, have stronger intellectual property regimes than others.[167] Finally, the OAPI and the ARIPO are underutilized because of lack of confidence in patent protection or general indifference.[168] But national patent laws and the OAPI and the ARIPO are

[160] Agreement on the Creation of the African Regional Intellectual Property Organization art. 1, Nov. 13, 2004, *available at* http://www.aripo.org (select "Downloads"; then choose "Laws & Protocols"; then view "The Lusaka Agreement on the Creation of the Organization").

[161] *Id.*

[162] *Id.* art. 3.

[163] Protocol on Patents and Industrial Designs Within the Framework of the African Regional Intellectual Property Organization § 1, Feb. 24, 2007, *available at* http://www.aripo.org (select "Downloads"; then choose "Laws & Protocols"; then view "The Harare Protocol on Patents, Utility Models, and Designs").

[164] *Id.* § 3(11) ("Provided it is maintained, a patent granted by the Office shall in each designated State have the same effect as a patent registered, granted or otherwise having effect under the applicable national law."); Nwauche, *supra* note 156, at Part V.I(b).

[165] Nwauche, *supra* note 156, at Part V.I(b).

[166] Jeremy Phillips, *Intellectual Property and Africa: The Agony and Entropy*, 3 J. INTELL. PROP. L. & PRAC. 205, 205 (2008).

[167] *Id.*

[168] *Id.* See Nwauche, *supra* note 156, at Part V.I(c), for an argument of the need for one intellectual property organization in Africa to promote the AU's goal of creating a common African market.

not the only sources of intellectual property within the AU. International bodies have attempted to shape intellectual property in developing countries and have consequently impacted AU countries, particularly in the context of public health.

C. The Compulsory Licensing Option Under the TRIPS Agreement and the Doha Declaration: A Potential Means of Addressing the Drug Crisis, but Not a Cure-All

Although the TRIPS Agreement is silent on parallel trade and leaves the selection of an exhaustion doctrine up to each WTO member country, the agreement offers compulsory licensing as another way for developing countries to obtain patented drugs. Article 31 of the TRIPS Agreement allows for the use of patented subject matter by a government or authorized third party without the permission of the patent right holder if certain requirements are met.[169] When a government grants a compulsory license, the patentee can no longer exclude others from using the claimed patented subject matter.[170] In the context of patented drugs, a compulsory license means a government can produce and sell a patented drug without the authorization of the pharmaceutical company.[171]

Although the WTO introduced compulsory licensing as another way of increasing access to patented goods, member countries recognized several limitations of the compulsory-license provision as provided in Article 31 of the TRIPS Agreement.[172] First, Article 31(b) says that a country seeking to use the compulsory-license mechanism should obtain consent from the patent holder to use the patented product, but countries can waive this requirement in national emergencies.[173] The Doha Declaration expanded the scope of Article 31(b) by broadly defining the phrase "national emergency."[174] Para-

[169] TRIPS Agreement, *supra* note 28, art. 31. Under Article 31(b), governments or authorized third parties seeking a compulsory license should make an effort to first obtain consent from the patent right holder. *Id.* art. 31(b). Governments or authorized third parties may waive this requirement during a national emergency. *Id.* According to Article 31(f), governments or authorized third parties can only grant a compulsory license for domestic use. *Id.* art. 31(f). As stated in Article 31(g), the license is terminated when the circumstances that led to the compulsory license no longer exist. *Id.* art. 31(g). Under Article 31(h), the entity granting the compulsory license should pay the patent holder remuneration to compensate for suspension of his patent rights. *Id.* art. 31(h).

[170] Harrelson, *supra* note 81, at 176.

[171] *Id.*

[172] Opderbeck, *supra* note 85, at 511–12.

[173] TRIPS Agreement, *supra* note 28, art. 31(b).

[174] *See* Doha Declaration, *supra* note 29, para. 5(c).

graph 5(c) of the declaration states that "[e]ach Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."[175] Second, the requirement in Article 31(f) of the TRIPS Agreement that a member country may only grant a compulsory license predominantly for domestic use is problematic for many developing countries because, even if they were to grant a compulsory license, they lack the manufacturing capability to produce pharmaceuticals domestically.[176] A resolution passed on August 30, 2003 (the "August 30 Decision") addresses this issue and includes a waiver for Article 31(f) that allows developed member countries to produce and export generic drugs to developing countries without manufacturing capabilities.[177]

Despite the ability of developed countries to export generic drugs to developing countries, only one developed country has granted a compulsory license for this purpose so far.[178] In October 2007, Canada granted a compulsory license permitting a Canadian pharmaceutical company to manufacture and export generic AIDS

[175] *Id.*

[176] *See* TRIPS Agreement, *supra* note 28, art. 31(f). Paragraph 6 of the Doha Declaration recognizes that because of the domestic use limitation in article 31(f) of TRIPS, "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement." Doha Declaration, *supra* note 29, para. 6; *see also* Opderbeck, *supra* note 85, at 512 ("The Doha Ministerial also acknowledged that the 'domestic use' limitation on compulsory licensing would limit the value of [the national emergency exception] for many developing countries and LDCs [(least-developed countries)] that do not have sufficient domestic manufacturing capacity."). In regards to the Article 6 problem of the Doha Declaration, developing countries argued that the broad language of TRIPS meant that member countries could grant compulsory licenses "for foreign suppliers to provide medicines in the domestic market" and that members could "grant compulsory licenses to supply foreign markets." Skyes, *supra* note 85, at 54–55 (citing *Developing Countries Push for TRIPS to Allow Cheaper Medicines*, 19 INSIDE U.S. TRADE 7 (June 22, 2001)).

