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Clause E. Barfield
American Enterprise Institute.

Mark A. Groombridge
Cato Institute

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Cover Page Footnote

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Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy

Claude E. Barfield*
Mark A. Groombridge**

INTRODUCTION

A. *The Argument*

Based upon an extensive analysis of the most recent economic and legal literature, the goal of this article is to evaluate the impact of parallel trade on the pharmaceutical industry and on the intellectual property protection granted through the patent system. Parallel trade occurs when differences in national economic, social, legal or regulatory regimes result in different prices among countries, creating opportunities for arbitrage.

Parallel trade can take place through several means, but typi-

* Claude E. Barfield is Director of Science and Technology Studies at the American Enterprise Institute.

** Mark A. Groombridge is Research Fellow in the Center for Trade Policy Studies at the Cato Institute.

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cally a distributor will obtain a product in a low-price country and ship it to an unauthorized distributor in a high-price country, who will then compete directly with the patent holder or the authorized distributor in that country.¹

The economics of parallel trade present some of the most complicated challenges to the international trading system, and much work remains to be done in this area. There is very little empirical research published, and most of the benefits and costs related to parallel imports have yet to be quantified. To be sure, quantification of parallel trade, which by definition occurs outside authorized distribution channels, is inherently difficult. Our conclusions are thus based largely on an analysis of the theoretical literature and on the more practical evidence adduced from the experience of private sector companies.

We should like to emphasize from the outset that the focus of the analysis and conclusions set forth in this article relate primarily to the pharmaceutical industry, though in some areas the points made are valid for the entire patent system, or even for copyrights and trademarks. The authors are aware that the rationale for patent is different in important respects from copyright and trademarks, respectively. We use the term 'intellectual property' collectively because it tracks the common usage of the literature in this area.

The overall rationale for the patent system stems from the belief that unfettered competition will produce too little innovation unless inventors are given market power for a limited time in order to block relatively costless imitation of new products.² Agreement on this proposition, however, leaves many questions hanging regarding a proper balance of rights between the inventor and society. Most economists would argue that in an ideal world, this bal-

1. Some analysts distinguish between *active* and *passive* parallel trade: in the passive mode, arbitrageurs buy in a low-price country and sell in a high-price country; in the active mode, a foreign licensee enters the domestic market himself to compete with the patent holder or his licensee. See Carsten Fink, *Entering the Jungle of Intellectual Property Rights Exhaustion and Parallel Imports*, Mimeo 1, (April 1999).

2. See *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966). The authors acknowledge that parallel trade is not just an intellectual property issue. Restrictions on parallel trade for products not covered by intellectual property rules have included phytosanitary regulations, contracts, and (unfortunately) import restrictions.

ance would be made on a case-by-case (product or sector) basis. As economist Keith Maskus has noted:

In theory, the appropriate balance of incentives would depend on numerous market characteristics in each product or artistic area. These characteristics include prospective demand, potential spillovers, the costs of research and development (R&D), impacts on market structure, and competitive aspects of the economy. Many of these factors are uncertain at the time [intellectual property right] decisions are made, suggesting that finely tuned policies are unworkable. Rather, [intellectual property rights] must be based on generally applicable standards rather than on a case-by-case system.³

Building upon this insight, we shall argue that there are special characteristics and circumstances relating to the research-based pharmaceuticals industry justifying rules that allow companies to control parallel trade. Specifically, economists have identified at least four market settings in which parallel trade is likely to reduce economic welfare; and the pharmaceutical industry exhibits elements of all four characteristics. These cases, or settings, are:

In high-technology industries, particularly those with a high ratio of sunk joint R&D costs, where parallel imports will inhibit the ability of firms to recoup R&D and other fixed costs and ultimately reduce their ability to innovate;

In situations where price discrimination (differential pricing) will enhance welfare by facilitating entry into new, low-priced markets and thus expanding output;

In cases where monopsony power by public authorities creates price distortions and drives price down below average fixed costs; and

In countries where free rider problems exist because parallel imports can freeze out authorized distributors through lower prices, thus undercutting information and service activities.

3. Keith E. Maskus, *The International Regulation of Intellectual Property*, 134 WELTWIRTSCHAFTLICHES ARCHIV: REVIEW OF WORLD ECONOMICS 188 (1998).

Critics of the argument we advance maintain that:

The problem [of parallel imports] no longer can be looked at from an exclusive perspective of maximizing intellectual property rights. It has to be dealt with from a perspective of creating equal level playing fields, avoiding distortions of market access and providing, at the same time, adequate protection of investment.⁴

We agree that it is important to incorporate these other perspectives but still maintain that on balance, the negative consequences of parallel trade, particularly in the research-based pharmaceutical industry, would greatly outweigh any limited and short-term benefits.⁵ Moreover, even if it were true that market distortions were taking place due to the anti-competitive actions of pharmaceutical companies, there are better mechanisms already in place to address such actions, specifically, anti-trust laws that counter abusive monopolistic practices.

After considering the available theoretical literature and the empirical evidence and practical experience that has been amassed over the past decade, this article concludes that a doctrine of international exhaustion of patent rights that would allow unrestricted parallel trade of pharmaceutical products would likely result in decreased economic welfare for producers—and consumers. An effective patent system depends on much more than laws concerning patent-length and penalties on infringement. An effective patent system also depends on the ability by the patent holder to control the distribution of its patented pharmaceuticals—a system that would be greatly undermined in a world of unfettered parallel imports. We agree with Patricia Danzon, who argues that allowing patent holders in the pharmaceutical industry to control parallel trade is a “normal competitive constraint . . . [that] is consistent with the purpose of patent protection, whereas competition from

4. Thomas Cottier, *The WTO System and Exhaustion of Rights 1* (Draft manuscript presented at the Conference on the Exhaustion of Intellectual Property Rights and Parallel Importation in World Trade, Geneva, Switzerland) (November 6-7, 1998).

5. See Claude E. Barfield and Mark A. Groombridge, *The Economic Case for Copyright Holder Control over Parallel Imports*, 1 J. WORLD INTELL. PROP. 903 (1998).

perfect substitutes, as occurs with parallel trade, undermines the intent of patent.”⁶

B. Intellectual Property Rights and the Multilateral Trading System

Though this article focuses its main attention on the particular issues related to the pharmaceutical industry, some discussion is warranted of the larger context of developments relating to intellectual property rights (“IPRs”) in national and international regimes. In January 1995 for the first time, intellectual property rights were brought into the multilateral trading system with the signing of the Agreement on Trade Related Aspects of Intellectual Property (TRIPS).⁷

The establishment of TRIPS in the WTO reflects the growing demand for increased intellectual property protection. It also reflects major changes in the dynamics of international competition and the growth of knowledge industries as the central elements of comparative advantage among the developed economies. There is both general and specific evidence for this evolution.

Over the past two decades, enormous public and private resources have been poured into research and development projects. In 1996, developed countries spent over \$600 billion (US \$250 billion) on R&D,⁸ with the developing countries spending about \$100 billion — a figure highly skewed by sizeable proportions coming from East Asia, India, China and Brazil.⁹ Meanwhile, global direct investment, an important indicator of technology transfer, increased fourfold between 1982 and 1994, doubling as a percentage of world gross domestic product (from 4

6. Patricia M. Danzon, *The Economics of Parallel Trade*, 13 *Pharmaceutics* 301 (March 1998).

7. See Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1995, 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 Agreement].

8. See Carlos A. Primo Braga et al., *Intellectual Property Rights and Economic Development*, TECHNET WORKING PAPER, 10 (July 1, 1999).

9. See *id.* at 11.

to 9 percent).¹⁰ Two more direct indicators of increased international economic activities in knowledge-based products were the surge in export growth in high-technology sectors, which from 1980 through 1994 doubled as a percentage of total world exports (12 to 24 percent);¹¹ and a huge increase in the demand for intellectual property protection.¹² Using the periods 1981-1982 and 1994-1995 as baselines, the number of patents granted more than doubled, from 320,000 to 670,000; and the number of trademark registrations increased 2.6 fold, from 420,000 to 1.1 million.¹³

Before discussing the substantive implications of these changes for the multilateral trading systems, two political economy facts should be posited. First, as one commentator has pointed out: “[T]he growing capacity of manufacturers in developing countries to penetrate distant markets for traditional industrial products has forced the developed countries to rely more heavily on their comparative advantages in the production of intellectual goods than in the past.”¹⁴ Second, in many sectors — and this is particularly the case with pharmaceuticals—the combination of a disproportionate rise in the cost of research, with a decreased product cycle and increasing vulnerability to free-riding imitation, has given stronger urgency to political pressure to upgrade IPR protection.

The TRIPS Agreements, while lauded as an important step in addressing the concerns of industries dependent upon IPR protection, leaves some issues unresolved. One particular standout is the issue of exhaustion of patent and other intellectual property rights. Under a system of national exhaustion, a patent holder can prevent parallel importation of his product from a foreign country, where it is sold either by the IPRs owner himself or by an authorized dealer. International exhaustion in the case of patents means that as soon

10. *See id.* at 14.

11. *See id.* at 13.

12. *See id.* at 15.

13. *See id.* at 16.

14. *See* J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement*, 29 INT'L LAW. 345, 346 (1995).

as a product is put on the market of any WTO member by the holder of a patent or with his consent, the patent can no longer block the importation of that product in any other WTO country.¹⁵

So divided were WTO members on the issue of the exhaustion of IPRs that the TRIPS Agreement explicitly acknowledged this lack of consensus.¹⁶ This should come as little surprise as the debate on parallel trade and the issue of exhaustion incorporates aspects of competition policy and passionate debates concerning the relationship between advanced-industrialized countries and less-advanced developing countries. As Cottier observes:

World trade law is only in its beginnings in dealing with this careful balance. While parallel imports amounts to perhaps the most central trade-related issues of IPRs, it has not been extensively dealt with in negotiations. Within the TRIPS Agreement it was mainly agreed to disagree, and leave the matter for further work.¹⁷

Indeed, Article 6 of the TRIPS Agreement expressly states that: “For the purposes of dispute settlement . . . nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”¹⁸

The issue of parallel imports represents the first test of the capability of the WTO to reconcile these competing principles and fulfill the obligations implicit in the decision to bring intellectual property rights into the multilateral trading regime. A frequent argument in favor of parallel imports and international exhaustion is that a system that allows restrictions on parallel imports conflicts with the basic principles of free trade that undergird the WTO. Frederick Abbott of the International Trade Law Committee (ITLC) states “the premise [is] that restrictions on the free movement of goods and services legitimately placed on the world market are inconsistent with the underlying objective of the GATT-

15. See Marco C.E.J. Bronckers, *The Exhaustion of Patent Rights Under WTO Law*, J. WORLD TRADE, October 1998, at 137.

16. See TRIPS Agreement art. 6.

17. Cottier, *supra* note 4.

18. TRIPS Agreement art. 6.

WTO system.”¹⁹ That being the case, he bluntly argues that:

[I]n light of the inherent tension between IPR-based territorial restrictions and the rules of the GATT 1994 . . . promoting the free movement of goods and services, it may be necessary to give priority to one set of values over the other. It is suggested here that the WTO Agreement places a priority on the liberalization of markets . . . as opposed to strict neutrality or a converse presumption.”²⁰

Against this view, we make two arguments: one is that, without quibbling over the terms of ‘equality,’ the TRIPS Agreement should at least be interpreted in a manner which does not undermine its very premises. Thus, in legal terms, we agree with Bronckers, who has written:

As a matter of principle, one may ask whether *any* issue of intellectual property protection can still be tackled or attacked on the basis of other WTO rules, notably the GATT’s principles. Proponents of international exhaustion have suggested that the overarching principle of the WTO is open trade or trade liberalization, a principle which is also supposed to guide the interpretation of the TRIPS Agreement. However, that view is one-sided. It does not comport with the text and objectives of the TRIPS Agreement [which is *sui generis*].

...

Indeed, the TRIPS Agreement balances two principles: trade liberalization as well as increased intellectual property protection, with the restrictions on trade this entails.²¹

On the even more basic issue of free trade versus IPRs, we would argue that the alleged contradiction stems from a failure to acknowledge the premises and implications upon which IPRs are

19. See Frederick M. Abbott, Discussion Paper for Conference on Exhaustion of Intellectual Property Rights and parallel Importation in World Trade 3 (Draft Paper for Conference on Exhaustion of Intellectual Property Rights and Parallel Importation in World Trade, Geneva, Switzerland) (November 6-7, 1998).

