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Medication Misadventures: The Interaction of International Reference Pricing and Parallel Trade in the Pharmaceutical Industry

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NOTES

Medication Misadventures: The Interaction of International Reference Pricing and Parallel Trade in the Pharmaceutical Industry

ABSTRACT

Governments in developing countries seeking to combat the rising costs of health care have increasingly focused on the pharmaceutical industry. They often set the amount they will pay for pharmaceutical prices through reference to other countries' prices when negotiating with pharmaceutical companies in an effort to control health care expenditures. This system of international reference pricing inhibits access to essential pharmaceuticals in underdeveloped countries and decreases pharmaceutical innovation and equitable research and development cost-sharing between developed countries.

This Note explores the tension between market forces in the pharmaceutical industry and promoting pharmaceutical innovation, equitable research, development cost-sharing, and access to affordable drugs in underdeveloped countries. The interaction of parallel trade and the lack of international regulation or restriction on the practice of international reference pricing causes this tension. The United States should enter into a series of free trade agreements with developed countries that utilize international reference pricing for pharmaceuticals providing for pricing principles restricting or limiting the practice of reference pricing, parallel trade, and other inhibitions on a socially optimal pharmaceutical market.

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I. INTRODUCTION

Recently, the Swiss drug manufacturer Novartis challenged South Korea's pharmaceutical pricing policy, warning the government that it would be denied its chronic myeloid leukemia drug Gleevec/Glivec if it refused to pay a reasonable price for the

product.¹ Meanwhile, due to European government cost-containment measures, the top sixteen pharmaceutical companies only launched ten new products in Europe last year, a drop for the second consecutive year.² Governments seeking to reduce escalating health-care costs increasingly focus on the pharmaceutical industry.³ A growing practice has been for developed countries' governments to set the amount they will pay for pharmaceutical prices by reference to other countries' prices in negotiations with pharmaceutical companies to control health care expenditures.⁴ This system of international reference pricing has inhibited access to essential pharmaceuticals in some countries and contributed to a decrease in new pharmaceutical development.

While this trend may appear consistent with notions of free trade and freedom of contract, it is far from ideal because of the nature of the pharmaceutical industry. This industry presents two primary competing interests: ensuring incentives for pharmaceutical research and development (R&D) and providing widespread consumer access to affordable pharmaceuticals. Applied to pharmaceuticals, international reference pricing and parallel trade decrease R&D incentives, inhibit equitable R&D cost-sharing between developed countries, and decrease underdeveloped countries' access to affordable pharmaceuticals.⁵

This Note explores the tension between market forces in the pharmaceutical industry, promoting pharmaceutical R&D, equitable R&D cost-sharing between developed countries, and access to affordable drugs in underdeveloped countries. This Note focuses on how parallel trade and the lack of international regulation or restriction on the practice of international reference pricing interact to cause this tension. Part II discusses the pharmaceutical industry and how it differs from other industries. Part III discusses the concept of international reference pricing and its role as an

1. *South Korean Drug Pricing Challenged*, PHARMA MARKETLETTER (London), Aug. 12, 2002.

2. *Declining Drug Launches in Europe Drives Imperative for Sustained Lifecycle Pricing*, PHARMA MARKETLETTER (London), July 22, 2002. These statistics are based on a study by Cambridge Pharma Consulting entitled *European Pricing and Reimbursement Review 2001*.

3. See *Pharma "Is Losing Control of Pricing, and Must Present a United Case Now."* KPMG, PHARMA MARKETLETTER, (London), June 17, 2002. Controlling increased health care expenditures by driving down drug prices is high on the agenda of governments around the world, according to John Morris, head of KPMG's pharmaceutical practice.

4. *Id.*

5. This Note assumes that optimal R&D of pharmaceuticals, equitable R&D cost-sharing between developed countries, and affordable access to pharmaceuticals in underdeveloped countries are more socially desirable conditions than low R&D incentives, inequitable R&D cost-sharing between developed countries, and lack of access to affordable pharmaceuticals in underdeveloped countries.

impediment to pharmaceutical R&D, equitable R&D cost-sharing between developed countries, and affordable access to pharmaceuticals in underdeveloped countries. Part IV presents a brief overview of the concept of parallel trade as applied to the pharmaceutical industry. Part V analyzes the interaction of international reference pricing and parallel trade as applied to the pharmaceutical industry. Part VI proposes that the United States enter into a series of free trade agreements with developed countries that are utilizing international reference pricing for pharmaceuticals. These agreements would provide for pricing principles restricting or limiting the practice of reference pricing, parallel trade, and other inhibitions on a socially optimal pharmaceutical market.

II. THE NATURE OF THE PHARMACEUTICAL INDUSTRY

A. *Indications: Research and Development*

The pharmaceutical industry is particularly vulnerable to regulation because of its unique cost structure.⁶ R&D costs are an unusually large component of total product output costs.⁷ Calculated into R&D are high upfront investments, costs imposed because of product liability, relatively low variable costs of production within capacity for most non-biotech products, and required long payback period dependent on patients.⁸ By the time a product is launched

6. Patricia Danzon, *Can Pharmaceutical Price Regulation and Innovation Co-exist?*, Remarks at Patients First, a Fraser Institute Conference (Nov. 3-4, 1997), available at <http://www.oldfraser.lexi.net/publications/forum/1998/march/health.html> (last visited Jan. 12, 2004).

7. *Id.*

8. *Id.*; see also Jaelyn L. Miller, *Drug Price Competition and Patent Term Restoration Act: The Elimination of Competition Between Drug Manufacturers*, 5 DEPAUL J. HEALTH CARE L. 91, 103-04 (2002).

[B]rand name manufacturers spend from \$400-500 million on the drugs that survive the approval process and are marketed for consumers. However, there are still far more drugs that brand name manufacturers pour money into which never make it through the FDA approval process. Drug manufacturers have stated that "every year scientists screen more than 126,000 chemicals for potential drug development. Of that number, they will actually follow up on about 1,000. Of that number only sixteen will ever make it through the regulatory process and eventually appear in the pharmacy. Only one tenth of one percent of all chemicals entering the process will finally be approved." This means manufacturers spend millions of dollars on research and development on compounds that most likely will never make a profit for them. Hence, the drugs that do make it to the pharmacy must reimburse not only the money spent to get it to market [sic], but also the money spent on researching the other possibilities that failed.

R&D costs, accounting for over thirty percent of total product output costs, have already been incurred.⁹ The costs remaining to be incurred by the time the product is introduced into the market are marginal costs, such as processing, packing, promotion, and distribution of additional units.¹⁰ When pharmaceuticals are introduced into the market, manufacturers must take into account both R&D and marginal costs in pricing their products. It is a widely accepted principle that industrialized countries should share R&D costs.¹¹ To what extent each country should contribute to these costs is disputed, generally unregulated, and highly inequitable.¹² This makes investment in pharmaceutical R&D both expensive and risky.

B. *Directions for Use: A Primer on Patents*

Despite the expense and risk associated with pharmaceutical R&D, pharmaceutical developers invest heavily in it because they expect ultimately to profit.¹³ Patents ensure this. Patents preserve incentives for future R&D by limiting or delaying generic (copy product) competition.¹⁴ The purpose of patents is to bar generic entry

9. Danzon, *supra* note 6.

10. *Id.*; Patricia Danzon, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*, 3 INT'L J. HEALTH CARE FIN. & ECON. 183, 185 (2003).

11. Sharan Parmar & Vivek Divan, Paper, *Drug Financing and Price Control: Legislative Intervention in the Public Interest* (June 2002), in GLOBAL TREATMENT ACCESS: LEGAL DEVELOPMENTS AND STRATEGIES: PAPERS PREPARED FOR: PUTTING THIRD FIRST: VACCINES, ACCESS TO TREATMENT & THE LAW (satellite meeting of the 14th International AIDS Conference, Barcelona, July 5, 2002).