[177] Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540, 43 I.L.M. 509 (2004) (decision of Aug. 30, 2003). The August 30 Decision requires certification that the importing country lacks domestic manufacturing capabilities, distinct labeling and packaging requirements, and limits remuneration only the exporting country. *Id.*; Opderbeck, *supra* note 85, at 514; Alexandra G. Watson, Note, *International Intellectual Property Rights: Do TRIPS' Flexibilities Permit Sufficient Access to Affordable HIV/AIDS Medicines in Developing Countries?* 32 B.C. INT'L & COMP. L. REV. 143, 146–47 (2009).

[178] Watson, *supra* note 177, at 147.

drugs to Rwanda.[179] The lackluster response to compulsory licensing may stem from fears that developed countries will exert undue influence over developing countries that accept the exports.[180] Many developing countries fear sanctions and business repercussions as a result of issuing compulsory licenses.[181] Consequently, compulsory licensing could be a valuable tool, but as evidenced by the controversies surrounding the WTO decisions and the lack of usage, compulsory licensing is not the cure-all to the problem of affordable drugs.

D. South Africa's Controversial Enactment of Parallel Trade and EU-Style Regulation

South Africa is a microcosm of the public health crisis in the AU and also a forerunner in addressing the drug problem. In 2007, approximately 5.7 million adults and children were living with HIV/AIDS in South Africa.[182] Although the country has not consistently addressed health-care inequities stemming from the AIDS epidemic,[183] South Africa took a significant step to address the lack of affordable medications in 1997. The South African government passed the Medicines and Related Substances Control Amendment Act, which explicitly authorizes parallel imports and compulsory licensing to promote access to affordable drugs.[184] South Africa enacted the

[179] *Id.*; *Canada Issues Compulsory License for HIV/AIDS Drug Export to Rwanda, in First Test of WTO Procedure*, 11 BRIDGES WKLY. TRADE NEWS DIG. 4 (2007), *available at* http://ictsd.org/downloads/bridgesweekly/bridgesweekly11-32.pdf.

[180] Watson, *supra* note 177, at 147.

[181] *Id.* at 158–59.

[182] WORLD HEALTH ORG., EPIDEMIOLOGICAL FACT SHEET ON HIV AND AIDS SOUTH AFRICA 4 (Sept. 2008), *available at* http://apps.who.int/globalatlas/predefinedReports/EFS2008/full/EFS2008_ZA.pdf.

[183] Hoosen Coovadia et al., *The Health and Health System of South Africa: Historical Roots of Current Public Health Challenges*, 374 LANCET 817, 824 (2009).

[184] Section 10 of the Medicines and Related Substances Control Amendment Act 90 of 1997 called for the addition of Section 15C to the Medicines and Related Substances Control Act of 1965 and reads as follows:

> The following section is hereby inserted in the principal Act [Medicines and Related Substances Control Act of 1965] after section 15B: "Measures to ensure supply of more affordable medicines 15C. The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public and in particular may—(a) notwithstanding anything to the contrary contained in the Patents Act 1978 (Act No. 57 of 1978) determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine or with his or her consent; (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality

doctrine of international exhaustion by permitting the importation of a patented medicine into the country that the patent holder first placed on sale outside of South Africa.[185]

South Africa set guidelines for the introduction of parallel imports into the market that resemble the parallel-import requirements under the regional exhaustion system in the EU.[186] The guidelines require prior registration of the patented medicine in South Africa and a trader must receive a permit from the Ministry of Health.[187] After receiving an importing permit, the trader must register the drug that it plans to import and provide information about the exporter and the labeler.[188] The guidelines also require repackaging of the drug using the name approved in South Africa and placement of the words "Parallel Imported Medicine" on the label.[189] The largest exporter of these drugs to South Africa is India,[190] which illustrates the global impact of parallel trade.

> standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported; (c) prescribe the registration procedure for as well as the use of the medicine referred to in paragraph (b).

Medicines and Related Substances Control Amendment Act 90 of 1997, *supra* note 35, § 10; *see also* Bart, *supra* note 20, at 998 (describing the enactment of the Medicines and Related Substances Control Amendment Act, which legalized parallel imports of expensive AIDS drugs); Bess-Carolina Dolmo, Note, *Examining Global Access to Essential Pharmaceuticals in the Face of Patent Protection Rights: The South African Example*, 7 BUFF. HUM. RTS. L. REV. 137, 140–41 (2001) (summarizing the implementation of and reaction to South Africa's legalization of parallel imports).

[185] Draft Regulations in Terms of Act 101 of 1965, as amended (2000) (S. Afr.), *available at* http://www.doh.gov.za/docs/regulations/2001/101draftregulations.pdf ("A medicine under patent in the Republic may be imported into and disposed of in the Republic if such medicine has been put onto the market outside the Republic by or with the consent of the patent holder of the medicine in the Republic subject to the provisions of the Act and these Regulations."); *see also* YOLANDA TAYLER, BATTLING HIV/AIDS: A DECISION MAKER'S GUIDE TO THE PROCUREMENT OF MEDICINES AND RELATED SUPPLIES 117 (World Bank Publications 2004) (summarizing the guidelines for parallel imports in South Africa under the rule of international exhaustion).

[186] *See supra* Part II.D (describing the parallel trade process in the EU).

[187] Guideline for Parallel Importation of Medicines in South Africa in GG25145 of 27 June 2003 (S. Afr.), *available at* http://www.info.gov.za/notices/2003/25145/25145h.pdf.

[188] *Id.*

[189] *Id.*

[190] Shubha Ghosh, *Pills, Patents, and Power: State Creation of Gray Markets as a Limit on Patent Rights*, 53 FLA. L. REV. 789, 814 (2001).

South Africa's implementation of international exhaustion was not without controversy. Questioning the constitutionality of the Medicines and Related Substances Control Amendment Act, thirty-nine pharmaceutical companies sued the South African government.[191] The United States also became involved in efforts to reverse the law.[192] But in the face of public pressure, the pharmaceutical companies dropped the lawsuit.[193] South Africa is an example of an African country that saw parallel trade as a viable means of increasing access to affordable drugs and took the broadest approach possible—international exhaustion.