20. See *id.* at 7.

21. Bronckers, *supra* note 15, at 143-44.

based. IPRs do restrict market forces for a period of time, on the assumption that the dynamic effects (effects over time) will produce greater economic welfare gains for society than would be the case without this grant of temporary monopoly. Here we agree with the analysis of economist Carsten Fink who has written extensively on IPRs and the WTO. Fink states:

[T]he exhaustion doctrine is primarily an issue of IPRs policy—and not an issue of free trade or restricted trade. The free trade argument in the context of parallel trade has two fundamental shortcomings. First, the conditions surround parallel trade do not fit into the assumptions on which standard static (short-term effects) trade models supporting the case for laissez-faire trade are built. Second, a static analysis with regard to IPRs is insufficient . . . [it] would require the removal of all rights to intellectual property! . . . [T]he main rationale for protecting IPRs lies in their dynamic effects. . . . By granting exclusive rights and thus enhancing market power, rights to intellectual property allow title holders to appropriate their investments in creating intellectual property.²²

C. *Plan of the Article*

In mobilizing evidence to support our conclusions, the authors organize the article as follows. In the next section, we discuss the extent of the problem and the current situation from a legal perspective, both within the WTO and in the national laws of major trading nations and blocs such as the European Union (EU). In section II, we briefly review the economics of the patent system, with particular reference to issues that have special relevance to the pharmaceutical industry, such as the extent of actual monopoly under patents and whether so-called ‘patent races’ decrease economic welfare. Also in this section, we describe in some detail recent scientific developments within the pharmaceutical industry and why parallel imports would prove particularly damaging in the

22. See Carsten Fink, Does National Exhaustion of Intellectual Property Contradict the Principle of Free trade? 3-4 (Draft Paper for Conference on Exhaustion of Intellectual Property rights and Parallel Importation in World Trade, Geneva, Switzerland) (November 6-7, 1998).

long-term to the ability of the industry to continue to produce a stream of innovative drugs. In the fourth section, we analyze the importance of an effective distribution system to realizing the benefits of the patent system. We also demonstrate how parallel imports would undermine economic and physical welfare specifically in the pharmaceutical industry. We then set forth the case for why the government must play a critical role in adopting and enforcing rules allowing patent holders control over parallel imports. Finally, the article concludes that at this time pharmaceuticals should be exempted from parallel trade.

I. RECENT ECONOMIC AND LEGAL DEVELOPMENTS ON PARALLEL TRADE

A. *Parallel Imports: The Extent of the Problem*

Markets for parallel imports—gray market goods—are by their nature hard to measure, but studies of individual and regional market trends demonstrate the likelihood that from a small base such imports in pharmaceuticals will grow substantially in future years. Already, for example, parallel trade is estimated to account for roughly 10 percent of pharmaceutical sales in the European Union, where such trade among member states is permitted unless prohibited by private contract. Further, this percentage jumps steeply when one counts only the most profit-making drugs which are still bound by patents—about 25 per cent of the total market.²³ In addition, a recent survey of 9 EU pharmaceutical companies conducted by the National Association of Economic Research estimated “the aggregate loss of revenues for the participating companies in Denmark, Germany, the Netherlands and the UK in 1996 to be ECU 323 million.²⁴ This is equivalent to seven percent of the total sales revenue of these companies in the markets concerned.”²⁵ The same research team also reported a survey in which almost 30 percent of U.S. pharmaceutical exporters to Asia stated that their local

23. See Danzon, *The Economics of Parallel Trade*, *supra* note 6, at 294. Throughout the paper, we use the terms parallel imports, parallel trade and gray market interchangeably.

24. National Economic Research Associates (NERA), *Survey of Parallel Trade*, 2 (May 1997).

25. *Id.* at 2.

distributors were experiencing problems with lower-priced parallel imports.²⁶

It should be noted that these parallel import penetration figures do not convey the full potential impact of the phenomenon. What they cannot measure is the extent to which pharmaceutical companies lower their prices in the higher-price market as a defense against price-cutting by parallel imports. While in the long-run this tactic is self-defeating,²⁷ there is evidence that companies are adopting this strategy.²⁸

There are two other current practices which magnify the effect of parallel importing in pharmaceuticals: one is the substantial discounting granted to developing countries and the other is the degree that parallel importers target or “cherry pick” the most profitable drugs to attack. For both economic and philanthropic reasons, pharmaceutical manufacturers sell a substantial number of drugs to developing countries at discount prices. In recent years, these markets have become major outposts for re-exportation back to developed countries. Consequently, Stuart Schweitzer notes that increasingly the “threat of cheaper versions of the patented drugs reentering the primary markets of the United States, Europe and Japan is serious.”²⁹

The research-based pharmaceutical industry’s ability to develop innovative new drugs, is also jeopardized by the practice of “cherry-picking major products.”³⁰ Parallel traders most often trade in “sure-bets,” or products just recently released that provide the bulk of profits for pharmaceutical companies. As Burstall and Senior note, “In practice parallel importers focus upon the best-selling, in-patent, branded medicines. [We] found that in 1990 six out of seven of the world’s best selling medicines were parallel

26. *See id.*

27. *See infra* pp 162 - 63.

28. *See* PATRICIA DANZON, PHARMACEUTICAL PRICE REGULATION: NATIONAL POLICIES VERSUS GLOBAL INTERESTS 85-86, (1997).

29. STUART O. SCHWEITZER, PHARMACEUTICAL ECONOMICS AND POLICY 229 (1997).

30. National Economic Research Associates (NERA), *Survey of Parallel Trade*, (May 1997), Key Conclusions.

traded in the European Community.”³¹ The particular negative impact of this practice is underscored by the fact that pharmaceutical companies often depend on a few so-called “blockbuster drugs” for long-term growth and success.³² Thus, the consequence of such trade could ultimately substantially undermine investment in R&D. As Warwick Rothnie argues:

[P]arallel imports affect the most successful drugs. These tend to be the ones with more improved therapeutic benefits, the drugs which it most desirable to encourage. Drug companies are also crucially dependent on them to sustain their levels of profitability. Therefore, greater encouragement of parallel imports is likely to have an exaggerated effect on both ability and incentives to carry out desirable R&D.³³

B. *The Current Legal Situation Regarding Parallel Trade*

Though the legal basis for patent holders to control the importation of patented goods or processes into the United States is fairly strong, recent events both in the United States and in foreign countries continue to leave some questions unanswered. This section will describe recent decisions in the United States and in Japan and the EU to illustrate the current international complexity regarding the right of patent holders to control importation.

First, in the U. S., decisions relating to parallel trade have been influenced and determined by legislative action and by the revolution in judicial attitudes regarding competition policy in general and vertical restraints in particular. Vertical restraints (also known as restrictions or arrangements) are contractual limitations imposed by a firm at one stage of production or the distribution process upon a firm at a different stage. Earlier, as Robert Anderson of the WTO has noted, there was a “fundamental tension between the goals of competition policy and IPRs”; but in recent decades, economic thinking has recognized that “voluntary arrangements for the licensing of intellectual property can enable firms to work to-

31. M.L. BURSTALL AND I.S.T. SENIOR, UNDERMINING INNOVATION: PARALLEL TRADE IN PRESCRIPTION MEDICINES 24 (1992).

32. *See infra*, pp. 24.

33. WARWICK A. ROTHNIE, PARALLEL IMPORTS 505 (1993).

gether (more) efficiently. . .and that ‘restrictive’ contractual arrangements such as . . .territorial market restraints, while capable of restricting competition in particular market circumstances, are often employed by firms for legitimate, pro-competitive purposes.”³⁴ In the 1977 *Sylvania* case, the Supreme Court adopted the basic premises of the new economic thinking and established a “rule of reason” standard for judging vertical restrictions by manufacturers over dealers or retailers in the U.S. domestic market.³⁵

In addition, under current U.S. law the patent owner has the right to exclude others from making, using, offering for sale, selling, or importing the patented invention.³⁶ Under section 261 of title 35 of the United States Code, the patent owner can impose and enforce territorial restrictions in the United States on sales on distributors.

Despite the statutory base and the favorable ruling in *Sylvania*, a second doctrine, the so-called ‘first sale doctrine,’ continues to complicate judicial views regarding parallel imports. Under the first sale doctrine, in the domestic market the patent (or copyright) holder cannot control or dictate the terms of distribution of a patented product once ownership has been transferred.³⁷

As Rothnie has noted, three arguments have been advanced defending the limitation: one is explicitly economic, to wit that the patent owner has received full value for the patent in the first sale; a second relates to the doctrine of “alienation of rights” or the right of the purchaser to exercise control a good once a legitimate sale has taken place; and the third, more broadly stems from a general

34. Robert D. Anderson, “The Interface Between Competition Policy and Intellectual Property in the Context of the International Trading System,” *Journal of International Economic Law*, vol. 1, no. 4 (1998), p. 659, and *passim*; for a second detailed discussion of the interface between competition policy and IPRs see, Rothnie, pp. 150-185.

35. *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36 (1977).

36. 35 U.S.C. § 271 (1994).

37. See DONALD S. CHISUM, *CHISUM ON PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY, AND INFRINGEMENT* § 16.03(2)(a) (1998); see also Neel Chatterjee, *Imperishable Intellectual Creations: The Limits of the First Sale Doctrine*, 5 *FORDHAM INTELL. PROP. MEDIA & ENT. L. J.* 383, 387 (1995)(defining the first sale doctrine as applied to copyrighted works).

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antagonism to monopolies and the desire to limit their effect.³⁸

38. See ROTHNIE, *supra* note 33, at 259-60.

Regarding infringement on patents by parallel imports into the United States, in general courts continue to uphold the territorial nature of the patent against claims of universal exhaustion.³⁹ In some lower court cases, however, judges have proved susceptible to arguments that allege that patent holders, through restricting parallel imports, are receiving “double profits” out of proportion to their contribution to the economic welfare of the country.⁴⁰

During the TRIPS negotiations, U.S. negotiators successfully argued that the ‘right of importation’ be included among the rights conferred to patent holders in the new TRIPS Agreement. Thus, Article 28 of TRIPS grants patent owners (for both products and processes) “exclusive rights . . . to prevent third parties, not having the owner’s consent from the acts of: making, using, offering for sale, selling or importing” said products or processes.⁴¹

In order to bring U.S. law fully into congruence with the new TRIPS, in 1994 Congress amended the U.S. patent law to provide that “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”⁴² Thus, at this point, there is full statutory backing for U.S. patent holders to block parallel imports, and there is no longer the necessity to rely on disparate court decisions. For pharmaceuticals, on health and safety grounds, Congress in 1987 banned the reimportation of pharmaceutical products except by the original manufacturer.⁴³

While for patents the statutory foundation is strong, a recent case involving copyrights and parallel imports has created confusion regarding the ultimate position of the U.S. regarding IPRs and competing non-pirated imports. In March 1998, a unanimous Supreme Court held that once a lawfully made product had been sold in an authorized manner—a “first sale,” in other words—the copy-

39. See *Boesch v. Graff*, 133 U.S. 697 (1890).

40. For a discussion of these cases, see ROTHNIE, *supra* note 33, at 170-85.

41. TRIPS Agreement art. 28; *see also*, Bronckers, *supra* note 15, at 141-42; *see also*, Harvey E. Bale, Jr., *The Conflict Between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals*, 1998 J. INT’L ECON. L. 638.

42. 35 U.S.C. § 271(a) (1994).

43. *See* Bale, *supra* note 41, at 651.

right owner had no further control over the product's fate.⁴⁴

Though the legal history and foundation for restricting parallel imports is much different in the patent area, the press widely trumpeted the ruling as a triumph for unrestricted parallel trade in general. Linda Greenhouse of *The New York Times* wrote: "The decision was a victory for those who champion what are sometimes called 'parallel imports' as an example of free trade that benefits American consumers."⁴⁵ Justice John Paul Stevens, who wrote the opinion, rather sweepingly opined that: "[t]he whole point of the first sale doctrine is that once the copyright owner places a copyrighted item in the stream of commerce by selling it, he has exhausted his exclusive statutory right to control its distribution."⁴⁶

In the EU, there is a dual stance regarding parallel imports. In the zeal to create a common market, the European Court of Justice (ECJ) in the 1970s handed down a series of decisions which adopted a doctrine of "international exhaustion" within the EU, allowing no restrictions on parallel trade among members of the community unless stipulated by private contract.⁴⁷ At the same time, the ECJ indicated that parallel imports from nations outside the EU would be treated differently and the territorial nature of IPRs would hold sway.⁴⁸

A recent case has underscored the bifurcated EU approach. In July 1998, in the so-called *Silhouette* case,⁴⁹ the ECJ found that a European Commission directive on trademarks mandates a community-only exhaustion rule, and thus EU member states are required to uphold the right of trademark owners to restrict parallel

44. See *Quality King Distribs., Inc. v. L'anza Research Int'l Inc.*, 523 U.S. 135 (1998).

45. Linda Greenhouse, *Ruling Aids 'Gray Market' in U.S. Goods*, N.Y. TIMES, March 10, 1998, at D1. For a more detailed description of the court's ruling see: *International Trade Reporter*, Vol. 15, No. 10, (March 11, 1998), pp. 415-416

46. See *Quality King*, 523 U.S. at 152.

47. A better term in this case might be "regional exhaustion," the point being that over the past several decades the individual nations of western Europe have been in process of evolving into states of the European Union. See ROTHNIE, *supra* note 33, chapters 6-7.

48. See *id.*

49. *Silhouette International Schmied GmbH & Co. KG v. Harlauer Handelsgesellschaft mbH*, Case C-355/96

imports. Thus, the court stated emphatically:

The 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 [The purpose of the Directive is only] . . . to safeguard the function of the internal market.⁵⁰

While the case in point concerned trademarks, it is widely assumed that the ruling would also apply to copyright and patent holders as well.