12. See, e.g., *European Drug Industry Urges Japan to Reward Pharma Innovation*, PHARMA MARKETLETTER, Nov. 14, 2003 (recapping meeting between European drugmakers and Japanese health authorities, whereby it was stressed that "both Japan and Europe are lagging behind the United States [in pharmaceutical innovation], and [there is an] urgent need [for Japanese authorities] to provide an adequate environment for pharmaceutical innovation . . . [by] establishing pricing rules for medicines that reward pharmaceutical innovation"); *Rich Nations Must Pay More for Drugs, Says U.S. FDA Head; Warns of Global R&D Crisis*, PHARMA MARKETLETTER, Sept. 26, 2003 (noting that the U.S. pays "most of the [global] costs of developing new [medicines]" leading to "a global crisis over affordable, safe and innovative medicines." Moreover, "even though people in countries such as Poland have significantly less economic wealth than the countries of western Europe, their drug prices are, on average, significantly higher than in France and Germany.") [hereinafter *Rich Nations Must Pay More*].

13. Christopher R. Stambaugh, Note, *State Price Control Laws are the Wrong Prescription for the Problem of Unaffordable Drugs*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 897, 903 (2002); see also Heinz Redwood, *Advantages and Risks of Differential Pricing for Prescription Drugs*, Remarks at the WHO-WTO Workshop on Differential Pricing and Financing of Essential Drugs, in Norway (Apr. 9, 2001), at <http://www.who.int> (last visited Jan. 12, 2004) ("The pharmaceutical industry has a moral, social and financial duty to make its contribution to solving the grave medical crisis of unaffordable access. It cannot stand apart and decorously avert its gaze. But it is an *industry*, not a charity.").

14. Danzon, *supra* note 10, at 185.

into the market for the term of the patent.¹⁵ This provides the product's original innovator the opportunity to price above marginal cost and thereby recoup their R&D expense.¹⁶

C. Side Effects and Adverse Reactions: Price Controls and Differential Pricing

For most products, particularly those manufactured on a global scale, price differences from country to country are unlikely to be significant.¹⁷ Companies would incur financial losses if they sold products at half price in developing countries.¹⁸ The pharmaceutical industry is different. Financially, it would make sense for pharmaceutical companies to take local affordability into account when setting (profitable) price levels in each country.¹⁹ This is impossible to do because there is no free market for pharmaceuticals in most countries.²⁰

As governments tend to be the sole purchasers of pharmaceuticals for an entire state or country, they have a great deal of market power to influence price.²¹ In the pharmaceutical market, the method of sale is typically between pharmaceutical companies and the government, whereby the government negotiates directly with each company to determine the price that will be paid for the products.²² The government, or a government-sanctioned body, reviews company price applications and determines whether the

15. *Id.*

16. *Id.* Because the original innovator has already performed the R&D, it is unnecessary for generic manufacturers to invest in these duplicative costs. Generic manufacturers may simply "copy" the original innovator's end product. Consequently, generic manufacturers may price products at marginal cost because there is no R&D expense to recoup. Of course, given the choice between an expensive brand-name drug and a vastly less expensive duplicate, the rational purchaser will choose the duplicate, preventing the original innovator from sufficient profit to recoup its R&D expense.

17. Ed Schoonveld, *Market Segmentation and International Price Referencing*, Remarks at the WHO-WTO Workshop on Differential Pricing and Financing of Essential Drugs, in Norway (Apr. 9, 2001), available at <http://www.who.int> (last visited Feb. 16, 2004).

18. *Id.*

19. *Id.*

20. *Id.*

21. Emma Squire, *Differential Pricing and the Problem of Access to Essential Medicines in Developing Countries* (2002) (Degree of Master of European Studies thesis, College of Europe, Bruges Campus), available at <http://www.EFPIAaward2002.htm> (last visited Feb. 16, 2004).

22. Bruce Stuart et al., *Appendix A: Issues in Prescription Drug Coverage, Pricing, Utilization, and Spending: What We Know and Need to Know* (Feb. 18, 2000) (report prepared for the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Policy and Evaluation, Office of Health Policy), available at <http://www.aspe.hhs.gov/health/reports/drugstudy/appa-4.htm> (last visited Feb. 16, 2004).

company's requested price is "fair." If it is not "fair," the government may set a lower price.²³ If that price is lower than the company requested, the company typically has a right to appeal the decision.²⁴ In any case, the pharmaceutical company is not obligated to sell if the government they are dealing with cannot negotiate satisfactory terms.²⁵

Because there is no free market for pharmaceuticals in most countries, these countries impose price controls on pharmaceuticals sold within their borders.²⁶ These price controls ensure more affordable drugs for their consumers but provide less profit for the pharmaceutical industry to compensate for R&D expenses, and invariably, those profits must be recouped elsewhere.²⁷ While price controls seemingly benefit consumers by regulating pharmaceutical profit margins, they discourage innovation and competition in the pharmaceutical industry.²⁸ A study examining the effects of countries' price regulations on R&D incentives revealed that no country with price controls has had innovative success in the pharmaceutical industry matching that of the United States—one of the few countries without pharmaceutical price controls.²⁹ From 1975 to 1989, U.S. companies produced forty-seven significant new pharmaceutical compounds, compared to fifty for the rest of the world.³⁰ Between 1970 and 1992, U.S. companies accounted for 42.8 percent of the world's breakthrough drugs.³¹ During a similar period, Britain accounted for fourteen percent, Germany seven percent, and France three percent.³²

Macroeconomic principles suggest that reduced profits will lead to reduced innovation.³³ The cost of capital is low when investors perceive a predictable profit stream, so their return is commensurate

23. *Id.*

24. *Id.*

25. There may be instances where pharmaceutical companies are obligated to provide their products to a country despite their lack of approval for the offered price. Such situations may occur under the threat of compulsory licensing. A compulsory license is a judicial or government annulment of patent rights, in effect removing the patentee's exclusivity, allowing others to make, use and sell the product before patent expiration. Article 31 of the Trade Related Aspects of Intellectual Property Rights Agreement allows countries to grant compulsory licenses in limited circumstances. Michelle M. Nerozzi, Note, *The Battle Over Life-Saving Pharmaceuticals: Are Developing Countries Being "TRIPped" by Developed Countries?*, 47 VILL. L. REV. 605, 612-13 (2002).

26. See Jerry Stanton, *Lesson for the United States from Foreign Price Controls on Pharmaceuticals*, 16 CONN. J. INT'L L. 149, 165 (2000).

27. See Nerozzi, *supra* note 25, at 627.

28. Stambaugh, *supra* note 13, at 913.

29. *Id.* at 914.

30. Stanton, *supra* note 26, at 153.

31. *Id.* at 154.