E. Other Proposals for Solving Africa's Drug Crisis: Attempts to Limit Parallel Trade

In an attempt to solve the problem of affordable drugs, existing proposals offered by outside organizations have addressed the role of parallel trade. Many of these proposals look primarily to the relationship between developed and developing countries and, as a result, view parallel trade as a harmful trade mechanism. Such proposals advocate limiting parallel trade with an eye towards promoting the pharmaceutical industry or licensing purchase rights on an international level. But a parallel trade system based on regional exhaustion has not been completely overlooked, which illustrates the need to further consider the feasibility of such a system.

The goal of the Developing Economies' Fund for Essential New Drugs (DEFEND) Proposal is to establish "a new international organization to purchase the license rights for designated areas and distribute the drugs at low cost with a required co-payment from local governments. Furthermore, governments would restrict parallel trade to support desirable price discrimination."[194] Supporters of the DEFEND Proposal advocate separating the cost of giving consumers access to drugs from incentives for pharmaceutical companies to improve and research drugs.[195] Supporters also look towards increased assistance from developed countries as a major source of funding for the project.[196]

The International Intellectual Property Institute's (IIPI) plan includes dividing national markets by ability to pay for pharmaceuticals,

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[191] Bart, *supra* note 20, at 998.

[192] Dolmo, *supra* note 184, at 138.

[193] Bart, *supra* note 20, at 998; Dolmo, *supra* note 184, at 138.

[194] ARFWEDSON, *supra* note 10, at 22.

[195] *Id.*

[196] *Id.*

adopting prices for pharmaceuticals based on ability to pay, and implementing a system of international subsidies to help poorer countries afford drugs.[197] The IIPI's plan focuses on global adoption of national exhaustion of IP rights.[198] According to the IIPI's proposal, rejecting international exhaustion protects pharmaceutical companies from the effects of parallel importing.[199] Developing countries, however, have not been supportive of national exhaustion,[200] likely because it shuts out access to parallel imports. The balance between the competing interests of developing countries and pharmaceutical companies is a difficult one to strike because so many variables are present.[201]

Both the DEFEND Proposal and the plan advocated by the IIPI aim to restrict parallel imports. But one scholar, Professor Keith Maskus, notes that regional exhaustion regimes among poor countries may be a viable option to improve access to drugs.[202] Professor Maskus suggests that the adoption of regional exhaustion by poorer countries would increase the size of the market in which prices are integrated, would allow low-income nations to avoid high prices for low-volume products, and would reduce transportation costs typically incurred with parallel trade on an international level.[203] The expectation would fall on regional groups consisting of low-income countries to ban parallel exports to high-income economies in order to keep supply available locally and not undermine pricing in countries outside the region.[204]

By outlining the potential benefits of a regional exhaustion system in developing countries and pointing to the need for self-imposed limits of such a system, Professor Maskus's proposal shows the value of considering all sides of parallel trade. Instead of looking

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[197] Harrelson, *supra* note 81, at 197–98.

[198] *Id.*

[199] *Id.*

[200] *Id.*

[201] *See, e.g.*, Kraus, *supra* note 103, at 552 ("The ideal solution would integrate three objectives: (1) allow for the promotion of pharmaceutical R&D, (2) create incentives for pharmaceutical companies to provide essential medicines to underdeveloped countries at an affordable cost (encourage differential pricing), and (3) promote principles of free trade.").

[202] KEITH E. MASKUS, PARALLEL IMPORTS IN PHARMACEUTICALS: IMPLICATIONS FOR COMPETITION AND PRICES IN DEVELOPING COUNTRIES, FINAL REPORT TO THE WORLD INTELLECTUAL PROPERTY ORGANIZATION 3 (2001), *available at* http://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/ssa_maskus_pi.pdf.

[203] *Id.* at 43.

[204] *Id.*

to shut out parallel trade, the growing prominence of this trade mechanism should be acknowledged. This approach is critical in light of the AU's desire for a common market and the establishment of parallel trade in South Africa to lower drug costs. Regional exhaustion in the AU has the potential to serve as an effective means for increasing access to affordable drugs while complementing the AU's goal of a common market and addressing the evolving presence of parallel trade.

IV. REGIONAL EXHAUSTION IN THE AFRICAN UNION: ANOTHER TOOL IN THE FIGHT FOR AFFORDABLE MEDICATIONS

In light of the EU's success with regional exhaustion and the urgent need for medications, the AU should consider a regional parallel trade system to supplement other measures, such as compulsory licensing, and increase the availability of affordable drugs. The impetus to adopt regional exhaustion is strong in the AU. African countries have a basic need for essential medicines at an affordable cost that is aggravated by extreme price differences between AU countries.[205] Recent activities by African countries demonstrate the willpower necessary to obtain affordable drugs and improve cohesion across the continent. For example, developing countries put up a strong fight with regard to expanding the scope of the compulsory licensing measures in the TRIPS Agreement to cover public health crises.[206] Furthermore, regional intellectual property organizations reflect the AU's goal of a common market.[207] South Africa turned to parallel trade in an attempt to make pharmaceutical drugs more affordable for its citizens and has reached out to countries like India to fulfill that goal.[208] Instead of looking outward, a parallel trade system built on regional exhaustion should be considered a viable means of bringing affordable drugs to Africa.

As with any proposal, both the intended and unintended consequences must be considered. To date, the parallel trade discussion has focused on the battle over pharmaceutical companies' profits and patent protection while pitting developed countries against developing countries. Despite continued debate over the exact impact of pa-

[205] *See infra* Part IV.A (explaining findings of significant variations in prices for similar drugs in AU countries).

[206] *See supra* Part III.C (describing the evolution of the compulsory licensing measure in the TRIPS Agreement).