In Japan, the situation is also in flux. Japan took an ambivalent position during the TRIPS negotiations regarding international exhaustion. This was because of conflicting decisions on the subject in Japanese courts (though the predominant opinion had favored national exhaustion and allowing restrictions). In 1997, however, the Japanese Supreme Court, to the surprise of many, ruled in favor of parallel imports unless the patent holder had explicitly provided for exclusion of such imports through a contract. The key paragraph in the decision reads as follows: “The patentee is not permitted to enforce his patent right in Japan against . . . third parties or subsequent purchasers . . . except where the patentee has agreed with the (first) purchaser (to exclude Japan from the territories for sale or use) . . . and has explicitly indicated the same on the patented product.”⁵¹ Though the court explicitly viewed this as a case of free trade vs. patent holder rights, it is not clear what stance the Japanese government will take on the issue in future WTO negotiations.

50. *Id.*; see also Allen Dixon, Covington and Burling, *Silhouette Case*, (Mimeo); Christopher Heath, *Parallel Imports and International Trade*, CRESPI, Vol. 28, No. 5 (1997), pp. 623-32 (containing background on the situation in the EU — though with conclusions with which the authors disagree).

51. Nanao Naoko et al., *Decisions on Parallel Imports of Patented Goods*, 36 IDEA 567 (1996); Tadayoshi Homma, *TRIPS and After—A Realist’s View*, 13 CHIBA J. L. & ECON. 2 (1998); see also, Heath, *supra* note 50; at 623-632.

One final point regarding the variety of national legal responses to the assertion of IPR owners of the authority to control parallel imports under a national exhaustion doctrine. Courts in the United States and other countries have tied themselves in knots over the implications that result from the geographic location of both the manufacturer and the first sale of the good or service. Four potential scenarios are possible regarding reimportation: (1) the goods are manufactured in the United States and then first sold within the United States, then sold abroad and finally reimported into the United States; (2) the goods are manufactured in the United States but first sold abroad; (3) the goods are manufactured abroad and first sold abroad; and (4) the goods are manufactured abroad and first sold in the United States. Though an extended analysis of the legal implications of each scenario is beyond the scope of this article, the authors would like to emphasize that economic rationales adopted in this article would dictate that under all four scenarios the patent owner should be granted authority to block the imports (the only possible exception would involve affiliates reimporting after first sale).

II. PHARMACEUTICALS: A SCIENCE-BASED INDUSTRY

A. *The Economics of the Patent System*

1. Economic Theory and the Patent System

Though in earlier centuries, ‘natural law’ (justice for the inventor) and ‘reward by monopoly theories’ were of great importance in giving legitimacy to the patent system, contemporary debates revolve entirely around economic issues. Recent analysis of the economic assumptions behind patents begins with the seminal research of Nobel Prize winner, Kenneth Arrow. In 1962, Arrow, using a simple economic model, stated the case for the temporary grant of market power for patents and copyrights.⁵² He pointed out that inventions, like all forms of knowledge, were ‘free goods’

52. See Kenneth W. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in *THE RATE AND DIRECTION OF INVENTIVE ACTIVITIES: ECONOMIC AND SOCIAL FACTORS*, NBER, (1962). For an excellent review of the economic literature on intellectual property see: Carlos A. Primo Braga, *Guidance from Economic Theory*, in *STRENGTHENING PROTECTION OF INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES: A SURVEY OF THE LITERATURE* (Wolfgang Siebeck, et al, eds. 1990).

(‘public goods’ in economists’ terms): that is, they can be used by more than one consumer without being reduced in quantity or quality (‘nonrivalrous’ in economists’ terms), and it is not easy to prevent others from copying or using them without incurring the costs of development (‘nonexcludable’ in economists’ terms). Thus, absent some special government intervention to overcome this market failure,⁵³ inventors would have little or no incentive to produce new technology and society would suffer from this suboptimal investment in knowledge. The patent system is one means of attacking this problem. As Kenneth Dam has stated in a recent paper:

[T]his problem—often called the “appropriability problem”—is that, if a firm could not recover the costs of invention because the resulting information were available to all, then we could expect a much lower and indeed suboptimal level of innovation. In short, the patent system prevents others from reaping where they have not sown and thereby promotes [R&D] investment in innovation. The patent law achieves this laudable end by creating property rights in inventions.⁵⁴

There are two aspects of the patent system that have special relevance for pharmaceuticals: the degree to which the system actually grants real monopoly and whether patent races can reduce economic welfare. We shall review these issues in the next two subsections.

2. Patents and Monopoly

There has been a great deal of discussion over the question of the degree to which the patent system in reality grants monopoly power to the inventor for long periods of time. In economists’ terms, the patent allows the inventor to price well above marginal costs, i.e., the cost of producing an extra unit of output, for much of the full term of the patent and to reduce output below the optimal level from society’s standpoint. The result could be substantial ‘dead weight loss,’ which occurs because the sale of a good at

53. Market failure occurs when the freely determined price regulatory mechanism fails to yield efficient outcomes.

54. Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247 (1994).

greater than marginal cost limits the resources devoted to producing that good in that some consumers who would have been willing to pay an amount equal to or greater than the marginal cost—but below the monopoly sales price—are prevented from buying the good.⁵⁵

In general, even economists with other doubts about the impact of the patent system, concede that patents do not confer such power in most cases. As Scherer has reported: “[s]tatistical studies suggest that the vast majority of all patents confer very little monopoly power.”⁵⁶ The reasons for this reality are various. First, while there are a few patents which may be truly unique, in most cases there are a number of competing products and processes. Also, as research has shown, even older, inferior products often continue to compete effectively with the newly patented products. For instance, in pharmaceuticals, the drug Recombinate (to treat hemophilia) was released in 1995; one year later, the drug Kogenate was introduced to treat the same symptoms. Similarly, the protease inhibitor for HIV/AIDS Invirase, introduced in 1995, was followed 3 months later by the protease inhibitor Norvir.⁵⁷ As shown below, brand name and consumer loyalty offset the effects of patent innovation. In these cases, then, the ability of the inventor to price his good for above marginal costs for a long period is much circumscribed.

Second, because patents must disclose significant information about the underlying technology and because information by its nature is difficult to monitor, there will be substantial spillover; and even with legal protection, imitation is likely to come quickly in many cases. One study found that about 60 percent of successfully patented inventions in the pharmaceutical, chemistry, electronics and machine industry were imitated within four years at an

55. See Erick Kaufer, *THE ECONOMICS OF THE PATENT SYSTEM* 18ff. (1989); Alden F. Abbott, *Developing a Framework for Intellectual Property Protection to Advance Innovation*, in *INTELLECTUAL PROPERTY RIGHTS IN SCIENCE, TECHNOLOGY AND ECONOMIC PERFORMANCE* 318-22 (Francis W. Cushing and Carole Ganz Brown eds., 1990).

56. F.M. Scherer, *The Value of Patents and Other Legally Protected Commercial Rights: Panel Discussion*, 53 *ANTITRUST L.J.* 535, 547 (1985).

57. See Pharmaceutical Research and Manufacturing Association (PhRMA), *PHARMACEUTICAL INDUSTRY PROFILE: 1999* 59 (1999).

average cost of less than two-thirds the original cost.⁵⁸ Another study of 100 U.S. firms found that information concerning development decisions was generally in the hands of competitors within 12 to 18 months of issuance; and information concerning the detailed nature and operation of the new product leaked within a year. For this article, it is of note that for pharmaceuticals, in 57 percent of the sampled cases detailed information about new drug products was generally in the hands of competitors within six months of issuance.⁵⁹

Finally, as Kenneth Dam has pointed out, features of a nation's regulatory and legal systems operate to limit the force of the monopoly. These include limitation on the duration of the patent, including, in the case of pharmaceuticals, substantial periods devoted to testing in the regulatory process; limitations on the breadth or scope of a patent; and finally, vigorous use of the judicial system to ferret out patent "misuse," or going beyond the bounds of the patent grant.⁶⁰

All of this has led some economists to argue that patents are no different than other forms of private property rights. As Meiners and Staaf state:

It is curious that almost everyone refers to a patent as a monopoly. Many textbooks refer to patents as the classic monopoly. Why are patents not considered like any other exclusive private property right? All private property rights exclude and thus have a monopoly element. Contracts create rights that are exclusive and thus have monopoly elements. Individuals have exclusive rights in their labor and real property. Exclusive rights create the same incentives that patent rights create by encouraging investments in goods and services.⁶¹

3. Too Much of a Good Thing?

58. See Edwin Mansfield et al., *Imitation Costs and Patents: An Empirical Study*, 91 *ECON. J.* 907, 909, 913 (1981).

59. See Edwin Mansfield, *How Rapidly Does Technology Leak Out?* 34 *J. INDUS. ECON.* 217, tbl. III (1985).

60. See Dam, *supra* note 54, at 247.

61. Roger E. Meiners and Robert J. Staaf, *Patents, Copyrights, and Trademarks: Property or Monopoly?* 13 *HARV. J.L. & PUB. POL'Y* 911, 915 (1990).

As we shall describe below, recent research has demonstrated a “burst of innovation” in the United States, evidenced by the huge increase in applications for patents in the last decade. While this burst of activity was experienced across a number of industrial sectors, biotechnology and pharmaceutical firms together represented a large element within the surge. A recent paper by Samuel Kortum and Josh Lerner calculated that in the decade between the early 1980s and the early 1990s, annual patent applications where the first-named inventor is a U.S. resident for biotechnology firms more than doubled, from about 1500 in the 1980s to over 3000 in the early 1990s.⁶² This leads to the question of whether these patent races are producing “too much of a good thing.”

The possibility of too much competition to produce patents has led some economists to suggest and model situations where the patent system will potentially reduce economic welfare through wasteful overinvestment in R&D to win a patent race. In a path-breaking article in 1968, Yoram Barzel demonstrated that competition in the prepatent stage, in certain cases, would lead not only to overinvestment but also to a situation where the innovation would be introduced sooner than would be socially optimal (without going into technical details, the model focused on the fact that for every innovation there is an optimal introduction time in terms of the maximization of present value).⁶³ Barzel’s article was followed by a cottage industry of economic analyses, which combined industrial organization principles with R&D patterns and game theory and applied these new tools to the patent system.

As examples, Dasgupta and Stiglitz showed that under certain plausible conditions, where demand for an innovation was inelastic and there is free entry into an industry, the result “may be excessive duplication of research effort . . . [and] industry-wide R&D expenditures [will] exceed[] the socially optimal level.”⁶⁴ In sev-

62. See Samuel Kortum and Josh Lerner, *Stronger Protection or Technological Revolution: What is Behind the Recent Surge in Patenting?* NBER WORKING PAPER, NO. 6204, (September 1997), p. 22 and Figure 10.

63. See Yoram Barzel, *Optimal Timing of Innovations*, 50 REV. ECON.& STAT. 348 (1968)

64. Partha Dasgupta and Joseph Stiglitz, *Industrial Structure and The Nature Innovative Activity*, 90 ECON. J. 266, 289 (1980); see also M. KAMIEN AND N. SCHWARTZ, MARKET STRUCTURE AND INNOVATION, 105-12 (1982).

eral other articles, Pankaj Tandon also modeled situations where excessive R&D competition produced socially inefficient outcomes.⁶⁵

In parallel with these negative assessments, and growing in force in recent years, is a stream of literature that takes a different view of the consequences of R&D patent rivalry. These scholars focus on the broader connections between the evolution of basic scientific knowledge and the pace and direction of invention and innovation, which is partially governed by the pursuit of private gains through intellectual property.

In a 1984 contribution, Burstein asserted that for knowledge-based products, which must be “sold bundled with education and other complementary assets,” the amount and intensity of knowledge diffusion will be directly related to intellectual property concerns. He argued, “that there is more reason to be concerned about too paltry grants of property rights in knowledge-based products than with the magnitude of quasi-rents to innovation.”⁶⁶

More recently, Richard Nelson and Robert Merges, writing together and separately, also point out that the other side of patent races are potentially large additions to the common pool of public knowledge. They note that technological developments tend to proceed much more vigorously under a regime where there are many rivalrous sources of invention, though competitive investments may result in inefficiencies.⁶⁷ It is this insight which drives their “first to invent” patent theory in which the motto, as they say, remains “faster is better.” Work by another Nelson co-author, Sidney Winter, reinforces this view by showing that “unimpeded imitation need not yield inferior results.”⁶⁸

65. See Pankaj Tandon, *Rivalry and Excessive Allocation of Resources to Research*, 14 BELL J. ECON. 152,165 (1983); see also Richard J. Gilbert and David M.G. Newbery, *Preemptive Patenting and the Persistence of Monopoly*, 72 AM. ECON. REV. 514 (1982). See also, Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 803 (1998).

66. M.L. Burstein, *Innovation and Property Rights*, 22 ECON. INQUIRY 608 (1984).

67. See e.g., Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990).

68. See Sidney Winter, *Patents in Complex Contexts: Incentives and Effectiveness*, in OWNING SCIENTIFIC AND TECHNICAL INFORMATION: VALUE AND ETHICAL

Finally, Scherer, an agnostic about the welfare implications of many aspects of the patent system, states the following concerning R&D and patent races:

When the success of any single project is uncertain, running duplicated projects hastens success unless the rivals conduct exactly identical experiments, which is unlikely. The greater the social gains from a successful innovation, the larger is the optimal number of parallel but uncertain approaches.