32. *Id.*

33. *Id.* at 168.

with their risk.³⁴ When that profit stream is reduced, the cost of capital will rise to reflect the diminished return and rise an additional quantum to reflect the uncertainty in future earnings predictability.³⁵ Thus, government price controls on pharmaceuticals decrease R&D incentives for pharmaceutical developers because profit incentives are decreased. Because price controls may demand prices that cover only slightly more than the marginal cost of manufacturing a drug, the pharmaceutical industry is reliant on consumers in countries without price controls to compensate for the low profit margin of countries imposing price controls in order to compensate for R&D.³⁶ Consequently, the few countries that do not enforce price controls on pharmaceuticals contribute an overwhelming portion to the funding necessary for innovation in the pharmaceutical industry.³⁷ Consumers in these countries pay a disproportionately higher price for prescription drugs than consumers in countries enforcing price controls.³⁸ This effectively allows other countries to free-ride on those funding innovation.³⁹

Pharmaceutical manufacturers argue that they cannot rely on price increases in less regulated markets, such as the United States, to achieve the necessary profit levels for R&D.⁴⁰ If R&D is to be sustained, then, some industrialized countries must restrict price controls and bear the financial burden of increased prescription drug costs either through the government or consumer pockets. As a result, the United States has pressured other countries to relax their regulations on drug prices.⁴¹ Still, differential pricing between

34. *Id.*

35. *See id.* This second aspect is based on investors' beliefs, not necessarily the resulting objective outcome. For example, the CEO of Genzyme Corp, a major U.S. biotech company, commented on his company's ability to raise capital while President Clinton was trying to advance Health Security Act in 1993: "We raised \$100 million for our new gene therapy product last year. If we tried to hold an offering today we couldn't do it. The threat of price controls has done more to damage the biotechnology industry than anything else that has happened in the industry's history." *Id.*

36. *See* Stambaugh, *supra* note 13, at 913.

37. *See* Stanton, *supra* note 26, at 170.

The various regulatory schemes employed around the world seem to have had a chilling effect on pharmaceutical innovation . . . While these other countries may still partake of the fruits of American . . . pharmaceutical advancement within their price control regimens, they have stunted domestic innovation. Every one of these foreign countries has become dependent on the U.S. . . . to innovate.

38. *See id.* at 165 (arguing that price controls hold down the price of the targeted pharmaceutical).

39. Stambaugh, *supra* note 13, at 913.

40. Parmar & Divan, *supra* note 11, at n.109.

41. Stambaugh, *supra* note 13, at 913.

countries in the pharmaceutical market is prevalent.⁴² It is not uncommon for Americans to pay over twice as much as Europeans for the same drug and dosage, leading critics to assert that the United States is in fact subsidizing European health care.⁴³

To a certain extent, differential pricing in the pharmaceutical market is ideal because it actually maximizes the total welfare of prescription drug purchasers.⁴⁴ Differential pricing offers price-sensitive consumers, who could not afford to participate in the market under a system of uniform pricing, low enough prices so that they are willing to participate in the market and contribute to shared R&D costs.⁴⁵ Purchasers paying the highest prices are also paying less than they would for the same R&D under a uniform pricing system.⁴⁶ Additionally, differential pricing allows pharmaceutical manufacturers to maximize profits and R&D because in economic terms, differential pricing is optimal when applied to industries with large joint costs (such as pharmaceutical R&D), relative to user-specific marginal costs (such as the cost of manufacturing a drug).⁴⁷

Economist Patricia Danzon argues that differential pricing can be maintained to resolve the competing interests in the pharmaceutical industry and is indeed the best way to resolve the conflict.⁴⁸ Differential pricing, however, will only be effective if policies are initiated to prevent low prices in developing countries from "leaking" into developed countries.⁴⁹ Such leakages occur primarily due to international reference pricing and parallel trade.⁵⁰ Remarkably, these practices remain unregulated on a global scale.⁵¹

Pharmaceutical manufacturers historically have had a great deal of pricing power due to legislated patent protections under international intellectual property law.⁵² To counter this power, most industrialized countries use legislative measures to intervene in this power and ensure drug affordability through systems of price control.⁵³ Systems of pharmaceutical price control vary considerably

42. See David J. Gross et al., *Prices for Prescription Drugs: The Roles of Market Forces and Government Regulation*, in *CONTESTED GROUND: PUBLIC PURPOSE AND PRIVATE INTEREST IN THE REGULATION OF PRESCRIPTION DRUGS* 124, 134 (Peter Davis ed., 1996).

43. Tom Buerkle, *EU Weighs Lifting of Price Controls—Bid to End Market Distortions*, *INT'L HERALD TRIB.*, Nov. 18, 1998, at 20.

44. Stambaugh, *supra* note 13, at 911.

45. *Id.*

46. *Id.*

47. *Id.*

48. Danzon, *supra* note 10, at 192.

49. *Id.*

50. *Id.*

51. See *supra* note 12 and accompanying text.

52. See Parmar & Divan, *supra* note 11 (arguing pharmaceutical manufacturers enjoy a monopoly pricing power).

53. *Id.*

from country to country and contain a number of elements.⁵⁴ This Note focuses on the element of international reference pricing.

III. INTERNATIONAL REFERENCE PRICING⁵⁵

A. *International Reference Pricing Defined*

At its most basic level, international reference pricing refers to the practice whereby a government in country A refers to usually lower prices in country B as a benchmark for regulating prices in country A.⁵⁶ Reference pricing may be formally built into a country's regulatory system, as in Canada, Italy, Greece, Belgium, Ireland and the Netherlands, or may be an informal benchmark.⁵⁷

Many European countries, including the United Kingdom, have adopted international reference pricing schemes in setting pharmaceutical prices.⁵⁸ Under these systems, a reference price is usually based on the weighted average of other countries' drug prices.⁵⁹ Regulators choose a group of countries (a "basket"), set the weights in each country, and adjust for exchange rate movements.⁶⁰ This scheme provides a wide degree of latitude in pricing due to large international price variations.⁶¹ The risk under this system is that low prices granted in underdeveloped countries will be either used as a benchmark in setting prices in developed countries or be thrown into the basket and averaged into the developed countries' prices.⁶² For these reasons, international reference pricing is the most important obstacle to lower pharmaceutical prices in underdeveloped countries.⁶³

54. Schoonveld, *supra* note 17.

55. In other literature, reference pricing is referred to as "benchmarking" and "external reference pricing."

56. Danzon, *supra* note 10, at 191.

57. *Id.*; see also Nicholas Bloom & John Van Reenen, *Regulating Drug Prices: Where Do We Go From Here?*, 19 FISCAL STUD. 321, 334 n.15 (1998), available at http://www.ifs.org.uk/publications/fiscalstudies/bloom_aug98.pdf (discussing Greece's reference pricing scheme).

58. Danzon, *supra* note 10, at 191.

59. *Id.*

60. *Id.*

61. *Id.*

62. *Id.*

63. See *id.* at 190.

B. Reference Pricing as an Obstacle to Affordable Pharmaceuticals in Underdeveloped Countries

For many patients in the least developed countries, essential medicines are unaffordable.⁶⁴ In response, many pharmaceutical companies have developed schemes of providing access to essential medicines in underdeveloped countries on humanitarian and corporate citizenship grounds.⁶⁵ While some companies offer donations,⁶⁶ many others engage in discounted pricing or investment programs.⁶⁷ Several manufacturers offer heavily discounted prices and donations to underdeveloped countries for certain pharmaceuticals.⁶⁸ Partnerships between pharmaceutical companies and governments, international organizations, or non-governmental organizations provide discounted pharmaceuticals.⁶⁹ These partnerships include the DOTS-Plus pilot project to ensure the supply of drugs for the treatment of multidrug-resistant tuberculosis (MDR-TB); the 1997 UNAIDS HIV Drug Access Initiative and the Accelerating Access Initiative, begun in May 2000, involving five major research-based companies, UNAIDS, the World Health Organization (WHO), and other UNAIDS partners to expand access to care and treatment for HIV/AIDS and resulting in prices for triple therapy as much as ninety-five percent below the initial developed-country price.⁷⁰

When developed countries calculate the discounted prices given to underdeveloped countries into the price they will pay for a product, pharmaceutical companies become hesitant to continue the practice of providing discounted pharmaceuticals to underdeveloped countries. The company response is to set a single uniform price.⁷¹ As a result, consumers in underdeveloped countries face higher prices and possibly denial of access to essential pharmaceuticals.⁷² Thus,

64. Squire, *supra* note 21.

65. *See id.* §§ 1.5-1.6.