[207] *See supra* Part III.B (noting the AU's desire for a single market).

[208] *See supra* Part III.D (summarizing South Africa's experience with parallel trade).

rallel trade on the research-driven pharmaceutical industry and questions about consumer savings, parallel trade of drugs does not show signs of stopping and simply cannot be dismissed any longer. Furthermore, the impact of any proposed solution to the drug crisis, including parallel trade, on the relationship between developed and developing countries should be acknowledged from the outset. Meaningful limits on regional parallel trade should be implemented to ensure that parallel imports reach the intended consumers in the AU and that developing AU countries do not have to fear repercussions from developed countries. By addressing potential consequences, the benefits of a regional parallel trade system can be fully appreciated. A parallel trade system based on regional exhaustion would provide the AU with another tool in the fight to bring affordable drugs to patients.

A. Drug Price Differentials Between African Union Countries and the Desire for a Common Market as Motivators for the Adoption of Regional Exhaustion

The choice of exhaustion doctrine is a sovereign decision and presents an opportunity to promote national or regional interests.[209] South Africa implemented international exhaustion in 1997, and the move caused immediate outcry from pharmaceutical companies and the United States.[210] In light of the controversy over international exhaustion,[211] adoption of an international exhaustion system across AU countries is unlikely to be politically feasible. But other factors—namely, price differentials between AU countries, the desire for a common market, and improved distribution—favor the enactment of a parallel trade system based on regional exhaustion in the AU.

First, the main driving factor for parallel trade is price differences between countries for similar products,[212] and the AU meets this prong of the test. Drug prices differ significantly between countries in the AU—not just between developed and developing countries globally. The extreme range of drug prices in Africa is evident from a recent empirical study: retail prices for the drug ciprofloxacin, which treats bacterial infections, ranged from $197 to $740; for metformin,

[209] *See supra* notes 66–67 and accompanying text (explaining the WTO's open stance on the principle of exhaustion).

[210] *See supra* Part III.D (describing the controversy surrounding South Africa's enactment of parallel trade).

[211] *See supra* Part II.C (noting the arguments for and against adopting international exhaustion).

[212] Bart, *supra* note 20, at 997.

a drug used for treatment of diabetes, prices ranged from $5 to $50.[213] The ratio of lowest to highest retail prices between African countries spread from 1:1.1 to 1:10.[214] Notably, the ratio for drug prices between OCED countries, which includes several European countries that are key parallel importers, such as Denmark, Germany, and the United Kingdom, ranged from only 1:1.6 to 1:3.6.[215] A recent study noted that even though the public sector may provide medicines at a reduced cost, such medicines are not consistently available and patients must still buy drugs in the private sector where they are often unaffordable.[216] For example, the mark-up of drug prices, which measures the difference between the manufacturer's selling price and the final price charged to patients after add-on costs such as taxes, varied from 56% in Tanzania to 358% in Uganda in the private sector.[217] Similarly, prices for the same drug differed by 124% between Ethiopia and Uganda.[218] Compared to African countries, the price differences between drugs in European countries is relatively small, yet parallel trade is still viewed in the EU as an effective means of reducing drug costs. The variation in prices is even greater between AU countries and the need to provide affordable drugs is even more urgent. The main motivation for parallel trade via regional exhaustion—price differences between localized countries—is present between AU member states.

Second, like the EU, the ultimate goal of the AU is to achieve a single African market based on free-trade principles. The EU turned to regional exhaustion as a means of achieving a common market; regional exhaustion has the potential to facilitate a common market in the AU as well. Importantly, the high degree of homogeneity among European member states is a large reason for the successful integration of the EU as a political and economic unit.[219] Therefore,

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[213] K. Bala and Kiran Sagoo, *Patents and Prices*, HAI NEWS (Health Action Int'l, Amsterdam, The Netherlands), Apr./May 2000, at tbl.7, *available at* http://www.haiweb.org/pubs/hainews/Patents%20and%20Prices.html.

[214] *Id.*

[215] *Id.*

[216] A. Cameron et al., *Medicine Prices, Availability, and Affordability in 36 Developing and Middle-Income Countries: A Secondary Analysis*, 373 LANCET 240, 245 (2009). The same study found that the availability of generic drugs, which are typically lower priced than branded drugs, varies widely within Africa, ranging from 14.8% availability in Chad to 79.1% in Ethiopia. *Id.* at 244.

[217] *Id.* at 245.

[218] MYHR, *supra* note 24, at tbl.9.

[219] Yi Feng and Gaspare M. Genna, *Regional Integration and Domestic Institutional Homogeneity: A Comparative Analysis of Regional Integration in the Americas, Pacific Asia and Western Europe*, 10 REV. INT'L POL. ECON. 278, 298 (2003).

even in the face of the ECJ decision in *Bayer* that could have potentially caused cracks in the European parallel trade system,[220] cohesion and commitment to a common market remains strong in the EU.

Likewise, to successfully implement a regional parallel trade system in the AU, strong cohesion between AU member countries is required. Under Article 73 of the Treaty of Abuja, members agree to promote and increase cooperation in the field of health as part of the goal of achieving a common economic market.[221] Although the AU strives for a unified African continent, substantial political, cultural, and economic differences exist between countries. But the activities of the African RECs offer hope for sustained regional economic cooperation. For example, the Economic Community of the West African States, consisting of fifteen states, including Ghana, Nigeria, and Senegal, has taken steps to promote free trade in its area.[222] This REC has prioritized health policy by creating the West African Health Organization to encourage health research, increase drug manufacturing, and establish quality controls.[223] The RECs would be a good place to initially implement regional exhaustion and parallel trade because they are already established and participating in shared economic activities. It will be easier to surmount any cultural or political differences when working with a group of countries that already interact on a regular basis and are committed to regional organization.