. . . [A]ny single firm (that is, monopolist) . . . is likely to have perceptual blind spots By propagating a greater diversity of approaches, competition often evokes a winning solution at lower cost despite seemingly inefficient duplication.⁶⁹

B. PHARMACEUTICALS: A SCIENCE-BASED INDUSTRY

1. The Burgeoning Patent System

The increasing importance of the patent system to U.S. knowledge-based industries is dramatically illustrated by the huge increase in applications for patents by U.S. inventors over the past decade. Applications for patents have risen more since 1985 than in any other decade this century. From 1900 to the mid-1980s, applications fluctuated between 40 and 80 thousand per year. Between 1985 and 1995, a steep rise occurred in annual applications; in 1995 over 120,000 applications were received by the U.S. Patent and Trademark Office (PTO).⁷⁰

Recent research has uncovered a number of striking facts and causes behind the surge. First, it represents a “real burst of innovation” in the United States and “changes in the management

ISSUES 41, 43 (Vivian Weil and John W. Snapper eds., 1989).

69. F.M. SCHERER AND DAVID ROSS, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* 644 (1990).

70. See Kortum and Lerner, *supra* note 62, fig. 1.

of innovation” which result from a significant move toward capturing the rewards of innovation through the patent system. Second, though the burst of activity was experienced broadly across a number of sectors, biotechnology and pharmaceuticals taken together represented a large element within the surge. Third, the globalization of technology and the desire of firms to achieve competitive advantage in foreign markets was illustrated by simultaneous surge in U.S. patenting abroad, which tracked the large increase in U.S. domestic patenting activity.⁷¹

By all standard measures, the pharmaceutical industry is the most science-based of all U.S. industries. In 1999, U.S. and foreign owned pharmaceutical companies are projected to invest over \$20 billion in the United States; and in addition, U.S. firms will spend about \$4 billion abroad. Research-based pharmaceutical companies have more than doubled their R&D expenditures since 1990, and in 1999 more than 20 percent of total sales will be devoted to R&D. This places pharmaceuticals at the very top of the technology scale, ahead—in terms of R&D investment—of other high-tech industries such as electronics, aerospace and office equipment (including computers).⁷²

Though the amount of R&D invested is an important determinant of technological advance and competitiveness, the productivity of that investment also must be factored in. For the U.S. pharmaceutical industry, the combined results of huge R&D investments and efficient research management has clearly paid off: a recent study of the country of origin of 265 drugs that spread to major markets worldwide between 1970 and 1992 showed U.S. domination, with 118 U.S.-based origins—more than the combined total of the next four competing nations (Japan, the U.K., Germany and Switzerland).⁷³ Further, in the early 1990s, U.S. pharmaceutical companies held patents for 92 of the 100 most commonly prescribed drugs in the United States.⁷⁴

2. Drug Innovation: Time, Cost Risk

71. *See id.* at 32-33.

72. *See* PhRMA, *supra* note 57, ch. 2.

73. *See* Heinz Redwood, *New Drugs in the World Market: Incentives and Impediments to Innovation*, AM. ENTERPRISE, Aug. 1993, at 72.

74. *See* SCHWEITZER, *supra* note 29, at 21.

Drug innovation is an expensive, high-risk and lengthy process. From applied research to commercialization, the development of new drugs takes on average eight to nine years; and adding in time spent on earlier fundamental research, the time may extend over fifteen or twenty years.

Over the past two decades, there have been numerous studies of the costs of drug development. These studies have all underscored two basic facts: that drug development costs are large and have grown in real terms over the period. Studying an earlier period, Gambardella estimates that in real terms (using 1986 dollars) individual drug development costs rose from \$97 to \$200 million between 1986 and 1990.⁷⁵ A more recent study by the Boston Consulting Group placed the costs of developing a drug in 1990 at \$500 million (1993 dollars) before taxes, including the direct costs of research, the costs of research failures and the interest costs over the entire period to commercialization.⁷⁶

Finally, drug development is a high-risk process. For instance, recent studies have shown that about only one in 65,000 compounds synthesized by pharmaceutical laboratories are successful, if success is measured in terms of global sales exceeding \$100 million annually;⁷⁷ a second study indicated that only 1 out of 5000 compounds synthesized during clinical trials eventually reached the market.⁷⁸ Further, other research has concluded that only three out of ten drugs that are brought to market cover development costs after taxes.⁷⁹ The same study showed that 20 percent of the products with the highest revenues generated 70 percent of the

75. See ALFONSO GAMBARDELLA, *SCIENCE AND INNOVATION: THE PHARMACEUTICAL INDUSTRY IN THE 1980S* 169, n. 2, (1995).

76. See BOSTON CONSULTING GROUP, *THE CONTRIBUTION OF PHARMACEUTICAL COMPANIES: WHAT'S AT STAKE FOR AMERICA* (1993); for other cost estimates, see also CONGRESS OF THE UNITED STATES, OFFICE OF TECHNOLOGY ASSESSMENT, *PHARMACEUTICAL R&D: COSTS, RISKS AND REWARDS*, 1-37 (1994), and J.A. DiMasi, et al., *The Cost of Innovation in the Pharmaceutical Industry*, 10 J. HEALTH ECON. 107 (1991).

77. See HEINZ REDWOOD, *THE PRICE OF HEALTH* 25 (1989).

78. See R.S. Halliday, et al., *R&D Philosophy and Management in the World's Leading Pharmaceutical Companies*, 1992 J. PHARMACEUTICAL MED. 139-154.

79. See H.G. Grabowski and J.M. Vernon, *A New Look at the Return and Risks to Pharmaceutical R&D*, *MANAGEMENT SCIENCE*, Vol. 37, No. 7, (1990), pp. 804-821.

profits during the period under scrutiny (1980-1984). Similar results were found by Scherer, who in another study estimated that 55 percent of industry profits came from about ten percent of the drugs.⁸⁰

3. Drug Discovery and the Revolution in Molecular Biology

In order to understand the special importance of intellectual property rights for the pharmaceutical industry—particularly for small biotechnology firms—it is necessary to review the revolutionary changes which have taken place in the pharmaceutical innovation process over the past two decades. Oversimplifying somewhat, it can be said that behind this revolution were major changes and advances in the biological sciences, highlighted by the dramatic breakthrough in genetics and genetic engineering, but also including increased knowledge in the fields of molecular and cell biology, peptide chemistry, and physiology, among others; the rise of ‘discovery by design,’ based upon computer-aided design experiments which hugely increased the potential for screening thousands of drugs; and advances in other experimental technologies and instruments, such as X-ray crystallography and nuclear magnetic resonance which greatly enhanced the analysis of protein structures and both complemented and underpinned computer design experiments.⁸¹

The revolution in genetic and molecular biology actually began forty years ago, with Watson and Crick’s discovery of the double helix structure of DNA.⁸² But the key technological advance came in the early 1980s with the Cohen-Boyer patent for a method of manipulating cell genetics so that the cell could produce a specific protein. Previously, proteins, which consist of long chains of amino acids, were too large and complex to be synthesized in commercial quantities through traditional fermentation methods. The Cohen-Boyer invention allowed the production of large quantities of individual proteins and because there are approximately

80. See F.M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, J. ECON. PERSP., Summer 1993, at 97.

81. See GAMBARDILLA, *supra* note 75, at 21.

82. See RICHARD V. KOWLES, GENETICS, SOCIETY, & DECISIONS 22 (1985).

500,000 different human proteins, each with a specific function, this vastly increased the potential for new drug discovery. The Human Genome Project, a global initiative to map and sequence the whole human genome, is slated to be completed by 2003.⁸³ At the present time, about 500 genes have been targeted for drug intervention to alter gene activity to achieve desired health outcomes (eradicate infection, for instance). When the project is complete, it is estimated that an additional 3,000 to 10,000 genes will be targeted.⁸⁴

The scientific advances identified with the molecular revolution (in genetics and molecular biology) have produced “two relatively distinct technical trajectories” and two distinct industry subsectors.⁸⁵ The first, which is identified in the public mind as biotechnology, uses genetic engineering to manufacture proteins—that is, large molecules—in quantities large enough to treat biological disfunctions. The second trajectory (the equivalent of what Gambardella labels “discovery by design”⁸⁶) uses recent advances in genetics and molecular biology to more efficiently “manufacture” conventional small molecule synthetic drugs.

Discovery by design techniques have made it possible for incumbent firms to utilize economies of scale and continue to dominate many areas of pharmaceutical research and product development. Successful incumbent drug companies increasingly organize their discovery process around teams of talented scientists with a broad array of knowledge in such disciplines as molecular biology, genetics, and peptide chemistry. These scientists not only take the lead in creating new science for product development within the firm, but also—of equal importance—keep the firm abreast of the latest developments in public science, i.e., increase the firm’s “ab-

83. The US. Department of Energy and The National Institutes of Health, *U.S. Human Genome Project 5-Year Research Goals: 1998 – 2003* (last modified Nov. 15, 1999) <http://www.ornl.gov/TechResources/Human_Genome/hg5yp>.

84. See PhRMA, *supra* note 57, at 8-9.

85. See Rebecca Henderson et al., *The Pharmaceutical Industry and the Revolution in Molecular Biology: Exploring the Interactions Between Scientific, Institutional and Organizational Change*, DRAFT FOR CCC MATRIX CONFERENCE, (Brewster, MA, September, 1996), p. 13.

86. See GAMBARDELLA, *supra* note 75, at 21.

sorptive capacity.”⁸⁷ As Rosenberg has stated, in-house research is the price firms pay to “plug into the outside information network.”⁸⁸

4. Biotechnology

In biotechnology and the production of large-scale molecules through exploitation of the techniques of genetic engineering as a production tool, small, new entrant firms have taken the lead. During the 1980s, entry rates in this area rose steeply and continued the rate of increase into the 1990s. By the end of 1992, there were almost 50 small, publicly trade biotechnology companies; and it is estimated that several times that number exist as privately held entities.⁸⁹ Most came into being as university spin-offs, backed by venture capitalists.

What has emerged is a division of labor between this growing number of small firms and larger incumbents. As Kenneth Arrow suggested in 1983, because of greater flexibility and less information loss across the organization, small firms potentially can make closer to optimal investments in riskier projects.⁹⁰ This seems to be occurring in the discovery and production of biotechnology-based proteins. (As described above, however, this does not mean that in certain areas incumbent firms are not maintaining, indeed increasing, their investments in research.)

In the field of biotechnology, incumbents play a key collaborative role through R&D contracts, joint ventures, and even venture capital investment. Large firms have large organizational capacities, which allows them to undertake systemic product development, including clinical testing and commercialization. They face lower capital costs and can spread uncertainty across a large number of activities.

87. Wesley M. Cohen and Daniel A. Levinthal, *Absorptive Capacity: A New Perspective on Learning and Innovation*, ADMIN. SCI. Q., Mar. 1990, at 128.

88. N. Rosenberg, *Why Do Firms Do Basic Research?* 19 RESEARCH POLICY 165-174.

89. See Henderson et al., *supra* note 85, at 24.

90. See Kenneth Arrow, *Innovation in Large and Small Firms*, in, ENTREPRENEURSHIP (J. Ronen ed., 1983).

Small firms invest in new drug development, with the knowledge that there is a market for their product and that large firms will take over the responsibility of shepherding the drug through clinical trials, regulatory approval and marketing. Arrow correctly predicted the process thusly:

The existence of markets for research outcomes . . . alters the incentives for research within large firms For now the [large] firm has an alternative supply of research outcomes on which to base its development of innovations If this analysis is meaningful, it suggests a division of labor according to firm size. Smaller firms will tend to specialize more in the research phase and in smaller development processes; larger firms will devote a much smaller proportion of their R&D budget to the research phase.⁹¹

For this article, there is another central condition that is crucial to the successful, economically efficient division of labor described by Arrow: that is the existence of strong intellectual property rights, particularly for the small research firms. Gambardella describes the relevance of IP rights to the division of labor:

the knowledge-base for drug discovery has become more 'divisible.' With suitable contracts and intellectual property rights, relevant 'fragments' of knowledge can be exchanged by specialized agents . . . [Small firms], which have a natural advantage in producing ideas, realize that, with 'divisibility' of science, they can invest in discovery, and sell their research outputs to larger firms. Patents and intellectual property rights will be very important to sustain the incentives of smaller firms to invest in upstream research.⁹²

C. How Important Is the Patent System for Innovation in the Research-Based Pharmaceutical Industry?

91. *Id.*

92. GAMBARDELLA, *supra* note 75, at 79.

1. Patents—A Vital Link to Pharmaceutical Research and Development

Ideally, the patent system would be tailored to individual products or, at least, sectors because the appropriate balance of incentives (through length and scope of patent, for instance) is based upon numerous individual market characteristics such as demand, costs of R&D, spillover effects and market structure, among others.⁹³ Because the information necessary to fine tune the patent system to fit the demand and technology benefits produced by each invention—or even large classes of inventions—is often unobtainable, national, and now international, patent systems have settled on a consensus of twenty years, though national systems still differ widely in interpreting patent scope, misuse and antitrust boundaries.