66. Companies utilizing donation programs include Pfizer; Merck & Co. Inc., offering donations to treat river blindness, lymphatic filariasis, and MMR II; GlaxoSmithKline, donating doses of the meningitis vaccine, malarial treatment, and others; and Novartis, donating enough antileprosy multidrug therapy for all patients in the world until the end of 2005 together with funds for shipping and independent quality control. Squire, *supra* note 21, § 1.5.

67. These companies include Abbott Laboratories, American Home Products/Wyeth, Aventis, AstraZeneca, Bayer, Bristol-Myers Squibb, Boehringer Ingelheim, Eli Lilly, Johnson & Johnson, Pharmacia Corporation, Roche, and Schering-Plough. *Id.*

68. *Id.*

69. *Id.*

70. Squire, *supra* note 21.

71. Patricia Danzon, *The Economics of Parallel Trade*, 13 PHARMACOECONOMICS 293, 295 (1998).

72. *Id.*

because there is no regulation of international reference pricing, and most developed countries have not restricted their behavior, underdeveloped countries face the threat of a loss of essential medicines.

C. Reference Pricing as an Obstacle to Equitable Joint Research and Development Costs Between Developed Countries

One might expect countries with higher per capita income to pay a greater proportion of R&D costs than countries with lower per capita income and countries with similar per capita income to pay a similar proportion of R&D costs.⁷³ However, this is not entirely the case. Some high-income countries have relatively low prices, while some low-income countries face high prices relative to their income level.⁷⁴ There are several reasons for this. First, regulators in some high-income countries use their bargaining leverage, combined with reference pricing, to reduce prices, leaving others to pay the joint cost of R&D.⁷⁵ Second, the tendency for prices in low-income countries to be high relative to their average per capita income likely reflects company concerns over price leakages—that granting lower prices to low-income countries would undermine potentially higher prices in other countries.⁷⁶ The concern may be that the prices low-income countries pay for pharmaceuticals will be averaged into the high-income countries' basket of price references.⁷⁷ This cycle reveals why international reference pricing produces highly inequitable results.

Additionally, most developed countries utilizing reference pricing factor differing variables into their reference prices, producing inequitable reference prices. In Canada, for example, the price for any new product cannot exceed the median of the prices for the United States, France, Germany, Italy, Sweden, Switzerland and the United Kingdom.⁷⁸ In Denmark and Italy, prices cannot exceed the European average price.⁷⁹ Spain and Greece demand the lowest price in Europe.⁸⁰ In Saudi Arabia, price is referenced to a list of forty countries.⁸¹ The United States does not practice reference pricing.⁸² As a result, U.S. consumers pay a significantly higher price for pharmaceuticals than their counterparts in other developed

73. See Danzon, *supra* note 10, at 191.

74. *Id.*

75. *Id.* at 192.

76. *Id.*

77. See *id.* at 191-92.

78. Schoonveld, *supra* note 17, § 4.1.

79. *Id.*

80. *Id.*

81. *Id.*

82. See Bloom & Van Reenen, *supra* note 57, at 4, tbl.1.

countries.⁸³ Layering this discrepancy, these counterparts pay inequitable portions of joint R&D costs. Thus, international reference pricing is incompatible with the notion that developed countries should equitably share R&D costs.

D. *The Law(lessness) of International Reference Pricing*

Currently, there is no international regulation on international reference pricing for pharmaceuticals. Essentially, every country may freely set the prices it will pay for pharmaceuticals then negotiate to terms with pharmaceutical manufacturers.⁸⁴ Notably, the United States is the only developed country that does not engage in international reference pricing for patented pharmaceuticals.⁸⁵ The European Union, on the other hand, heavily engages in reference pricing, as do other developed countries, such as Canada.⁸⁶ Following are case studies of selected countries' legal policies on the practice.

1. The United States

In the United States, President Clinton's unsuccessful 1993 Health Security Act proposal would have limited U.S. prices to the lowest price in twenty-one reference group countries.⁸⁷ The basic objectives of the Act for pharmaceuticals and other health care services were universal coverage and cost control.⁸⁸ The Act would have set up an Advisory Council on Breakthrough Drugs that would evaluate the reasonableness of prices for new pharmaceuticals.⁸⁹ Additionally, the Secretary of Health and Human Services (HHS) would be empowered to negotiate supplementary rebates to Medicare for any new drugs marketed at a lower price in the twenty-one reference countries, or those deemed to have "excessive" prices.⁹⁰ Where HHS and manufacturers were unable to agree on a new drug's price in the Medicare program, it would be excluded from coverage.⁹¹ The Act would have had the effect of requiring pharmaceutical

83. See, e.g., *Rich Nations Must Pay More*, *supra* note 12 (stating that "Americans account for a fraction of prescription drug use worldwide, yet this year they will pay for around half of all pharmaceutical expenditures worldwide").

84. See Bloom & Van Reenen, *supra* note 57, tbl. 1, at 4.

85. See *id.*

86. *Id.*

87. The Health Security Act was introduced in the Senate by Senator George Mitchell and in the House of Representatives by Representative Richard Gephardt on Nov. 20, 1993. S. 1757, 103d Cong., (1993); H.R. 3600, 103d Cong. (1993).

88. Henry Grabowski, *The Impact of the Clinton Health Care Reform Plan: Health Reform and Pharmaceutical Innovation*, 24 SETON HALL L. REV. 1221, 1221 (1994).

89. *Id.*

90. *Id.*

91. *Id.*

manufacturers to comply with the U.S. reference price or be excluded from Medicare coverage, thus replacing the free market for pharmaceuticals with a reference pricing system.⁹² Notably, most of the twenty-one comparable countries in the proposal have significantly lower standards of living than in the United States, and only a few have research-intensive pharmaceutical and biotechnology industries.⁹³

2. Canada

In Canada, maximum prices have been established for patented pharmaceuticals since 1987 by setting a “ceiling” to which companies may price products.⁹⁴ The Patented Medicine Prices Review Board (PMPRB) fixes prices at market entry and may adjust them later if necessary.⁹⁵ For innovative products, prices are compared to the same product in nine other countries.⁹⁶ The Board’s primary mandate is to “prevent brand name firms from abusing their monopoly position during the market exclusivity period.”⁹⁷ The system has been relatively successful in controlling prices in Canada.⁹⁸

3. New Zealand

Because New Zealand does not have a domestic pharmaceutical industry, it has adopted punitive state-trading practices designed to shift the principle burden of health-care cost containment to foreign producers, such as the U.S. and European researched-based pharmaceutical companies.⁹⁹ New Zealand has granted exclusive control over pharmaceutical purchases and reimbursement to a state-trading entity, Pharmac.¹⁰⁰ Employing its monopsonistic pricing power, Pharmac has implemented a “sole-source, single tendering” system that denies U.S. and European companies “adequate

92. *Id.*

93. *Id.*

94. *Global Treatment Access: Legal Developments and Strategies* (papers prepared for Putting Third First: Vaccines, Access to Treatment & the Law, A Satellite Meeting of the 14th International AIDS Conference Barcelona, hosted by CHLN, AIDS Law Project, and Lawyers Collective HIV/AIDS Unit) (July 5, 2002), available at http://www.dec.org/pdf_docs/PNACQ319.pdf (last visited Jan. 12, 2004).

95. *Id.*

96. *Id.*

97. Stuart, *supra* note 22, § 4.5.1.

98. See *supra* note 94 and accompanying text.

99. PhRMA, Position Paper, *Bilateral and Multilateral FTA Negotiations: Opportunities for Improved IP Protection and Market Access*, Appendix B (2001), available at <http://www.phrma.org/international/resources/2001-04-12.42.pdf> (last visited Jan. 8, 2004).