Other reasons exist for selecting regional exhaustion and encouraging parallel trade between AU member states. As noted by Professor Maskus, the exchange of drugs between African countries could reduce transportation costs,[224] as compared to an exchange between, for example, South Africa and India. Lower transportation costs further efficient regional distribution. Additionally, if there are fewer steps in the supply chain, then there will be less of a chance for drug tampering or counterfeiting.[225] Moreover, Africa is not yet in a position to be completely independent from foreign support. There-

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[220] *See supra* notes 111–14 and accompanying text (discussing the *Bayer* decision).

[221] Treaty of Abuja, *supra* note 146, art. 73.

[222] William Onzivu, *Globalism, Regionalism, or Both: Health Policy and Regional Economic Integration in Developing Countries, an Evolution of a Legal Regime?* 15 MINN. J. INT'L L. 111, 163–65 (2006).

[223] *Id.*

[224] MASKUS, *supra* note 202, at 43.

[225] *See* Chuka Odita, *Nafdac's Strategies For Winning*, THIS DAY (Lagos, Nig.), Sept. 17, 2009, *available at* http://allafrica.com/stories/200909180048.html (explaining that in response to counterfeit drug imports from China and India, Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) is trying to find ways to increase drug regulation).

fore, a regional parallel trade system should supplement other measures, such as compulsory licensing, to provide affordable drugs. If all AU countries were to adopt international exhaustion, they may alienate pharmaceutical companies, as well as developed countries that provide foreign aid, because of the wide scope of international exhaustion. But under regional exhaustion, the mere threat that a neighboring African country could import a drug may motivate pharmaceutical companies to reduce prices in the region.[226] Regional exhaustion is a contained, efficient means of exchanging drugs at lower costs.

Recent findings of significant differences between drug prices in AU countries reinforce the need to adopt a solution to the drug problem that accounts for market forces within the AU. Price differentials, coupled with the desire for a single market in the AU and increased distribution efficiency, mean that regional parallel trade has the potential to reduce drug costs while serving the interests of the AU. Although regional exhaustion may be less controversial than international exhaustion, no solution to the African drug problem works in isolation. As such, the impact of a regional-based parallel trade system in the AU on the pharmaceutical industry and the involvement of developed countries must be further reviewed, keeping in mind the ultimate goal of reducing drug costs.

B. Lower Drug Costs, Strong Regulation, and Robust Intellectual Property Regimes: Regional Parallel Trade Can Thrive in the African Union

Adopting regional exhaustion in the AU would introduce both benefits and concerns, many of which would be unique to Africa. The potential benefits are evident—lower drug costs, increased economic development, and promotion of regional and national economic and intellectual property interests. Yet strong regulation of parallel trade is necessary to ensure the safety of the parallel imports and reduce possible corruption of the system. This will require affirmative work on the part of the AU and cooperation from developed countries. The balance between intellectual property and market forces in the pharmaceutical context hinges on a commitment to

[226] *See Glaxo Offers Cheaper AIDS Drugs*, BBC NEWS (Feb. 21, 2001), http://news.bbc.co.uk/2/hi/business/1182652.stm (noting that as the Kenyan government prepared to introduce a bill that would allow the importation of cheap, generic HIV/AIDS drugs, the pharmaceutical company GlaxoSmithKline promised to heavily discount AIDS drugs).

improving public health. Regional parallel trade in the AU offers an opportunity to further that commitment.

1. Regional Parallel Trade as a Long-Term Solution Alongside Drug-Donation Programs to Lower Drug Costs in the African Union

The establishment of parallel trade based on regional exhaustion in the AU must be considered in light of other drug-price-reduction measures. Regional parallel trade will allow AU consumers to obtain drugs at lower costs by increasing market competition in African countries where drug costs are prohibitively high. In addition, regional parallel trade in the AU could make up for the inadequacies in the compulsory licensing system, especially because many developed countries have been reluctant to put the August 30 Decision regarding paragraph 6 of the Doha Declaration into action by producing low-cost drugs for export to developing countries.[227] Moreover, any profit cuts suffered by the pharmaceutical companies as a result of parallel trade within the AU would not devastate the drug industry. The effect of reduced profits has been small in the EU,[228] and drug companies do not typically patent their drugs in Africa.[229] Many of the essential medicines needed in Africa are for diseases that are far less prevalent in the developed world and would not likely provide pharmaceutical companies with large profits.[230] Small reductions in profits are not a sufficient reason to discourage parallel trade in the AU.

Although Western pharmaceutical companies would likely survive any profit cuts, they may respond to the adoption of parallel trade in the AU with a reluctance to participate in drug-donation programs. Pharmaceutical companies have addressed the drug crisis by donating drugs to developing countries or relief organizations or by offering price discounts.[231] Although some drug-donation programs have been successful, some companies have imposed stipula-

[227] *See supra* Part III.C (explaining the history behind the Doha Declaration).

[228] Macarthur, *supra* note 79, at 9.

[229] Attaran & Gillespie-White, *supra* note 140, at 1889.

[230] *See* Dolmo, *supra* note 184, at 161 ("Developing world markets are a very small income source for the pharmaceutical industry. The market represents only about 10% of international sales and just 1.6% in the continent of Africa.").