Research over the past several decades has also established that industrial sectors vary widely in their dependence on, and use of, the patent system as a means of preventing imitation or for royalty income. In one of the most widely cited studies, Levin et al. queried 650 U.S. R&D executives to evaluate the effectiveness of patents versus other methods of appropriating private returns such as secrecy, moving quickly down the learning curve, first mover advantage and superior sales and service. Averaging across 130 industries, for both products and processes, nonpatent strategies such as secrecy and first-mover advantage were found to be substantially more important than patent protection. In only 25 of the 130 industries, did patents as a means of preventing imitation exceed 5 on a 7-point scale (moderate to very effective range). Significantly, however, pharmaceuticals are placed right at the top of the scale for patent dependence.⁹⁴

In 1985, another survey asked chief R&D executives of 100 U.S. firms what proportion of the inventions they developed be-

93. See PAUL STONEMAN, *THE ECONOMIC ANALYSIS OF TECHNOLOGY POLICY* 106 (1987).

94. See Richard Levin et al., *Appropriating the Returns from Industrial Research and Development*, BROOKINGS PAPERS ON ECONOMIC ACTIVITY, No. 3, 783 (1987). An earlier study by two British economists had produced similar results. See C.T. TAYLOR AND Z.A. SILBERSTON, *THE ECONOMIC IMPACT OF THE PATENT SYSTEM*, (1973).

tween 1981 and 1983 would not have been developed without patent protection. Pharmaceuticals, once again, displayed strong dependence on patent protection, with the pharmaceutical executives claiming that 60 percent of their drugs would not have been developed without patents, versus only 17 percent for the machinery industry, 12 percent for fabricated products, and 11 percent for electrical equipment. Further, the industry stated that 65 percent of the drugs would not have been commercially introduced without protection. The study also found that 82 percent of patentable drugs were indeed patented, as were over 50 percent in most other industries. Finally, the study demonstrated that, contrary to some reports, firms in most industries had about as much propensity to patent as they had in the mid-1960s—with the propensity in the 1980s rising somewhat for pharmaceuticals over the previous period.⁹⁵

Two reasons have been advanced for the significant importance attached to patents by the pharmaceutical industry. First, pharmaceutical companies can obtain unusually ‘strong’ patents because pharmaceutical innovations take well-defined forms, i.e., new compounds, which can be described easily and in detail. Conversely, a second reason stems from the negative implications of the first: that is, that well-defined compounds are easily copied, and pharmaceutical firms must quickly move to defend their new discoveries with intellectual property protection.⁹⁶

2. Intellectual Property and Economic Development

Over the past few years, and particularly after the TRIPS became a reality, interest in the connection between intellectual property, FDI and trade burgeoned—especially the implications for developing economies. Earlier literature on the impact of intellectual property on developing countries had been strongly negative.⁹⁷ More recently, a much more complex picture has emerged, and at this point a number of studies have posited large potential benefits from effective intellectual property rules for the world trading sys-

95. See Edwin Mansfield, *Patents and Innovation: An Empirical Study*, MANAGEMENT SCIENCE, February 1986, at 175.

96. See GAMBARDILLA, *supra* note 75, at 44.

97. See E. Penrose, THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM 220 (1973).

tem as a whole, as well as for developing economies. Developing country regimes have themselves reacted to the changing perception of the role of intellectual property: since 1987, over 40 developing countries unilaterally have strengthened intellectual property laws (although in some cases, it should be admitted external pressure from the U.S. and the EU played a role).⁹⁸

In light of this more complex, evolving picture of the relationship between effective IPR protection and economic development, Abbott's arguments against parallel imports restrictions—and by implication strong IPRs—seems a throwback to the “dependency” theories of earlier decades. In conceding that by and large parallel imports have been blocked in most countries during the postwar decades, Abbott goes on to argue that during that period “developing countries have not made the kind of economic progress that would be desirable,” a circumstance which he attributes to restrictions on parallel imports. He later concludes specifically: “Restrictions on parallel imports are likely to constrain the export opportunities of producers established in developing countries, and to limit capital formation and economic growth in those countries.”⁹⁹

Abbott's conjectures fly in the face of overwhelming evidence that many developing countries, particularly in East Asia and more recently in South America, posted huge economic growth rates throughout the past four decades. Their level of economic development and per capita GDP have steadily converged with developed economies in the West.

In general, available data tend to support the view that, over time, both world economic welfare and the welfare of developing countries, will benefit by a more effective worldwide IPR system, including restrictions on parallel imports. Two caveats must be added, however: (1) direct evidence is difficult to come by because of the indirect and subtle ways IPRs operate and because of scattered data on IPR transactions; and (2) it is clear that an effective

98. See Keith E. Maskus, *Strengthening Intellectual Property Rights in Asia: Implications for Australia*, 46th Joseph Fisher Lecture, University of Adelaide, (November 19, 1997) [Hereinafter Maskus, George Fisher Lecture].

99. Abbott, Discussion Paper, *supra* note 19, at 8, 17.

IPR regime is only one prerequisite for strong economic growth in developing economies. Usually, the decision to put in place a strong IPR system is accompanied by other important policy and structural changes, including sound macroeconomic policies, investment in education and skilled labor, and trade and investment liberalization—all attributes of economies which are building solid technological assets and capabilities.

That stated, this section attempts to distill some of the major conclusions from recent studies of the connection between strong national intellectual systems and FDI, trade and technological development. Regarding FDI, several fundamental facts should be established first. Multinational firms have a choice, obviously, whether to export to a host country or to invest (possibly also through licensing) in the country. The decision will be based on a number of factors, including: capacity of the host country to absorb the technology; input prices across nations; transport costs; political and economic stability and import protection laws; and level and skill of both labor and management.

Recent research has also revealed a common development pattern for inward direct investment. The least developed countries, with little supportive infrastructure and with low levels of education, skills and productivity attract little or no FDI. As some countries have moved up the technological and economic scale—by improving education, skills, infrastructure and government efficiency—they have gradually become attractive locations for FDI, particularly for intrafirm vertical operations such as labor-intensive assembly. Over time, some countries achieve income and technological levels that allow them also to become attractive locations for producing differentiated consumer and capital goods; and horizontal investment (and trade) replaces vertical investment (and trade) as the dominant connection with MNEs.

Because of this progression and because of special characteristics of the pharmaceutical industry, that sector is especially characterized by larger numbers of affiliates operating licensing arrangements. Indeed, pharmaceuticals tops the list of foreign affiliates per U.S. parent, with 33.8 affiliates per firm.¹⁰⁰ Pharmaceuticals

100. See Keith E. Maskus, *The Role of Intellectual Property Rights in Encour-*

(as part of the overall chemicals group) also have a strong presence in emerging markets—particularly in Latin America and China.¹⁰¹

3. Current Views on the Impact of Effective Patent Protection on Developing Economies

There is a growing consensus that countries with stronger IPRs attract a good deal more FDI than countries without such systems. Edwin Mansfield surveyed 100 firms in six major industries, regarding the importance of IPRs (in this case patents) in their investment location and licensing decisions, broken down by type of investment facility (sales, assembly and basic production, components, complete manufacturing and R&D facilities). The result was that the higher the type of activity (sales vs. research) the greater the concern for patent protection. All sectors showed considerable negative reaction to the lack of strong IPR when locating R&D facilities, and most also would be much less inclined to locate full production facilities in such economies. Of particular note for this article, the chemicals industry (including pharmaceuticals) demonstrated strong concerns for all production stages, including 87 and 100 percent of the firms, respectively, for full production and R&D facilities.¹⁰² In a follow-up paper, Mansfield found the same overall numbers in Japanese and German firms considering FDI.¹⁰³

Mansfield and Lee extended this survey research in 1996 with a study comparing the volume of U.S. direct investment in a selected group of countries against perceived weaknesses in IPR protection (they corrected for market size, degree of industrialization, measure of openness, among other things). They found that weakness of IPR had a significant negative impact on the location of U.S. FDI—and once again, this result was strongest in the chemi-

aging Foreign Direct Investment and Technology Transfer, 9 DUKE J. COMP. & INT'L L. 109, 118 (1998).

101. *See id.* at 117-18.

102. *See* Edwin Mansfield, *Intellectual Property Protection, Direct Investment and Technology Transfer*, INTERNATIONAL FINANCE CORPORATION, (WORLD BANK) DISCUSSION PAPER 19 (1995).

103. *See id.* at 27.

cal (pharmaceutical) industry.¹⁰⁴ Maskus et al., extended this research with a more comprehensive study that factored in multiple investment modes and opportunities exploited by MNEs and analyzed the results in terms of patent strength. They found that patent strength is strongly and positively connected with FDI, as measured by asset stock.¹⁰⁵ This coincides with findings in an earlier paper, where Maskus and Penubarti had also shown empirically that (1) stronger patent protection produced greater bilateral trade flows (data from 77 countries and 24 industrial sectors); and (2) exporting firm discriminate on the basis of local patent protection in their sales decisions, with stronger protection resulting in larger export flows.¹⁰⁶

Utilizing a different econometric model, Braga and Fink confirmed the basic conclusions of Maskus et al. that patent protection did increase trade flows between developed and developing countries and that this was particular evident for larger developing countries.¹⁰⁷ In 1997, Smith also confirmed empirically that weak patent rights pose a trade barrier to U.S. exports in developing countries because of the threat of imitation by U.S. firms.¹⁰⁸ Finally, as noted above, Gould and Gruben performed regressions using as variables, patent protection and openness to trade and country-specific characteristics. Their results showed that patent protection was an important determinant of economic growth, es-

104. See Jeong-Yeon Lee and Edwin Mansfield, *Intellectual Property Protection and U.S. Foreign Direct Investment*, 78 REV. ECON. & STAT. 181-86 (1996).

105. See Keith E. Maskus et al., *Patents, Trade, and Foreign Direct Investment*, (1997) (unpublished manuscript, on file with University of Colorado).

106. See Keith E. Maskus and Mohan Penubarti, *How Trade-Related are Intellectual Property Rights?* 39 J. INT'L ECON. 227, 248 (1995). Maskus and Penubarti point out that strengthening IPRs can potentially have two quite different effects on trade flows because trade is simultaneously increased through market expansion effects and decreased through market power effects. For most cases, they conclude that the market expansions effects prevail.

107. See Carlos A. Primo Braga and Carsten Fink, *The Economic Justifications for the Grant of Intellectual Property Rights: Patterns of Convergence and Conflict*, in PUBLIC POLICY AND GLOBAL TECHNOLOGICAL INTEGRATION, 99 (Frederick M. Abbott and David J. Gerber eds., 1997).

108. See E.J. Smith, *Are Weak Patent Rights a Barrier to U.S. Exports?*, Department of Economics, University of Delaware, (mimeo 1997). Smith's conclusions did not hold for very poor developing countries which posed little threat of imitation.

pecially when combined with relatively liberal trade regimes.¹⁰⁹

Technology transfer through joint ventures and licensing also works to improve the economic performance of developing countries. License and FDI provide access both to technology and to the managerial assets of MNEs. This is accomplished through a variety of means, including information in patents, activity aimed at “inventing around” existing patents and adoption of more advanced production inputs to reduce and refine overall production costs. Patents, even though they do result in rents to developed country producers, through enforced disclosure also pave the way for significant technology transfer.¹¹⁰ As one study noted: “Since patents are clearly defined, they allow the technical and territorial scope of any technology transfer transaction to be precisely defined.”¹¹¹ Finally, an OECD survey of over 100 manufacturing executives demonstrated the negative consequences of weak IPR on technology transfer. These executives listed lack of IPR protection as the most significant deterrent to licensing in developing countries.¹¹²

The two most recent surveys of recent economic literature both conclude that, on balance, the new TRIPS Agreement and stronger IPR regimes in developing countries will, under many circumstances, have positive welfare benefits for world trade and for the individual countries. Braga et al. state: “there is mounting evidence that IPRs are indeed ‘trade-related.’ These results . . . suggest that the implementation of TRIPS will have a net trade creating impact. Although no precise welfare predictions can be derived from them, they suggest that TRIPS may have a positive

109. See David M. Gould and William C. Gruben, *The Role of Intellectual Property Rights in Economic Growth*, 48 J. DEV. ECON. 323 (1996).

110. See Jonathan Eaton and Samuel Kortum, *Trade in Ideas: Patenting and Productivity in the OECD*, 40 J. INT’L ECON. 251 (1996).

111. H. Ullrich, *The Importance of Industrial Property Law and Other Legal Measures in the Promotion of Technological Innovation*, INDUS. PROP., , 111 (1989).