100. *Id.*

opportunity" to compete in the New Zealand market on the basis of commercial considerations.¹⁰¹ The result has been for pharmaceutical companies to withhold essential medicines from the New Zealand market, denying its citizens access to essential medicines.¹⁰²

IV. PARALLEL TRADE

A. *Parallel Trade Defined*

Parallel trade occurs when a product covered by intellectual property rights in country *A* is exported and resold to country *B* without the right holder's authorization.¹⁰³ The incentive for parallel trade is a sufficient difference in prices between countries *A* and *B* to cover shipping and transaction costs and still offer gains to both the shipper (country *A*-exporter) and the buyer (country *B*-importer).¹⁰⁴

B. *The Law*

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was established as part of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) completed in 1995 and is the most comprehensive international agreement on intellectual property rights.¹⁰⁵ Prior to TRIPS, few countries had strong intellectual property protection laws.¹⁰⁶ TRIPS became the starting point in harmonizing the patent laws of developed and developing signatory nations.¹⁰⁷

The agreement requires World Trade Organization (WTO) member countries to establish minimum standards of intellectual property protection for foreign and domestic products and processes, including the implementation of pharmaceutical patent laws.¹⁰⁸

101. *Id.*

102. *See id.*

103. See F.M. Scherer, *The Economics of Parallel Trade in Pharmaceutical Products*, Revised Summary for WTO-WHO Workshop, Apr. 2001 (summarizing generally F.M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries*, 5 J. INT'L ECON. L. 913 (2002)).

104. *Id.*

105. *TRIPS and Development*, Background Briefing (Dept. for Int'l. Development/Trade Matters Series, London), Sept. 2001, at 1, available at <http://www.dfid.gov.uk> (last visited Feb. 11, 2004); see also Samantha Shoell, Note, *Why Can't the Poor Access Lifesaving Medicines? An Exploration of Solving the Patent Issue*, 4 MINN. INTELL. PROP. REV. 151, 158 (2002) (stating that 117 countries signed the Agreement).

106. Shoell, *supra* note 105, at 158.

107. *Id.*

108. Naomi A. Bass, *Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*,

Despite the comprehensive requirements, however, TRIPS permits some flexibility in the manner member countries may choose to execute their intellectual property laws domestically.¹⁰⁹ TRIPS does not explicitly restrict governments from controlling drug prices.¹¹⁰ TRIPS does not prevent governments from allowing the importation of legitimate goods from the cheapest international sources (parallel importing).¹¹¹ Moreover, TRIPS allows governments to authorize use of the subject of a patent without the patent holder's consent (compulsory licensing).¹¹² Article 1.1 of TRIPS leaves WTO member countries free to determine the appropriate method of implementing TRIPS within their own legal system, leaving room for different interpretations.¹¹³

Developed countries, led by the United States, interpret TRIPS narrowly, proposing more control for patent owners.¹¹⁴ The main reason for this is that inadequate patent protection will impede R&D.¹¹⁵ Developing countries, including South Africa, India and Thailand, interpret TRIPS broadly, proposing less control to the patent holder.¹¹⁶ While developing countries acknowledge that patent protection is a prerequisite for R&D, they believe in balancing all interests to prevent abuse by the patent holder.¹¹⁷ By limiting patent rights, developing countries may more easily exploit generic competition.

Substantive provisions of international law most relevant to patented pharmaceuticals are Section 5 of TRIPS and Article 1709 of NAFTA.¹¹⁸ TRIPS provides that patent holders are to receive exclusive rights to prevent parties from making, using, offering for

35 GEO. WASH. INT'L L. REV. 191, 191; *see also* Shoell, *supra* note 105, at 158. Prior to TRIPS, many countries did not recognize pharmaceuticals as patented matter.

109. Bass, *supra* note 108, at 191.

110. Parmar & Divan, *supra* note 11.

111. *TRIPS and Development*, *supra* note 105, at 5.

112. *Id.* Compulsory licensing can only be used in exceptional circumstances such as a national emergencies, or under specified conditions such as when adequate remuneration is paid to the patent holder.

113. *Id.* at 6.

114. Nerozzi, *supra* note 25, at 615.

115. *Id.* at 620. Developed countries raise three secondary issues for a narrow interpretation of TRIPS: (1) the concessions TRIPS already grants to developing countries; (2) the misuse and abuse of drugs in developing countries; and (3) fear of black market or parallel trade. *Id.* at 621.

116. *Id.* at 617.

117. *Id.* at 624.

118. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round Vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS]; North American Free Trade Agreement, Dec. 17, 1992, 31 I.L.M. 612 [hereinafter NAFTA].

sale, selling, or importing the product without the owner's consent.¹¹⁹ Rights articulated in NAFTA are similar.¹²⁰ Patent protection philosophically conveys the power for a company to discriminate in pricing between countries because the patent holder in each country can enjoin unauthorized distribution including parallel imports.¹²¹ However, parallel trade is largely permitted in most countries.¹²² The concept of parallel trade is centered on the "exhaustion" of patent rights and protection.¹²³ After a product containing an intellectual property right is sold, the intellectual property owner no longer has control over the fate of that product.¹²⁴ His rights have been exhausted.¹²⁵ Once a patent becomes exhausted, the initial purchaser may resell the product without infringing on the original seller's patent right.¹²⁶

Parallel trade frustrates intellectual property holder attempts to maximize the value of their property rights.¹²⁷ Intellectual property rights are granted and enforced at a national level; thus, intellectual property holders must seek protection in each country individually.¹²⁸ Because there is no international standard on parallel trade, the legality of barriers to parallel trade, such as laws regulating exhaustion, depend on national laws.¹²⁹ Due to inequities in pharmaceutical prices between countries and their varying laws regulating (or not regulating) parallel trade, the pharmaceutical industry's profits can easily be affected by parallel trade.

While exhaustion is mentioned in TRIPS, it is largely left unregulated.¹³⁰ Article 6 of TRIPS simply states that "nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights."¹³¹ Any conflicts between nations concerning exhaustion are to be "resolved bilaterally between

119. TRIPS, *supra* note 118.

120. *Id.* art. 28; NAFTA, *supra* note 118, art. 1709.

121. Danzon, *supra* note 71, at 296.

122. *Id.*

123. Shoell, *supra* note 105, at 163; *see also* Bryan Baer, Note, *Price Controls Through the Back Door: The Parallel Importation of Pharmaceuticals*, 9 J. INTELL. PROP. L. 109, 110 (2001) ("The most fundamental limitation on an intellectual property right . . . is exhaustion upon first sale.")

124. Baer, *supra* note 123, at 110.

125. *Id.* This is commonly known as the first sale doctrine.

126. Hillary A. Kremen, Note, *Caveat Venditor: International Application of the First Sale Doctrine*, 23 SYRACUSE J. INT'L L. & COM. 161, 162 (1997).

127. Baer, *supra* note 123, at 111.

128. *Id.* at 112.

129. *See* Scherer, *supra* note 103.

130. Shoell, *supra* note 105, at 164.

131. TRIPS, *supra* note 118, art. 6.

individual nations.”¹³² Thus, parallel trade remains an “entirely domestic legal concern.”¹³³

C. Case Studies in the United States and the European Union

1. The United States

The United States does not allow parallel imports. In *Boesch v. Graff*, the U.S. Supreme Court addressed the issue of whether a dealer can purchase articles patented in another country and import and sell them in the United States without the license or consent of the owner of a U.S.-granted patent for the same invention.¹³⁴ Albert Graff and J.F. Donnell filed suit against Emile Boesch and Martin Bauer to recover for patent infringement of an improvement in lamp burners.¹³⁵ The invention was patented in both the United States (to Donnell & Co., represented by Graff and Donnell), and Germany (to Carl Schwintzer and Wilhelm Graff).¹³⁶ Boesch and Bauer later purchased the lamp burners in Germany from an authorized seller there and imported and sold them in the United States without the license or consent of the U.S. patent holder, Donnell & Co.¹³⁷

The Supreme Court held that although the laws of Germany allow the selling of a product, this does not authorize the selling of “articles in the United States in defiance of the rights of patentees under a U.S. patent The sale of articles in the United States under a U.S. patent cannot be controlled by foreign laws.”¹³⁸ Thus, where a patent for the same invention is held in both the United States and another country, the U.S. patent holder’s consent is required before the invention may be purchased in the other country and resold in the United States.