[231] *Pfizer Donates Drug to South Africa's Poor*, AIDS WKLY., Apr. 17, 2000, at 18–19; *see* Albert I. Wertheimer et al., *Successful Public/Private Donation Programs: A Review of the Diflucan Partnership Program in South Africa*, 3 J. INT'L ASS'N PHYSICIANS AIDS CARE 74, 74–76 (2004) (summarizing recent drug donation and price reduction initiatives by pharmaceutical companies).

tions on distribution of the donated drugs.[232] Notably, however, a partnership between the drug company Pfizer and South Africa has received attention for its cooperative nature.[233] In exchange for free donation of the drug Diflucan to treat cryptococcal meningitis, a brain infection that can occur in HIV patients, and registration of the drug by Pfizer according to South Africa's requirements, the South African government agreed to monitor the storage and distribution of Pfizer's drug to ensure it was properly administered, secured from theft, and provided to patients free of charge.[234] The program's success is attributed to the established guidelines and this drug-donation program has expanded to other countries.[235]

In light of pharmaceutical companies' opposition to parallel imports, they may cut their participation in drug-donation programs in protest to an established parallel trade system. Parallel imports, however, are not bought or sold for free—they are the original drugs produced by pharmaceutical companies that have been placed on the market by the company.[236] Therefore, parallel imports are separate from drug donations, which are primarily distributed through relief organizations like the United Nations Children's Fund or through a specified program, such as the Diflucan Partnership Program in South Africa.[237] Notably, Pfizer was willing to establish a partnership with South Africa after South Africa implemented parallel trade,[238] which demonstrates that both solutions can coexist. Moreover, parallel trade is a long-term solution that does not require reliance on a donation program with an unknown duration. Pharmaceutical companies would still earn revenue from the drugs they initially placed

[232] Henry & Lexchin, *supra* note 23, at 1590. Drug-donation programs are not without their concerns. An overall fear is that such programs are a means for pharmaceutical companies to keep drug prices high worldwide while helping developing countries. *Id.* Doctors Without Borders takes the position that spending money on generic drug development would be a more sustained method of supplying drugs than donation programs. *Id.* at 1590–91. The WHO developed guidelines to ensure the safety of donated drugs. *Id.* at 1591.

[233] Wertheimer et al., *supra* note 231, at 78.

[234] *Id.* at 76–77; *Pfizer Donates Drug to South Africa's Poor, supra* note 231, at 18–19.

[235] Wertheimer et al., *supra* note 231, at 76–77.

[236] *See* EURACTIV, *supra* note 25 ("[P]arallel trade only offers the original products of the industry itself . . . .").

[237] Wertheimer et al., *supra* note 231, at 74; *Pfizer Donates Drug to South Africa's Poor, supra* note 231, at 18–19.

[238] South Africa passed the Medicines and Related Substances Control Amendment Act in 1997. Medicines and Related Substances Control Amendment Act 90 of 1997, *supra* note 35. The Diflucan Partnership Program was created in 2000. *Pfizer Donates Drug to South Africa's Poor, supra* note 231, at 18–19.

on the market. Drug-donation programs are philanthropic measures and should not be used as a threat against the free-market competition that results from parallel trade.

Another fear is that traders may use the donated drugs as parallel imports in profiteering schemes, which also may stop pharmaceutical companies from donating drugs. Strong restrictions on the use of donated drugs as parallel imports will be required. South Africa, in its partnership with Pfizer, has already shown a willingness to regulate the distribution of donated drugs.[239] Similar regulations can be incorporated into the registration requirements for parallel imports. For example, in South Africa, as in the EU, traders must register the drug that they wish to import, provide information about the exporter, and comply with repackaging criteria.[240] These disclosure stipulations can serve as safeguards against traders who attempt to repackage and sell donated drugs in African countries. Strict guidelines for parallel imports would reassure pharmaceutical companies that donated drugs will not become a part of parallel trade. Drug-donation programs can work alongside the free competition inherent in parallel trade to reduce drug costs in the AU.

2. Parallel Trade Within the African Union as a Stimulus for Economic Growth

A regional exhaustion system would encourage free trade and leverage economic development within Africa. The EU system is flexible enough to include new member countries and new drugs as it expands and similar growth could occur in the AU as it moves toward an integrated market. Additionally, the efficiency of local production will increase.[241] For example, the drug company Quality Chemical Industries Limited (QCIL) recently opened a plant to produce malaria and antiretroviral drugs in Uganda.[242] Because of a small market,

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[239] Wertheimer et al., *supra* note 231, at 76–77.

[240] *See supra* notes 187–89 and accompanying text (outlining the parallel trade requirements in South Africa).

[241] *See* Harrelson, *supra* note 81, at 195 ("One attractive aspect of parallel importing for many African nations is that they lack the local capacity to manufacture needed pharmaceuticals even if they require compulsory licensing.").

[242] Roger Bate, *When Local Production Is Not the Answer*, THE AMERICAN (Sept. 2, 2009), http://www.american.com/archive/2009/september/bernarticle.2009-09-01.0954500383.

> The Ugandan private market size is too small for QCIL to benefit from economies of scale, which means its prices are likely to be high. . . . QCIL cannot compete and probably never will. . . . QCIL wants a 15 percent tariff against cheaper, quality-assured foreign drugs. And QCIL is not alone; the rest of the industry in Uganda wants protection,

QCIL is unlikely to compete with foreign-produced drugs that are offered at lower prices.[243] Instead of each AU country trying to support its own producer, a regional parallel trade system could enable producers in countries like Uganda to increase their market size and sell to other African countries within a REC without the fear of competing with imports from India. Furthermore, in addition to working towards the goal of a common African market, strong regional coalitions promote strengthened representation of the coalition countries in the WTO.[244] Regional exhaustion will contribute to strengthening the RECs economically.

One of the reasons that the EU parallel trade system has endured is because it is supported by strong political and judicial oversight. Although the AU Commission, unlike the European Commission, does not have powers of its own,[245] the AU could oversee a regional parallel trade system in other ways. The Protocol on the Establishment of an African Court on Human and Peoples Rights[246] and the Protocol of the Court of Justice of the African Union[247] both establish judicial review options for implementing legal principles and resolving disputes and have jurisdiction over the RECs.[248] The Pan African Parliament,[249] charged with implementing AU policies and objectives, has law-making powers and could work to coordinate and harmonize health policy and intellectual property laws between

> for the same reasons as QCIL, as do producers in Ghana, Kenya, Tanzania, Nigeria, and the rest of the continent. Tanzania has put in place a 10 percent tariff on [foreign] drug imports.