112. See Claudio R. Frischtak, *The Protection of Intellectual Property Rights and Industrial Technology Development in Brazil*, in, INTELLECTUAL PROPERTY RIGHTS IN SCIENCE, TECHNOLOGY, AND ECONOMIC PERFORMANCE: INTERNATIONAL COMPARISONS 61, 80-81 (Francis W. Rushing and Carole Ganz Brown eds., 1990).

allocation impact at the global level.”¹¹³

Maskus reaches the same conclusion regarding IPR and FDI but places IPR within the context of other important policy initiatives that also influence FDI, namely technology transfer and enhanced economic growth. He writes:

While there is evidence that strengthening IPRs can be an effective means of inducing additional inward FDI, it is only one component among a broad set of important factors. Emerging economies must recognize the strong complementary relationships among IPRs, market liberalization and deregulation, technology development policies, and competition regimes.¹¹⁴

And, as Maskus continues, regarding the special place of IPRs in fostering innovation and technology diffusion in pharmaceuticals:

Surveys indicate that patents are important inducements to inventive activity in some sectors, including pharmaceuticals, chemicals, instruments. . . . Patents or related devices also matter in plant varieties and basic biotechnological inventions. In these sectors, the TRIPS Agreement should promote technology development and have the further benefit of inducing additional research into the product and technical needs of developing countries, including tropical medicine.¹¹⁵

While the above studies do not analyze the impact of allowing parallel imports directly, there are strong, negative connections, identified thusly in one recent paper:

With parallel imports, developing countries are likely to lose in two important ways: (1) where developing countries might initially have relatively low prices, parallel trade would result in diversion of supply away from the local market, pushing prices higher . . . and (2) to the extent that international exhaustion threatens parallel

113. Primo Braga et al., *supra* note 13, at 113.

114. Maskus, *Role of Intellectual Property Rights*, *supra* note 100, at 152.

115. Maskus, *The International Regulation of Intellectual Property*, *supra* note 3, at 200.

exports from low priced developing countries, patent holders will be less likely to transfer technology and production capacity to them through direct investment and licensing.¹¹⁶

V. THE PHARMACEUTICAL DISTRIBUTION & MARKETING SYSTEM: A KEY TO INNOVATION AND PROTECTING HEALTH AND SAFETY

A. *The Role of Territorial Vertical Restraints*

1. Overview of the Debate

The previous section discussed the role that a strong patent system plays in promoting innovation in the research-based pharmaceutical industry. This section analyzes the crucial role that the distribution system plays in supporting a strong patent system. Strong patent protection is of little benefit if pharmaceutical companies are unable to distribute their product effectively and safely to market. To the extent that parallel trade undermines this distribution system, it has the potential to inflict damage on the pharmaceutical industry and consumers. To be sure, it is important to note at the outset that the distribution chain in the pharmaceutical industry is complex and varies significantly by country. This is due in large part to the myriad of government regulations to which the industry is subject.¹¹⁷

A common feature of the pharmaceutical distribution system is that the manufacturers and producers will sign contracts with authorized distributors within a defined geographic region. These limits on geographic distribution (and marketing) are referred to as territorial arrangements, restrictions or restraints. Such territorial limitations are but one form of 'vertical' arrangement (also re-

116. Bale, *supra* note 41, at 648.

117. There is little disagreement that this stems from the multifaceted health regulatory policies throughout the world to which the pharmaceutical industry is subject. For example, some countries, usually in the developing world, have a monopsonistic system, whereby one entity (usually state-owned and regulated) purchases and distributes the pharmaceutical product. Other countries rely on different licensing practices, whereby particular distributors are licensed to sell the pharmaceutical product. For an excellent review of these different end-stage distribution practices, see DANZON, PHARMACEUTICAL PRICE REGULATION, *supra* note 28, ch. 3.

ferred to as restraints and restrictions),¹¹⁸ which are contractual limitations imposed by a firm on one stage of production or the distribution process upon a firm at a different stage.¹¹⁹ While vertical allocation of primary distribution territories can take a variety of forms, they all have in common the goal of limiting the location in which a distributor can sell a product. As Mathewson and Winter explain:

Territorial restrictions take on a rich variety of forms in observed distribution contracts. Under the strongest form of this type of restraint—closed territory distribution—the retailer has monopoly rights to all customers within a specified area. In other variations sales to customers of competing retailers may be allowed. A retailer may be granted the exclusive right to locate within an area, but be free to send sales representatives to other areas. The contract may allow sales by the retailer in another’s territory only with a royalty paid to the competing outlet. Alternatively, sales outside the assigned territory may be allowed, but only at list price. Finally, the retailer may be prohibited from sending representatives outside a designated area, but be free to sell to visiting consumers.¹²⁰

This section focuses on the economic rationale for this system. As discussed below, though, there are a number of non-economic reasons related to health and safety for pharmaceutical manufacturers to enter into these types of contracts with only authorized distributors.

What concerns some is that these types of restraints enable firms to engage in a practice known as “price discrimination.” Price discrimination for economists is a value-neutral term meaning that a producer sells the identical product to consumers at different prices. While there are different kinds of price discrimination,¹²¹ the one that is of relevance here is the common practice

118. The other primary form of vertical restraint is to enter into a contract which somehow regulates the price that a distributor can charge.

119. See SCHERER AND ROSS, *supra* note 69, at 541.

120. Frank Mathewson and Ralph A. Winter, *On Vertical Restraints and the Law: A Reply*, 19 RAND J. ECON. 298 (1988).

121. There are three types of price discrimination generally discussed by

known as “third degree” price discrimination, whereby a seller charges a different price to customers who can be segmented into a relatively few identifiable markets. This market segmentation is based on the different demand function of consumers, or how much a consumer wants or will pay for a particular good or service. For example, senior citizens or children will sometimes receive discounts at restaurants; individuals might pay less for an airline ticket if they reserve a seat well in advance; or individuals will pay higher cab fares during peak times.

The particular form of third degree price discrimination at issue here concerns territorial-based market segmentation, whereby pharmaceutical companies charge different prices to consumers based on their geographic location. In other words, pharmaceutical companies divide the world into discrete geographic regions and charge different prices to consumers based on the region in which they buy the product.

The underlying motivations of why firms engage in price discrimination is subject to considerable debate. Different scholars attach benign or malignant motivations to territorial restrictions. Broadly speaking there are two camps. Those in the efficiency or Chicago School¹²² take the view that a firm would favor such restraints because it would “increase its net revenue by increasing distributive efficiency.”¹²³ Others take the opposite view, subscribing to the Post-Chicago school, which contends that, “Vertical

economists. “First degree” or “perfect” price discrimination is when each consumer pays the maximum he or she is willing to pay for the good. This assumes that the seller can identify each individual buyer and his or her demand function—an assumption that is rarely met (if ever) in the real world. ‘Second degree’ price discrimination occurs when sellers adopt price schedules that give buyers an incentive to separate themselves into different price categories, despite the fact that the buyers have identical demand curves. For example, sellers might provide progressive discounts based on the quantity bought (buy one get one free), charge a cover, or tie the sale to the purchase of another good. ‘Third degree’ price discrimination occurs when sellers divide customers into two or more discrete groups with different demand functions. Usually, they are divided into a relatively few identifiable markets such as age, or in this case, geographic location.

122. So-called due to the preponderance of scholars at the University of Chicago that promulgate the efficiency idea.

123. Robert Bork, *The Rule of Reason and the Per Se Concept: Price Fixing and Market Division*, 75 YALE L. J. 373, 403 (1966).

restraints are often anticompetitive” and that territorial restraints promote “the furtherance of cartels.”¹²⁴ We now analyze these divergent views in more detail. In so doing, we explore one of the classic debates in law and economics.

2. The Chicago ‘Efficiency’ School

By the late 1960s and early 1970s, economic efficiency concerns were becoming increasingly salient in the United States. With growing concern about U.S. competitiveness, there was an increasing fear that the courts and government were too hostile to corporations in the prior decade and hyper-paranoid about the possibility of monopolistic abuses. Even economists were not immune from this criticism as evidenced clearly by Nobel economist Ronald Coase, who argued that: “If an economist finds something—a business practice of one sort or another—that he does not understand, he looks for a monopoly explanation.”¹²⁵ He particularly lamented that the leading texts were overly preoccupied with “the study of pricing and output policies, especially in oligopolistic situations (often called a study of market structure).”¹²⁶

What coalesced from much of Coase’s writings, and formalized in legal scholarship by Robert Bork and Richard Posner, was the ‘efficiency’ or ‘Chicago School’ view toward vertical restraints. Instead of emphasizing the anticompetitive aspects of vertical restraints, the Chicago School adherents began looking for the procompetitive reasons that firms might enter into vertical arrangements, such as limiting the territory in which a distributor may sell a product. As Bork argues,

In the case of an individual manufacturer’s imposition of restraints upon competition among its resellers . . . the

124. Eleanor M. Fox and Lawrence A. Sullivan, *Antitrust—Retrospective and Prospective: Where Are We Coming From? Where Are We Going?*, 62 N.Y.U. L. REV. 936, 984-5 (1987). Within the monopoly school, some go further, singling out territorial vertical restraints are more anti-competitive to vertical price restraints, stating that: Vertical distribution restrictions are on many counts more obnoxious than vertical price restraints. See, Robert L. Steiner, *The Nature of Vertical Restraints*, 30 ANTITRUST BULL. 143, 146 (1985).

125. Ronald Coase, *Industrial Organization: A Proposal for Research*, in POLICY ISSUES AND RESEARCH OPPORTUNITIES IN INDUSTRIAL ORGANIZATION 67 (V.R. Fuchs ed., 1972).

126. See *id.* at 62.

manufacturer's motive can never be restriction of output. An alternative explanation for the manufacturer's behavior is necessary, and the only satisfactory alternative hypothesis is that the manufacturer believes the restraint will increase its net revenue by increasing distributive efficiency. . . . Otherwise, the manufacturer would not employ the restraint.¹²⁷

Coase and others such as Oliver Williamson, were also formalizing this new thinking in the language of economists. Specifically, Coase emphasized the transaction costs, or the costs of contracting (ex-ante and ex-post), as being influential in determining how firms organize, or the type of contractual relationships they enter.¹²⁸ In a world of imperfect and incomplete information, and in a world where court ordering is not efficacious (particularly with contracts between firms in two different countries), producers may find vertical restraints as a way to operate more efficiently.

With these considerations in mind, there has been a growing consensus among economists such as Williamson that "efficiency purposes are sometimes served by restraints on trade" and that "[a] more even-handed assessment in which both monopoly and efficiency purposes are admitted is needed."¹²⁹ For example, by not allowing unauthorized distributors to sell a product, it is easier for producers to monitor the quality in which distributors handle products and lower the costs of gathering information so as to make efficient investment decisions. Another reason for a producer to enter into a vertical relationship with only authorized distributors is to eliminate what economists refer to as the 'free-rider' problem. What incentive would authorized distributors have to provide pre-sales marketing and after-sales services, which are costly, if unauthorized distributors could import products from elsewhere and sell

127. Robert Bork, *The Rule of Reason and the Per Se Concept: Price Fixing and Market Division*, 75 YALE L.J. 373, 403 (1966).

128. Ronald Coase developed these thoughts in his classic paper: *On the Nature of the Firm*. For an interesting discussion on IPR liability rules and the application of the Coase Theorem, see: Robert P. Merges, *Of Property Rules, Coase, and Intellectual Property*, 94 COLUM. L. REV. 2655 (1994).

129. Oliver E. Williamson, *Assessing Contract*, 1 J. L. ECON. & ORG. 177, 203 (1985).

them at a lower price? As Posner argues:

[I]t is necessary to recall that the manufacturer's objective in restricting competition among its dealers or distributors is to induce them to provide greater services to the consumer. For example, a distributor with an exclusive territory will not stint in providing services that enhance demand for the product out of fear that another distributor will take a free ride on his efforts by selling into the territory that he has cultivated.¹³⁰

With this in mind, Rothnie observes that consumers could be worse off if unauthorized distributors free-rode on the marketing and services provided by authorized distributors. As he notes: "The parallel importer will rarely incur these (pre-sales marketing and after-sales service) costs and so can sell more cheaply than the authorized outlets If they stop providing these services, though, it is quite possible that consumers would be less well off."¹³¹

3. The Post-Chicago Approach

This Chicago school view gained increasing acceptance in the late 1970s and predominated throughout the 1980s and into the early 1990s. Indeed, by the 1990s, it was common to read with regard to the United States that: "Over the past fifteen years, the courts and enforcement agencies have created Robert Bork's anti-trust paradise. Antitrust has adopted the Chicago School's efficiency analysis and the Chicago School's conclusions about the effects of business practices."¹³²

By the 1990s, however, there was growing momentum for a qualification of the Chicago School position. The outgrowth of this backlash was the Post-Chicago school, whose adherents claimed that: "These new post-Chicago theories neither ignore nor reject the economic analysis of the Chicago School. Instead, they apply the newer methodology of modern industrial organization

130. Richard A. Posner, *The Next Step in the Antitrust Treatment of Restricted Distributions: Per Se Legality*, 48 U. CHI. L. REV 6, 11 (1981).