More recently, in October 2000, Congress passed legislation authorizing reimportation of patented pharmaceuticals from Canada into the United States subject to approval from the Department of Health and Human Services.¹³⁹ Despite this, then Secretary of

132. *Id.*

133. Schoell, *supra* note 105, at 164.

134. *Boesch v. Graff*, 133 U.S. 697, 702 (1890).

135. *Id.* at 698.

136. *Id.* at 699.

137. *Id.* at 698.

138. *Id.* at 703.

139. Shubha Ghosh, *Pills, Patents, and Power: State Creation of Gray Markets as a Limit on Patent Rights*, 53 FLA. L. REV. 789, 793-94 (2001) (referring to congressional legislation of Oct. 2000 on reimports, H.R. Conf. Ref. No. 106-948, at 39 (2001) (“Making Appropriations for Agriculture Rural Development, Food and Drug Administration, and Related Agencies Programs for the Fiscal Year Ending Sept. 30, 2001, and for Other Purposes,” amending 21 U.S.C. § 381 et seq.)).

Health and Human Services, Donna Shalala, refused to authorize the reimports, concerned that these pharmaceuticals would not meet U.S. safety standards.¹⁴⁰

2. The European Union

Parallel trade has been permitted in Europe since the Treaty of Rome and has recently become more common because the European Medicines Evaluation Agency (EMEA) permits a drug to go through a single registration process, involving safety, efficacy, and labeling reviews.¹⁴¹ Once approved by EMEA, the product may be placed on the market in all European countries with standardized labeling and dosage.¹⁴² This greatly reduces costs to parallel wholesalers because they do not have to repackage and re-label the product.¹⁴³

The European Union supports parallel trade. The first case where the European Court of Justice applied exhaustion of rights to patents was *Centrafarm v. Sterling*.¹⁴⁴ Sterling Drug Inc. held patents in the United Kingdom and the Netherlands for a drug. Centrafarm purchased the drug in England and imported it into the Netherlands, benefiting from the fact that the price in England was fifty percent lower than that in the Netherlands.¹⁴⁵ Sterling Drugs brought an action in the Netherlands for infringement of its Dutch patent.¹⁴⁶ The case was referred to the European Court of Justice (ECJ).¹⁴⁷ The court held that once a product has been put on the market by the patentee or with his consent, his intellectual property right is exhausted and may no longer be invoked to prevent parallel imports.¹⁴⁸ The ECJ's ruling is based on the assumption that the right to first marketing, guaranteed by a patent, provides sufficient opportunity for the patentee to reap the rewards of his invention.¹⁴⁹

140. *Id.* at 794, citing Robert Pear, *In a Turnaround, White House Kills Drug-Import Plan*, N.Y. TIMES, Dec. 27, 2000, at A1; Marc Kaufman, *Shalala Halts Bid to Lower Drug Costs; Reimportation Bill's 'Fatal Flaws' Cited*, WASH. POST, Dec. 27, 2000, at A1; Alissa J. Rubin, *Plan Dropped to Reimport U.S. Made Medications*, L.A. TIMES, Dec. 27, 2000, at A1.

141. *See* Danzon, *supra* note 6.

142. *Id.*

143. *Id.*

144. *Centrafarm v. Sterling*, 2 C.M.L.R. 480 (1974).

145. *Id.*

146. *Id.*

147. *Id.*

148. *Id.*

149. David Perkins et al., *Exhaustion of Intellectual Property Rights—The EU Perspective*, Practising Law Institute, San Francisco (Nov. 1999). The ECJ defined the subject matter of a patent as

[T]he guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an intervention with a view to manufacturing industrial products and putting them into circulation for the first time, either

However, this was not the case because the price for the drug in the United Kingdom was kept artificially low by government interference while at the same time parallel imports into the higher priced Dutch market eroded profits there.¹⁵⁰ Thus, Sterling Drug was unable to control its reward.¹⁵¹ The ECJ did not agree with this argument, instead asserting the primacy of free trade.¹⁵²

In *Merck v. Stephar*,¹⁵³ the ECJ again found that a patent right had been exhausted in circumstances where no parallel patent protection was available in the Member State where the product had first been marketed.¹⁵⁴ Merck held patents for its drug Moduretic in a number of Member States, but not in Italy, where at the time, no patent protection for pharmaceuticals was available.¹⁵⁵ Consequently, there was a thriving domestic generic industry in Italy and prices were low.¹⁵⁶ Nonetheless, Merck sold its drug on the Italian market.¹⁵⁷ Stephar then imported the drug from Italy to the Dutch market at a price below Merck's retail price there.¹⁵⁸ Merck brought proceedings against Stephar for infringement on its Dutch patent.¹⁵⁹ The ECJ held that by putting the drug on the Italian market, it had exhausted its patent rights, despite the fact that there was no patent protection there.¹⁶⁰ The legal effect was that if a patentee put its drug on the Italian market, it had no ability to obtain a reward for its invention, undermining its patents in other Member States.¹⁶¹ Commercially, until Italy changed its laws to patent pharmaceuticals, companies delayed or restricted supply of essential drugs on the Italian market.¹⁶²

Finally, In *Merck v. Primecrown*,¹⁶³ the ECJ again affirmed the primacy of free trade over patent protection.¹⁶⁴ The ECJ held that a manufacturer's patent rights are exhausted EU-wide once a product

directly or by the grant of licenses to third parties, as well as the right to impose infringement.

150. *Id.*

151. *Id.*

152. *Id.*

153. *Merck v. Stephar*, 3 C.M.L.R. 463 (1981).

154. *Id.*

155. *Id.*

156. *Id.*

157. *Id.*

158. *Id.*

159. *Merck v. Stephar*, 3 C.M.L.R. 463 (1981).

160. *Id.*

161. *Id.*

162. *Id.*

163. *Joined Cases C-267/95 and C-268/95, Merck v. Primecrown*, 1 C.M.L.R. 83 (1997).

164. *Id.*

is placed on the market in any EU country.¹⁶⁵ This holds even where the exporting country does not recognize patents and the effect of parallel trade is to nullify the patent holder's rights in the importing country.¹⁶⁶

D. Analysis

Several reasons have been advanced for the differences in U.S. and other countries' attitudes toward parallel trade. First, because most pharmaceutical companies are based in the United States, it is suggested that the United States has a strong interest in protecting pharmaceutical company profits.¹⁶⁷ By allowing parallel trade, pharmaceutical prices drop, causing U.S. companies to lose profits.¹⁶⁸ Second, as expressed in *Merck*, the European Union and other countries allowing parallel trade place great value on relatively unrestricted trade.¹⁶⁹ Finally, it has been suggested that the incentive to control health-care spending has increased as EU governments attempt to limit their budget expenditures to comply with the Maastricht Treaty.¹⁷⁰

Proponents of parallel trade advance the argument that it is consistent with principles of free trade established by the WTO.¹⁷¹ However, while restricting parallel trade will consequently decrease the liberalization of markets, this argument ignores the consequences that parallel trade places on both developing countries and the development of new medicines. When prices among national markets largely differ and parallel imports are permitted, a manufacturer has three options: (1) maintain differential pricing, (2) set a higher uniform price worldwide, or (3) market the drug exclusively in high price countries.¹⁷² Under each option, developing countries are adversely affected. Where a manufacturer takes the first option, a parallel trader may purchase mass quantities of the product in low price countries and re-import into higher priced countries, undercutting the price there and reducing profits.¹⁷³ While prices will fall in high price markets, prices will rise in low price markets due to increased demand of the product as a result of a new consumer, the parallel trader.¹⁷⁴ Consequently, a uniform price emerges and

165. *Id.*

166. *Id.*

167. Schoell, *supra* note 105, at 167.

168. *Id.*

169. *Merck v. Stephar*, 1 C.M.L.R. 83 (1997).