Id.

[243] *Id.*

[244] *See* Ryan L. Vinelli, Note, *Bringing Down the Walls: How Technology Is Being Used to Thwart Parallel Importers Amid the International Confusion Concerning Exhaustion of Rights*, 17 CARDOZO J. INT'L & COMP. L. 135, 166 (2009).

[245] *See supra* note 150 and accompanying text (explaining the role of the AU Commission).

[246] Protocol to the African Charter on the Establishment of an African Court on Human and Peoples Rights, OAU Doc.OAU/LEG/EXP/AFCHPR/PRO(1) Rev.1 (1997), *available at* http://www.achpr.org/english/_info/court_en.html.

[247] Protocol of the Court of Justice of the African Union, July 11, 2003, *available at* http://www.au.int/files/PROTOCOL_COURT_OF_JUSTICE_OF_THE_AFRICAN_UNION.pdf.

[248] *Id.* art. 19; Protocol to the African Charter on the Establishment of an African Court on Human and Peoples, *supra* note 246, art. 3; Onzivu, *supra* note 222, at 160–63.

[249] Protocol to the Treaty Establishing the African Economic Community Relating to the Pan-African Parliament art. 2, Mar. 2, 2001, *available at* http://www.africanreview.org/docs/civsoc/pap.pdf.

member countries.[250] As these entities are relatively young, their capabilities have yet to be fully tested.[251] Looking to EU institutions as a model for promoting a common market could assist entities like the Pan African Parliament in regulating a regional parallel trade system.[252] Following South Africa and the EU, RECs could implement similar licensing and labeling requirements for importers within their region. The relative success of RECs, such as the Economic Community of the West African States, which has worked towards free trade and set up a regional health organization,[253] demonstrates that regional regulation is possible in the AU.

Strong regulation of parallel trade by AU entities is necessary to establish and maintain the system. AU countries, in implementing regional parallel trade, would have to ensure that the parallel imports did not make their way back to high-income markets, where traders could resell them at higher price to make a profit.[254] Likewise, developed countries should ban parallel imports from developing countries to ensure that the drugs reach the intended recipients.[255] Although enforcement in both cases may prove difficult, preventing reimportation is necessary to maintain "pro-poor" differential pricing.[256] The WTO has recognized that differential pricing between developed and developing countries helps promote access to affordable drugs in developing countries while encouraging continued research and development of new drugs.[257] Implementing parallel trade in the AU would remedy the significant price differences between developing African countries. An AU regional parallel trade system is not meant, however, to address price differences between developed and developing countries that correspond to national wealth. Such prices differences enable pharmaceutical companies to provide lower-priced drugs to developing countries because of continued revenue from

[250] Onzivu, *supra* note 222, at 163.

[251] *Id.* at 160–63.

[252] *See* Richard Frimpong Oppong, *Private International Law in Africa: The Past, Present, and Future*, 55 AM. J. COMP. L. 677, 715 (2007) ("The European Union jurisprudence may, however, become very useful in forging the African common market as envisaged under the Treaty establishing the African Economic Community.").

[253] Onzivu, *supra* note 222, at 163–64.

[254] Matthews & Munoz-Tellez, *supra* note 11, at 1431–32.

[255] *Id.*

[256] *Id.*

[257] WORLD HEALTH ORG. & WORLD TRADE ORG. SECRETARIATS, REPORT OF THE WORKSHOP ON DIFFERENTIAL PRICING AND FINANCING OF ESSENTIAL DRUGS 2 (Apr. 8–11, 2001), *available at* http://www.wto.org/english/tratop_e/TRIPS_e/hosbjor_report_e.pdf.

developed countries.[258] Therefore, parallel imports exchanged within the AU must not be exported to high-income countries. This measure will ensure that the pricing scheme between developed and developing countries is not undermined. A significant reduction in revenue from sales in developed countries would hinder the ability of pharmaceutical companies to offer drugs at lower prices in developing countries and only worsen the drug crisis in Africa.

Moreover, robust oversight is needed in the AU to prevent corruption of the free-trade market that grows with a parallel-import regime. Strict regulations are necessary to prevent a parallel-import industry built on counterfeit drugs and to reduce safety concerns over drug tampering. The risk of consuming unsafe drugs would seriously inhibit the parallel trade system. Another concern, which reflects the price differential issue discussed above, is that government officials may attempt to create a secondary market by diverting cheap parallel imports to wealthy countries for profit. Although such activity is difficult to predict, perhaps the best proof that a parallel trade regime in Africa can thrive is illustrated through South Africa's adoption of parallel trade for the chief purpose of increasing access to affordable drugs and improving the health of its citizens. Although concerns over corruption reflect the high stakes that accompany implementation of free trade in the AU, the overwhelming need for affordable drugs is a strong impetus for AU entities to create regulations that promote the success of parallel trade.

3. Using Regional Parallel Trade to Shape Intellectual Property Protection in the Best Interests of the African Union

Developing countries in Africa have the opportunity to define or redefine their patent regimes because developing countries have until 2016 to become TRIPS compliant and offer pharmaceutical patents.[259] Although many African countries have established patent regimes,[260] intellectual property protection is not strongly regarded in Africa, evidenced by the fact that many developed-world drug companies do not apply for patents in Africa.[261] Becoming TRIPS compliant is an opportunity for governments to determine what degree of

[258] *See* Henry & Lexchin, *supra* note 23, at 1594.

[259] Press Release, World Trade Org., *supra* note 31.

[260] *See supra* note 152 and accompanying text (listing a sample of African countries with patent acts).

[261] *See* Attaran & Gillespie-White, *supra* note 140, at 1889 (finding that many antiretroviral drugs are not patented in Africa).

intellectual property protection they want to offer to best meet their domestic needs. Intellectual property regimes are an important aspect of a common economic community and can ultimately lead to stronger international presence and facilitate free trade and market integration.