131. ROTHNIE, *supra* note 33, at 565.

132. Jonathan B. Baker, *Recent Developments in Economics That Challenge Chicago School Views*, 58 ANTITRUST L. J. 645, 655 (1989).

theory to more realistic market structures . . .” to “identify situations where vertical mergers and other vertical restraints can raise significant competitive concerns.”¹³³

With specific regard to vertical territorial restraints, for example, Rey and Stiglitz examine “the role of exclusive territories in reducing the effective degree of competition among firms” and how “exclusive territories may be used to deter entry.”¹³⁴ These scholars specifically link territorial restrictions to the foundation of the patent system, arguing that a “danger exists with territorial restrictions purportedly used to facilitate price discrimination”¹³⁵ because it “raises the problem of disproportionately high rewards to patentees, which . . . can make for bad patent policy independent of how such discrimination fares under antitrust analysis.”¹³⁶ These disproportionate profits, according to adherents of the school, would allow firms to raise the costs to smaller rivals and make entry by newcomers more difficult. Similarly, for the large firms that did survive, the “increase in the market power of a firm through a vertical agreement may provide it with sufficient power to initiate or enforce collusive horizontal behavior.”¹³⁷ In other words, the largest firms in competition with each other, would collude to fix artificially high prices.¹³⁸

133. Michael H. Riordan and Steven C. Salop, *Evaluating Vertical Mergers: A Post-Chicago Approach*, 63 ANTITRUST L. J. 513, 515 (1995).

134. Patrick Rey and Joseph Stiglitz, *The Role of Exclusive Territories in Producers' Competition*, 26 RAND J. ECON., 341, 445-46 (1995).

135. Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARVARD L. REV. 1815, 1879 (1984).

136. *Id.* at 1875.

137. Martin Gaynor & Deborah Haas-Wilson, *Vertical Relations in Health Care Markets*, in MANAGED CARE & CHANGING HEALTH CARE MARKETS 151 (Michael A. Morrissey ed., 1998).

138. Two adherents to this view, Krattenmaker and Salop, theorize that: Raising rivals' costs can be a particularly effective method of anticompetitive exclusion. . . . By embedding a collusive agreement in a vertical contract that raises input prices by restraining sales to rivals, the firm reduces coordination costs, making it more efficient at preventing cheating and distributing the gains from collusion. Thus, these strategies involve creating additional horizontal market power through the mechanism of vertical contracts.

Thomas G. Krattenmaker and Steven C. Salop, *Anticompetitive Exclusion: Raising Rivals' Costs To Achieve Power Over Price*, 96 YALE L.J. 209, 224 (1986).

Since 1992, the Post-Chicago school has been gaining ground.¹³⁹ The policy implications of such a view would be clear with regard to parallel trade. In the ideal Post-Chicago world, parallel trade would be allowed which would undermine the ability of firms to price discriminate. The reason is straightforward as Demaret explains: “When domestic laws no longer permit import restrictions, parallel imports become possible between territories; it becomes unfeasible to quote different prices in each territory for the patent protected good.”¹⁴⁰ Distributors or other middlepersons will engage in arbitrage, until a law of one price predominates.

4. Problems with the Post-Chicago Approach

While the authors acknowledge the high level of scholarship of many of these Post-Chicago studies, we remain skeptical of many of its conclusions. We find that there is very little difference between the Post-Chicago approach and antiquated and debunked theories of the old Monopoly school.¹⁴¹ Adherents to the school attempt to distinguish themselves from both the Monopoly and Chicago approach by noting that they employ new advanced economic tools and methods, particularly game theory. As two writers within the post-Chicago approach, Michael Riordan and Steve Salop, argue: “Along with other advances in economic theory, the game theoretic analysis of strategic behavior forms the core of

139. One of the first actions by assistant attorney general Anne Bingaman, for example, was to repeal the 1985 Vertical Restraints Guidelines developed during the Reagan administration. One Congressman, Jack Brooks, even wrote to Justice that: “It is not that vertical integration of production and distribution automatically poses a competitive threat of foreclosure and barriers to entry to new entrants; it may not. The difficulty faced is that vertical mergers, for the past 12 years, were deemed barely worthy of any careful competitive scrutiny at all by the antitrust enforcement agencies.” Letter from Congressman Jack Brooks, Chairman of the House Judiciary Committee, to DOJ Assistant Attorney General Anne Bingaman and FTC Chairman Janet Steiger, (Nov. 4, 1993), in Riordan & Salop, *supra* note 133, at 514.

140. PAUL DEMARET, PATENTS, TERRITORIAL RESTRICTIONS, AND EEC LAW: A LEGAL AND ECONOMIC ANALYSIS 71 (IIC Studies: Studies in Industrial Property and Copyright Law, Vol. 2, Freidrich-Karl Beier et al. eds., 1978).

141. Indeed, the language that scholars in this approach sometimes use suggests this to be the case. As Baker notes in his survey article on the distinctive characteristics of the post-Chicago approach, “economists have recently rehabilitated the old view, questioned in Chicago, that scale economies can create an entry barrier.” Baker, *supra* note 132, at 651.

what has been termed the post-Chicago approach.”¹⁴²

While game theory is not new, it appears that post-Chicago scholars are talking about recent developments in games in which firms have imperfect (and perhaps incomplete) information. The distinction between games of perfect and imperfect information is critical to understanding the post-Chicago approach. The distinction between the two types of games is straightforward. In games of perfect information, players (in this case firms) know and possess full information about what has happened in the past. This contrasts with games of imperfect information where players are not sure about all that has happened in the past.¹⁴³

While games of incomplete information correspond more closely with reality, it is still vital to make certain assumptions about how individuals interpret that reality. Not surprisingly, these assumptions are subjective. Overwhelmingly, scholars within the Post-Chicago approach assume that firms have a predisposed bias to collude with one another to fix prices in an anti-competitive fashion. For example, it is widely accepted that cartels tend to break down over the long-term because individual firms have incentives to cheat—in other words, maintain output but just slightly undercut the prices of other cartel members in order to increase market share (a classic prisoner’s dilemma situation). Proponents of the Post-Chicago school argue, though, that if firms are colluding in a cartel to fix prices in a world of imperfect information, they will not know whether firms are cheating other cartel members or there is some other idiosyncratic phenomenon accounting for the price change. In the words of one adherent, the new (and better) post-Chicago game-theoretic models:

[P]resume that colluding firms have imperfect information about the explanation for price declines: they cannot initially tell the difference between a random decline in industry demand and a rival cheating on their cartel. In such an industry, collusive price can be maintained for a long time, punctuated by occasional episodes of increased competition

142. Riordan & Salop, *supra* note 133, at 518.

143. See Ken Binmore, *FUN AND GAMES* 100(1992).

whenever demand declines unexpectedly.¹⁴⁴

But one could just as easily reach the opposite conclusion as well, depending on one's assumptions about trust. These scholars assume that firms are relatively trusting of each other and would not attach malicious motives to each others' actions. In short, they would view price differences between cartel members as an aberration. Cynics or skeptics might view the world quite differently, and to the authors' knowledge, the business world is not particularly known for being trusting of competitors. Other assumptions made by post-Chicago scholars are troubling as well because they exclude *any* procompetitive or efficiency motivations due to vertical integration.¹⁴⁵

This is not to say that Chicago or efficiency school advocates do not make simplifying assumptions as well. Indeed, they do but this speaks to the broader problem of using highly abstract game-theoretic models to justify public policy conclusions. There is no reason that games of imperfect information could not be designed where one starts with different base-level assumptions that could lead to wildly different conclusions.

144. Baker, *supra* note 132, at 650.

145. In agreement with Klass and Salinger, many of the post-Chicago models are perhaps best described as "exemplifying theories." In other words, they make some very restrictive assumptions. The models of Hart and Tirole, for example, rule out "any potentially procompetitive effect and leaving room only for the anticompetitive effect. It provides no foundation for asking what facts one would examine to distinguish between procompetitive and anticompetitive vertical mergers." Michael W. Klass & Michael A. Salinger, *Do new theories of vertical foreclosure provide sound guidance for consent agreements in vertical merger cases?*, 1995 ANTITRUST BULL. 667, 679-80. A similar point can be made about the post-Chicago games developed by Ordoover, Saloner and Salop because their assumptions preclude any efficiency from mergers. *See id.* at 681. In general, the price in a duopoly market can be anywhere between the perfectly competitive and the monopoly price. Ordoover et al. make the extreme assumption, that prior to a vertical merger, the perfectly competitive price prevails upstream. As a result, they too rule out any efficiencies to the merging firm from transferring the input at marginal cost. That assumption is fine for demonstrating what might happen, but it is of no value for trying to assess the conditions under which the harmful effects from vertical mergers outweigh the beneficial ones. *See id.* at 682.

It is this ambiguity within game-theory itself that leads the authors to question the degree to which the post-Chicago approach justifies a shift on government scrutiny of vertical relationships. While the pharmaceutical industry is not necessarily representative, our previous work on this subject¹⁴⁶ does lend support to the conclusion of scholars who conclude that the Post-Chicago approach “does not justify substantially more intervention” on the part of government to limit vertical arrangements between firms.¹⁴⁷ Part of the reason we concur with this view is that abusive price discrimination, particularly in the pharmaceutical industry, is a difficult condition to achieve, much less maintain. The next section examines this claim in more detail.

B. Possibilities for Abusive Price Discrimination

1. The Prerequisites for Abusive Price Discrimination

As defined above, price discrimination is the process of charging different prices to different consumers, in this case in different geographic regions. There are three basic prerequisites for price-discrimination, all of which must hold simultaneously. First, there must be two or more distinct groups of consumers whose demands for the product differ in sensitivity or elasticity to price. In short, consumers have different tastes and vary in the amount they demand a product. Second, trade between the higher-price and lower-price consumers must be restricted or impossible. Finally, third, the seller must be relatively free from competition by sellers of equivalent products.¹⁴⁸

The first condition we stipulate exists. As Schweitzer acknowledges, “The first consideration in explaining international drug price differences is differences in tastes and preferences that alter demand. Significant differences exist across cultures, for ex-

146. See Barfield & Groombridge, *supra* note 5.

147. See Klass & Salinger, *supra* note 145, at 669. Others concur as well, arguing that: “Although examples can be constructed in which welfare decreases with restraints . . . a rule superior to *per se* legality of purely vertical restraints has not, in our view, been offered.” Mathewson and Winter, *supra* note 120, at 300. They are referring to the 1986 Rey and Tirole piece which conforms to the Post-Chicago approach. See Patrick Rey & Jean Tirole, *The Logic of Vertical Restraints*, 76 AMERICAN ECON. REV. 921 (1986).

148. See Scherer and Ross, *supra* note 69, ch. 13.

ample, in choice of drugs as well as their dosage and form of administration.”¹⁴⁹ It is also clear that allowing pharmaceutical patent holders the right to sign contracts limiting the territory in which the distributor may sell the product satisfies the second prerequisite for price-discrimination. As Batson argues, “For price tiering to work (allowing appropriate prices to be set for different markets early in the life cycle) the vaccine market must be segmented by purchasing power and have minimal risk of parallel imports.”¹⁵⁰ The point, though, as developed in more detail below is that this is entirely consistent with promoting a strong research-based pharmaceutical industry. While speaking to the case of patent-based industries at-large, Demaret argues, and we concur that:

Territorial discrimination is consistent with the patent rationale. It increases the patentee’s reward by enabling him to capture a larger part of the potential value attached to his invention and, thereby, intensifies the incentive to invent. To be implemented, however, a system of territorial discrimination often requires that inter-territorial competition between patentee’s buyers or licensees, and between subsequent purchasers of the product based on the patent be curtailed.¹⁵¹

The third condition, however, related to the freedom of competition from equivalent products, is also crucial to the ability of pharmaceutical companies to price discriminate, particularly in an abusive fashion. It is important to make this qualification because linguistically the term ‘price discrimination’ is misleading; it takes on a number of negative connotations stemming from the word discrimination.¹⁵² Thus, it is more accurate to say abusive or putative price discrimination, or perhaps, price differentials.

149. SCHWEITZER, *supra* note 29, at 147.

150. A. Batson, *Win-Win Interactions Between the Public and Private Sectors*, NATURE MEDICINE: VACCINE SUPPLEMENT, May 1998, 489-90.

151. DEMARET, *supra* note 140, at 35.

152. As Rozek and Rapp note, “Because of the legal provisions against price discrimination in the U.S. (and Europe), it has taken on a pejorative tone—akin to *race discrimination*—rather than retaining the more appropriate value-neutral definition.” Richard P. Rozek and Richard T. Rapp, *Parallel Trade in Pharmaceuticals: The Impact on Welfare and Innovation*, 7 J. ECON. INTEG. 183 (1992).