170. Danzon, *supra* note 71, at 297.

171. Baer, *supra* note 123, at 129.

172. *Id.* at 127-28.

173. *Id.* at 128.

174. *Id.*

developing countries pay more for the product.¹⁷⁵ On the other hand, companies may respond to parallel trade by increasing the price in the low price countries to deter the incentive for parallel trade. This may result in a worldwide uniform price. This will lead to the third option inevitably chosen because developing countries will not be able to afford a higher price. Consumers in developing countries, then, are denied essential medicines.¹⁷⁶ Thus, under each option, parallel trade harms developing countries by decreasing or denying access to essential pharmaceuticals.

V. THE INTERACTION OF INTERNATIONAL REFERENCE PRICING AND PARALLEL TRADE

A. *Economic Implications*

A significant characteristic of R&D as distinguished from marginal cost for pricing purposes is that R&D is a global joint sunk cost.¹⁷⁷ The cost is the same regardless of the number of consumers or countries served.¹⁷⁸ The problem of pricing to cover joint R&D costs is exacerbated by the fact that these costs are largely sunk by the time of product launch and price negotiation.¹⁷⁹ Marginal costs, on the other hand, account for approximately thirty percent of total cost.¹⁸⁰ Purchasers are inclined to free-ride, paying only their user-specific marginal cost, leaving others to pay the joint sunk-costs.¹⁸¹ Where product markets are either highly competitive or monopsonistic (i.e. where there is a sole purchaser), prices are driven down to marginal cost.¹⁸²

The incentive for parallel trade is a sufficient difference in prices between the exporting country and importing country to cover shipping and transaction costs and still offer gains to both countries.¹⁸³ A monopsonistic government purchaser has the leverage to drive prices down to the country-specific marginal cost since any producer will rationally continue to supply a product as long as the price covers marginal cost.¹⁸⁴ These countries, then, free-ride off

175. *Id.*

176. *Id.*

177. Danzon, *supra* note 71, at 295.

178. *Id.*

179. *Id.* at 296.

180. *Id.*

181. *Id.*

182. *Id.*

183. Danzon, *supra* note 71, at 296.

184. *Id.* at 295.

others that pay the joint cost of R&D.¹⁸⁵ Because R&D expenses may account for up to thirty percent of product output, and some countries' are paying more than their fair share of R&D expenses due to free-riding behavior, a sufficient difference in prices between countries develops.¹⁸⁶ This situation provides the opportunity for both parallel trade and international reference pricing to take over.¹⁸⁷

Since there are no barriers to parallel trade in most countries and the incentive of sufficient price differentials is present, those countries whose governments are paying more for pharmaceuticals to cover R&D expenses may now import pharmaceuticals from lower price countries, reducing direct manufacturer purchases and R&D profit.¹⁸⁸ Moreover, with the use of international reference pricing, countries formerly covering R&D expenses are now inclined to utilize their monopsony power to free-ride using other free-riding countries' prices as justification for their economic behavior.¹⁸⁹ Such domestic international reference pricing reduces domestic prices across the board to the lower foreign price level, and hence, is equivalent to 100 percent parallel trade.¹⁹⁰

In EU countries, the government is either the monopoly provider of national health insurance, as in the United Kingdom and Italy, or is heavily involved in regulating the quasi-private social insurance funds, as in Germany, France, and the Netherlands.¹⁹¹ A regulator of a country that accounts for only a small percentage of global pharmaceutical revenues may reason that its failure to contribute to the global joint costs of R&D will have a negligible impact on the future supply of medicines.¹⁹² However, parallel trade and international reference pricing permit diffusion of low prices from one country to other countries.¹⁹³ Pharmaceutical sales in the United Kingdom account for about three percent of the world market.¹⁹⁴ As a result, a cut in prices for pharmaceuticals in the United Kingdom would seem only to effect global R&D returns.¹⁹⁵ However, if a sufficient number of countries cut their prices, this could have a more cumulative effect of seriously damaging global R&D.¹⁹⁶ Moreover, UK prices actually directly feed into the pricing schemes of many other

185. *Id.*

186. *Id.*

187. *Id.*

188. *Id.*

189. Danzon, *supra* note 71, at 296.

190. *Id.* at 294.

191. Patricia Danzon, *Price Discrimination for Pharmaceuticals: Welfare Effects in the U.S. and EU*, 4 INT'L J. ECON. BUS. 301, 306 (1997).

192. *Id.*

193. *Id.*

194. Bloom & Van Reenen, *supra* note 57, at 322.

195. *Id.*

196. *See id.*

countries utilizing international reference pricing.¹⁹⁷ Seemingly insignificant reductions in UK prices can thus have a broader global effect.

A pharmaceutical manufacturer's profit-maximizing response to the increase in parallel trade and international reference pricing driving down prices will be to set a single uniform price in all markets connected through trade or international price comparisons.¹⁹⁸ Already, several major multinational companies attempt to obtain a uniform launch price throughout the European Union for new drugs.¹⁹⁹ For example, on February 24, 2003, a pharmaceutical company, Roche, announced that it was setting a European price of fifty-two euros a day, or more than \$20,000 a year, for its new AIDS drug, Fuzeon.²⁰⁰ The drug's cost is abnormally high compared to other AIDS-related medicines.²⁰¹ The company, however, has justified this cost by the need to recoup R&D expenses.²⁰² At the time of this writing, the price had not been set for the United States.²⁰³ However, David Reddy, head of Roche's HIV products, said it would be in line with U.S. products, even though drugs in the United States have typically been priced five to twenty-five percent more than those in European countries.²⁰⁴ If Roche's new drug is priced similarly in the United States and the European Union, it would be an indication that Roche is attempting to set a more uniform launch price, perhaps to prevent international reference pricing and parallel trade from affecting its recoup of R&D expenses.

Uniform pricing will adversely affect both consumers in traditionally low price countries (such as those in unindustrialized countries where manufacturers are currently altruistically inclined to reduce prices to increase access) as well as those in traditionally high price countries.²⁰⁵ Consumers in traditionally low price countries will face higher prices and possibly loss of access to innovative drugs, even though they would have been willing to pay a price sufficient to cover

197. *Id.* at 324. Countries including UK prices into the reference basket include Austria, Belgium, Canada, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, and Spain.

198. *See* Danzon, *supra* note 71, at 299.

199. *Id.* at 300. Glaxo accepted a delay for several years for Imigran, an antimigraine in France rather than accept a low price that would have undercut its higher price elsewhere. In 1996, Merck launched Crixivan, a protease inhibitor at a common EU price.