As developing countries attempt to define the contours of their intellectual property systems, the difficulty in balancing the goals of such a system against a humanitarian crisis is apparent. A respectable patent-law system affords adequate protection to inventors. But with such protection comes reluctance on the part of the patent holder to give up the exclusive rights to make, use, and sell the product. As such, prior to the TRIPS Agreement, many developing countries had weak patent regimes because they felt that strong patent protection favored foreigners at the expense of local producers.[262] This concern is questionable in light of the fact that many pharmaceutical companies do not patent drugs in Africa.[263] Furthermore, there is a growing consensus that countries with strong intellectual property systems attract more foreign direct investment than countries without such systems.[264] Facilitating regional parallel trade in the AU could be a first step towards creating a robust intellectual property regime that prioritizes the needs of local consumers, particularly in light of the public health crisis. Adopting the doctrine of regional exhaustion in the AU would give notice to industries in developed countries that an established intellectual property regime exists in Africa. Moreover, as in the EU, regional exhaustion in the AU would mean parallel imports from outside the region are not permitted and thus an assured degree of intellectual property protection is provided. Regional exhaustion in the AU would reflect the need for affordable drugs and the value in respecting intellectual property rights.

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[262] Harrelson, *supra* note 81, at 179.

[263] Attaran & Gillespie-White, s*upra* note 142, at 1889.

[264] Barfield & Groombridge, *supra* note 76, at 218. For insight into the effect of changing intellectual property law, see Ghosh, *supra* note 190, at 816–17. Brazil enacted patent legislation in 1996 to comply with the TRIPS Agreement. *Id.* at 816. But "the legislation exempts patent protection for anything that was commercialized anywhere in the world prior to May 14, 1997." *Id.* Therefore, patentees who sold their patented goods anywhere in the world prior to May 14, 1997 have exhausted their rights. *Id.* As a result, the price of drugs with no generic equivalent in Brazil dropped 9% from 1996 to 2000 and the price of drugs with generic equivalents manufactured in Brazil dropped 79%. *Id.* Brazil's model may not be an option for some African countries (for countries that already have patent laws, retroactive legislation would not be helpful), but parallel trade may be an effective option. *Id.* at 816–17.

Implementing regional exhaustion in the AU is unlikely to occur without controversy from the intellectual property law community. The Revised Bangui Agreement, which governs African countries participating in the African Intellectual Property Organization, has, in essence, created a microcosm of a regional parallel trade system in Africa. International organizations, however, expressed criticism because of the restrictive approach in prohibiting parallel imports from outside the OAPI region.[265] Given these concerns and the fact that countries like South Africa already import drugs from outside Africa,[266] regional parallel trade should act only as a supplementary means of bringing affordable drugs to Africa. Africa must not isolate itself with respect to any solution implemented to address the public health crisis. Significant cooperation within Africa as a continent and, most importantly, with developed countries is needed. Although regionalism is an efficient means of promoting public health within a group of select countries, any approach taken must be flexible and adaptable to the changing needs of AU consumers and accommodate the goal of a common African market.[267] Regional parallel trade contributes to this goal by reducing drug costs in countries where it is most needed and shaping market forces and intellectual property law to best serve the interests of the AU.

V. CONCLUSION

A parallel trade system based on regional exhaustion should be implemented in the AU. The AU has a strong desire for cohesion and a unified economic market—factors that motivated the EU to adopt a functioning, enduring parallel trade system. Africa already has created RECs to promote the free-trade movement. An even stronger reason for regional parallel trade than existed in the EU is present in the AU—the need for essential drugs. Although many political, social, and economic factors must be considered, reviewing the

[265] *See generally* COMM'N ON INTELL. PROP. RIGHTS, *supra* note 158, at 161 ("[The Revised Bangui Agreement] does not explicitly allow parallel imports . . . ."); World Health Org., *supra* note 158, at 35 (expressing concern over the strict conditions on intellectual property in the Revised Bangui Agreement); Sell, *supra* note 159, at 385–86 (characterizing the Revised Bangui Agreement "Trips Plus"); Press Release, Médecins San Frontières, *supra* note 157 (explaining the objections of the WHO and Doctors Without Borders to the Revised Bangui Agreement).

[266] Kenya has also adopted international exhaustion. *See* Shianya, *supra* note 8.

[267] Onzivu, *supra* note 222, at 186 ("It is important that developing countries actively participate in inter-national law and policy making to promote the public health of their people. However, the way forward for developing countries is to work to ensure that the new regionalism in which they participate fully meets the health goals of member states.").

drug crisis from the perspective of patent law and drawing on the EU experience demonstrates that a similar system has the potential to work in Africa. Significant price differences exist between drugs in African countries. Parallel trade on a regional level can address this situation by increasing free-market competition and lowering drug costs. The AU is in the process of developing and strengthening governing entities that can serve to regulate such a system. Now is the time to strike a balance between health policy and intellectual property law that truly works in the best interests of the AU.

The pharmaceutical drug crisis in Africa calls for comprehensive consideration of all potential solutions. Importantly, any solution must be considered primarily from the perspective of African consumers. With respect to parallel trade, the current focus is on the negative aspects of international exhaustion. But policymakers and scholars should fully consider regional exhaustion as well. The parallel-import market only shows signs of growing in the EU. Outside the EU, parallel trade is becoming increasingly common as countries like India expand their manufacturing capabilities and countries like South Africa, desperate for essential medicines, attempt to leverage this trade mechanism. Instead of looking outside the continent, Africa is a potential arena for a parallel trade system based on regional exhaustion. Regional parallel trade could play an important role in increasing access to pharmaceutical drugs and, coupled with continued international support, could provide another piece of the puzzle to alleviate the drug crisis in Africa.