200. Alison Langled & Melody Petersen, *AIDS Drug is Priced by Roche*, N.Y. TIMES, Feb. 25, 2003, at W1.

201. *Id.*

202. *Id.*

203. *Id.*

204. *Id.*

205. Danzon, *supra* note 71, at 295.

the marginal cost under differential pricing.²⁰⁶ Consumers in initially high price countries may benefit if the uniform price is below the price they would have paid with differential prices.²⁰⁷ In the long run, however, as revenue declines under uniform pricing, the supply of innovative medicines will be reduced, eliminating some products they would have been willing to pay for.²⁰⁸

B. Legal Implications

The obstacles to improving the economic structure of the pharmaceutical market primarily consist of inadequate restrictions, lack of uniform laws on parallel trade, and a complete lack of regulation or law on international reference pricing. Once a pharmaceutical company obtains a patent on a product, the company negotiates the price it will receive for sale of the patented product with governments on a country-by-country basis.²⁰⁹ If the company and government reach an agreeable price, the transaction is complete.²¹⁰ If an agreement cannot be reached, the company has two options: (1) sell for a lower price, or (2) deny supply.²¹¹ Under both options, international reference pricing and parallel trade may take place.²¹²

In the event that the company sells for a lower price, this price may now serve as a reference under which other countries will use to negotiate prices for the same or similar products.²¹³ Through setting a lower price which the company will sell the product to one country, they may also functionally set a ceiling for all subsequent transactions.²¹⁴

If the company simply walks away from the transaction and denies supply of the product to the country, that country may then parallel import the same product from another country that has chosen to buy at a lower price, such as from a developing country.²¹⁵ Thus, under the current market system, without legal constraints, reference pricing and parallel trade create a negative impact.

206. *Id.*

207. *Id.*

208. *Id.*

209. *Id.*

210. *See id.* at 296.

211. Danzon, *supra* note 71, at 296.

212. *Id.*

213. *See id.* at 297.

214. *Id.*

215. *Id.*

I. THE R_x

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. Essential to promoting R&D is to maintain income from sales adequate to cover research and marginal costs, as well as to generate manufacturer profit.²¹⁶ While patents are intended to ensure these objectives, most countries dilute their effectiveness through parallel trade and international reference pricing.²¹⁷ Thus, patent protection must be enhanced. If pharmaceutical companies are to provide affordable, essential medicines to developing countries (at costs insufficient to cover R&D), they must be assured that those discounted prices do not leak into developed countries. Otherwise, R&D costs cannot be recouped and either essential medicines will no longer be developed, or manufacturers will discontinue the practice of providing affordable medicines to those who cannot otherwise afford them. This objective calls for protection against price leakages. Finally, most countries place great value on the notion of free trade. Any objective aimed at eliminating free trade altogether, including the free trade of pharmaceuticals, is unrealistic. Thus, some level of free trade with regard to pharmaceuticals must be maintained.

While parallel trade is widely acknowledged and discussed, legal commentators have largely ignored international reference pricing as a contributing factor in the pharmaceutical dilemma and as an area of potential regulation or reform in reaching a solution.²¹⁸ Most legal proposals on this topic have dealt primarily or exclusively on restricting or eliminating parallel trade.²¹⁹ This is theoretically a good solution for rectifying the first two objectives. However, if

216. *Id.*

217. Danzon, *supra* note 71, at 297.

218. The lack of attention given to international reference pricing may be due to the lack of any international guidance or regulation on the practice.

219. See generally Ellen 't Hoen, *Public Health and International Law: TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: a Long Way From Seattle to Doha*, 3 CHI. J. INT'L L. 27 (2002); Ghosh, *supra* note 139; Shanker A. Singham, *Symposium: Third Annual Latin American Competition and Trade Round Table: Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry*, 26 BROOKLYN J. INT'L L. 363 (2000); Claude E. Barfield & Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 185 (1999).

parallel trade is restricted or eliminated, free trade no longer exists, or is at least greatly burdened. Thus, this solution fails to incorporate the third objective. These proposals have not been successful because most countries staunchly guard freedom of trade. The lack of success with the extensive commentary on eliminating parallel trade exemplifies the need to incorporate the third objective of free trade into a solution.

The most efficient way to regulate international reference pricing would be for the United States (the only developed country that does not use international reference pricing for pharmaceuticals, thus bearing a disproportionate portion of R&D expenses as compared to other developed countries) to enter into a series of free trade agreements (FTAs) with other developed countries that use international reference pricing for pharmaceuticals. These FTAs would establish pricing principles restricting or limiting reference pricing.²²⁰

An initial obstacle to this proposal is that developed countries whose citizens are financially benefiting from the practice of international reference pricing are unlikely to restrict or eliminate the practice, at least on purely economic grounds. In this regard, the United States, the pharmaceutical companies and countries utilizing international reference pricing would need to discuss incentive options for these countries' cooperation.

Bilateral trade agreements between the United States and developed countries utilizing reference pricing offer the greatest opportunity for success. Over the past decade, there has been a trend toward bilateral trade agreements to resolve trade interests.²²¹ Bilateral, as opposed to multilateral agreements, allow for more expedient resolution of trade issues because participating governments need only resolve the trade issues specific to their

220. The incorporation of provisions for pricing principles into future FTAs was set forth in H.R. 1942, introduced by Representatives Crane, Dreier, and Johnson on May 26, 1999.

221. S. Tamer Cavusgil, *Globalization of Markets and Its Impact on Domestic Institutions, Symposium: The Globalization of Law, Politics, and Markets: Implications for Domestic Law Reform*, 1 IND. J. GLOBAL LEGAL STUD. 83, 91 (1993). The United States has current or future FTA negotiations with Chile, Singapore, Morocco, Latin America (FTAA), and Australia, among others. The United States/Jordan FTA is an example of a successful bilateral FTA. Agreement on the Establishment of a Free Trade Area, Oct. 24, 2000, U.S.—Jordan, available at <http://www.ustr.gov/regions/eu-med/middleeast/textagr.pdf>. In December 1999, Jordan became the 136th WTO member. Through the WTO accession process, Jordan amended all of its intellectual property and related legislation, including bringing its patent and Unfair Competition and Trade Secrets Law to meet international standards. Jordan additionally provided for linkage between regulatory and intellectual property authorities to ensure the full weight of its government stood behind its intellectual property commitments. The U.S./Jordan FTA framework illustrates the possibilities of how these objectives may be realized.

relationship. Moreover, with fewer governments participating in negotiations, fewer competing interests and conflicts will ensue.²²²

Procedurally, the recent signing of the Trade Promotion Authority (TPA) legislation gives the U.S. President proper congressional guidance to move forward with a proactive trade agenda.²²³ If the United States is successful in negotiating FTAs requiring developed countries to restrict or eliminate reference pricing in place of a free market system, pharmaceutical manufacturers may be more motivated by the potential to recoup R&D costs to invest more in future R&D. Similarly, with the decrease in reference pricing, the United States will no longer pay as disproportionate share of R&D expenses.

VII. CONCLUSION

Applied to patented pharmaceuticals, international reference pricing and parallel trade coincide to decrease R&D incentives, decrease access to affordable pharmaceuticals in underdeveloped countries, and inhibit equitable R&D cost-sharing between developed countries. Presently, there is no international regulation on international reference pricing and very little on parallel trade. While the concept of parallel trade has been highly analyzed and commented upon, scant legal literature discusses international reference pricing, a current area of discussion amongst some economists. The best approach to promoting pharmaceutical R&D and encouraging pharmaceutical companies to provide affordable medicines to underdeveloped countries, while maintaining free trade, is through a system of bilateral trade agreements.

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222. As a hypothetical, suppose the United States is only able to convince country A to partially restrict reference pricing, possibly by limiting the "basket" of references to developed countries. Now suppose the United States successfully encourages country B to eliminate the practice of reference pricing altogether. Under a multinational FTA dealing with both countries A and B in a single agreement, the United States may have to settle for the lowest common denominator—that is—country A's agreement to partially restrict reference pricing, possibly by limiting the "basket" of references to developed countries. Under two separate bilateral FTAs, the United States may settle in the first case with country A but fully win its position with country B in the second case. In such a situation, bilateral trade agreements are the best option.

223. *Cf.* Agreement on the Establishment of a Free Trade Area, U.S.—Jordan, *supra* note 221.

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