2. The Relationship Between Market Structure & Collusion

This section establishes why abusive price discrimination is difficult to maintain, particularly in the pharmaceutical industry. For the moment, the article makes the extreme (and false) assumption that the price differentials between countries are based solely on the decisions of pharmaceutical manufacturers to price discriminate. Proponents of a doctrine of international exhaustion favor parallel trade because it will undermine the ability of firms to price discriminate. According to those who support parallel trade, pharmaceutical companies charge different (and in high-priced regions abusive) prices to consumers in order to maximize profits to such an extent that consumer welfare suffers. As one trade association wrote about parallel trade at-large, "Parallel trade means that the consumer obtains the same goods for less money," and that, "[p]arallel trade depresses price fixing."¹⁵³ This bold (and largely unsubstantiated) claim gets to the heart of the debate on parallel importation. Others speak of broader issues such as a well-functioning market place and efficient allocation of resources. As Frederick Abbott maintains:

If developed country producers are not pressured to become more efficient as a consequence of price competition, this will distort the efficient allocation of resources in the developed country Parallel imports will serve to assure that adequate level of price competition is maintained in international markets. Price competition is essential to the effective operation of comparative advantage, and to achieving efficiency gains throughout the international trading system.¹⁵⁴

Abbott's argument that markets will operate more efficiently rests on a faulty assumption—that intrabrand competition is the only way to promote efficient and contestable markets. This assumption ignores the crucial role that interbrand competition plays.

153. European Merchants Association, *Trade Marks Directive and Parallel Trade* 3 BROADCAST Mimeo, (October 1998).

154. Frederick Abbott, *First Report (Final) To The Committee on International Trade Law Of The International Association On The Subject Of Parallel Importation*, 1998 J. INT'L ECON. L. 621-22 (1998).

Claims that pharmaceutical manufacturers engage in price-fixing by definition assume that there is horizontal cartel behavior on the part of firms. The reason is that if a pharmaceutical (or any) manufacturer of a product is charging too high of a price then the market is ripe for entry by competitors. In short, inter-brand competition will mitigate the problem. This is particularly the case if the market structure of the industry is non-concentrated, where a large number of firms operate in the industry.

What often concerns proponents of parallel trade, however, is the prospect that competitors will collude to continue charging the higher price. In essence and practice, the leading pharmaceutical firms collude explicitly or tacitly on prices.¹⁵⁵ If this claim is right, then even interbrand competition will be insufficient to undermine the abusive price discriminatory practices of firms, in this case pharmaceuticals.

There is a rich literature in economics on the conditions that would foster such collusion, stemming back to the pioneering work of Augustin Cournot in the 1838. Broadly speaking, the consensus of the literature is that anti-competitive horizontal collusion is more successful as the number of firms in an industry decreases. As Williamson notes: “anticompetitive effects are likely to exist in highly concentrated industries; but because vertical integration in low or moderately concentrated industries is likely to promote efficiency, it will rarely pose an antitrust issue.”¹⁵⁶

The argument of Cournot is that in a duopolistic (two-firm) situation, both firms are better off by choosing an output that maximizes the profits of the firms in comparison to engaging in cut-throat competition. The key insight of Cournot is that the cartel is more difficult to maintain as the number of firms in the industry increase. As Radner notes, “a larger number of firms would

155. As defined by Friedman: “The idea behind tacit collusion is that the firms in an industry can collude, or, more properly, attain the kind of outcome that is usually associated with collusion, in the absence of any kind of agreement or even discourse. Somehow, all firms know what is in their best interest, and without explicit coordination, they do the right thing.” JAMES FRIEDMAN, *OLIGOPOLY THEORY* 132 (1983).

156. Oliver E. Williamson, *Vertical Merger Guidelines: Interpreting the 1982 Reforms*, 71 CAL. L. REV. 604, 615 (1983).

lead to a larger industry output and a lower price (in equilibrium) and that as the number of firms increased without limit, the corresponding equilibria would converge to the situation he called ‘unlimited competition,’ in which marginal cost equaled price.”¹⁵⁷

There are several reasons why this might be the case. First, the cost of organizing larger numbers is higher in non-concentrated sectors than in concentrated ones. As Mitchell argues, “When an industry has many firms and entry is easy, collusive behavior becomes nearly impossible.”¹⁵⁸ Second, statistically speaking, there is a lower chance of what Bowman calls a “maverick firm”—one which sabotages cooperative efforts for “‘irrational’ ideological or psychological reasons.”¹⁵⁹ Third, it is more difficult to monitor and sanction violators of collusive agreements. Apart from the practicalities involved in finding out the quantities produced by other firms, the actions of individual firms in non-concentrated sectors are less affected by the actions of others firms. This contrasts with the situation, where “in a market that will continue in operation for a long time, an oligopolistic firm will naturally be concerned with how its present actions may influence the behavior of its rivals in the future.”¹⁶⁰ The threats of firms to punish violators by disrupting the market are thus more credible. As Chamberlin argues:

If each seeks his maximum profit rationally and intelligently, he will realize that when there are only two or a few sellers his own move has a considerable effect upon his competitors, and that this makes it idle to suppose that they will accept without retaliation the losses he forces upon them. Since the result of a cut by any one is inevitably to decrease his own profits, no one will cut, and although the sellers are entirely independent, the equilibrium result is the

157. Roy Radner, *Collusive Behavior in Noncooperative Epsilon-Equilibria of Oligopolies with Long but Finite Lives*, 22 J.ECON. THEORY 22, 136-154 (1980), reprinted in *GAME THEORY OF ECONOMICS* 373 (Ariel Rubinstein ed., 1990).

158. EDWARD J. MITCHELL, *VERTICAL INTEGRATION IN THE OIL INDUSTRY* 42 (1976).

159. JOHN BOWMAN, *CAPITALIST COLLECTIVE ACTION: COMPETITION, COOPERATION, AND CONFLICT IN THE COAL INDUSTRY* 17-18 (G.A. Cohen, et al, eds. 1989).

160. FRIEDMAN, *OLIGOPOLY THEORY*, *supra* note 155, at 1.

same as though there were a monopolistic agreement between them.¹⁶¹

3. The Market Structure of the Pharmaceutical Industry

The above theoretical discussion needs to be applied to the specific case of the pharmaceutical industry. In so doing, it becomes clear that the possibility of illegal price collusion and fixing would be very difficult to achieve, much less maintain, in the pharmaceutical industry. The reason is that competition is alive and well in the pharmaceutical industry and there is a very low level of concentration. There are new entrants into the field—and those that fail exit and do so rapidly. In the language of economists, the pharmaceutical industry is not oligopolistic, where only a few firms dominate.

While some argue that pharmaceutical companies collude to “raise the height of the barriers to entry faced by entrants to particular patented products,”¹⁶² the bulk of evidence suggests otherwise. In one of the most comprehensive studies to date, scholars concluded that: “The evidence does not, however, suggest any substantial scale-economy barriers in production or distribution.”¹⁶³ And that, “we see little in this evidence that suggests any very active attempt by producers of branded drugs to deter the entry of rivals . . . [and that] the overall response seems to be one that takes the likely extent of entry as given.”¹⁶⁴ This trend has largely been the case since the end of World War II. As these scholars note:

[T]he [pharmaceutical] industry assumed its modern research-oriented form after World War II, when a number of firms emerged that both carried out extensive research and maintained extensive sales forces to promote their innovations. Their rise, however, was not accompanied by a decline in the number of small firms, and even among the re-

161. EDWARD HASTINGS CHAMBERLIN, *THE THEORY OF MONOPOLISTIC COMPETITION* (1933), *quoted in* JEAN TIROLE, *THEORY OF INDUSTRIAL ORGANIZATION* 240 (1988).

162. Daniel Chudnovsky, *Patents and Trademarks in Pharmaceuticals*, 11 *WORLD DEV.* 188 (1983).

163. Richard E. Caves et al., *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, *BROOKINGS PAPERS: MICROECONOMICS* 10 (1991).

164. *Id.* at 46-47.

search-oriented firms, concentration is low.¹⁶⁵

The recent data on market structure of the pharmaceutical industry coincide with these findings, as the table in Appendix A demonstrates.

Two important points from the attached table stand out. The first is that the market share of the top firms is quite small. When the top four firms have a market share of roughly only 20%, it seems unlikely that they would successfully be able to enforce a cartel and price-fix. Even with mergers taking place in the industry, however, there is clearly a role for small manufacturers. One report, for example, notes that: “With an increasing trend for pharmaceutical companies to outsource raw materials, there are tremendous manufacturing and sales opportunities for chemical companies who supply pharmaceutical actives and intermediates.”¹⁶⁶ A role for small pharmaceutical companies is clearly in place, and indeed encouraged by the big players.

The second point is that the market shares can fluctuate wildly, which would make cartel behavior even more difficult. This coincides and supports the thesis discussed above that investing in pharmaceutical research and development is an inherently risky endeavor, with few products actually resulting in a profit for pharmaceutical companies. In a four year period, for example, Pharmacia and Upjohn went from the 11th largest producer to 18th, while Hoescht went from #3 to #9. Conversely, some pharmaceutical companies found their research and development paying off handsomely: Merck went from #4 in 1993 to #1 in 1997; similarly, Pfizer moved from up #10 to #6. Overall, though, as Comanor notes, there are “substantial shifts in market share” and that:

Despite the controversy over the degree of monopoly power exercised by leading firms in this industry, there has been little dispute over the presence of extensive product competition. New products are introduced into therapeutic markets where they compete actively with existing products, and those that cannot maintain their market position

165. *Id.* at at 8.

166. See IMS Health Report, *Business Solutions* (current as of November 1998) <www.ims-global.com/solution/bulk.htm>.

are often withdrawn. High rates of product introduction and obsolescence are found regardless of the magnitude of price-cost margins.¹⁶⁷

4. The Rapid Introduction of Competitors

Critics will point out that the above discussion is misleading because specific drugs have no competitors. They argue that “market behavior is essentially oligopolistic and assessing the extent of competition by simply counting drugs would be erroneous.”¹⁶⁸ As explained by Schut and Van Bergeijk:

Since drugs are by their very nature rather heterogeneous (a gastric ulcer should not be healed with aspirin), the pharmaceutical market can be divided into a large number of independent sub-markets (characterized by low cross elasticities of demand), which correspond to certain therapeutic classes. A low level of concentration for the industry as a whole (some 5% market share for the largest drug firm) thus conceals the real market power which is exercised at the sub-market level¹⁶⁹

Economists call such a situation where some firms might have temporary market power in a sub-market a ‘differentiated oligopoly.’ And while it is true that such a condition potentially exists in the pharmaceutical industry, several qualifications are in order. First, the number of drugs that achieve this temporary market power are very few. In contrast to Schut and Van Bergeijk, Rothnie observes that:

Many drugs affect people in different ways Thus, there is sometimes scope for different types of drug or different formulations to be used against the same or similar ailments. Therefore, demand for even the best-selling drugs is quite small as a proportion of the overall demand

167. William S. Comanor, *The Political Economy of the Pharmaceutical Industry*, 24 J. ECON. LITERATURE 1178, 1186 (1986).

168. Julio J. Nogues, *Social Costs and Benefits of Introducing Patent Protection for Pharmaceutical Drugs in Developing Countries*, THE DEVELOPING ECONOMIES, XXXI-1, (March 1993), p. 29.

169. Frederick T. Schut and Peter A.G. Van Bergeijk, *International Price Discrimination: The Pharmaceutical Industry*, 44 WORLD DEV. 1141, 1142 (1986).

for drugs. Some achieve market shares of about 5 percent, but most successful drugs usually only approach 1 to 2 percent.¹⁷⁰

Second, at most such a condition can operate only for the life of the patent. Given lengthy testing periods, such a temporary monopoly could exist at most for several years. Third, and most important, there is overwhelming evidence that competitors to drugs appear well before the expiration of a patent for a particular drug. Contrary to what Schut and Van Bergeijk claim, “An innovative drug in a new therapeutic class may have temporary market exclusivity; however, the entry of similar but chemically distinct ‘therapeutic’ substitutes has accelerated over time and now typically occurs within months of the first entrant.”¹⁷¹

This is even more likely if a pharmaceutical company is taking advantage of its temporary monopoly and charging inordinately high prices. The reason is that entry barriers are so low in the industry, and “although actual competitors for a given drug or therapy may be few, potential entrants are numerous.”¹⁷² Pharmaceutical manufacturers have to be wary of charging too high of a price. In such a situation, the market is ripe for interbrand competition because “a relatively high introductory price will prevent the product from gaining market share and thus may not be sustained.”¹⁷³ For this reason, as Schweitzer notes: “As important as patent protection is in granting marketing exclusivity, it must be remembered that technology evolves quickly in this industry, and competitive products are frequently introduced even during an originating drug’s patent period.”¹⁷⁴ He also notes that:

Even when a drug is made by only one company, this does not mean that it has no competitors. Often several different drugs appear on the market to treat the same medical condi-

170. ROTHNIE, *supra* note 33, at 479.

171. Danzon, *The Economics of Parallel Trade*, *supra* note 6, at 296.

172. Caves et al., *supra* note 163, at 9.

173. Richard P. Rozek and Ruth Berkowitz, *The Effects of Patent Protection on the Prices of Pharmaceutical Products—Is Intellectual Property Protection Raising the Drug Bill in Developing Countries?*, 1 J. WORLD INTELL. PROP. 179, 215-16 (1998).

174. SCHWEITZER, *supra* note 29, at 230.

tion Some of these imitative drugs can serve as important competitors for a single-source drug because they use the same biological mechanism as innovative drugs. Although similar to the innovative drug, the imitative products are distinct chemical entities. They can therefore introduce competition into the market well before patents expire, thus limiting the ability of the innovative drug manufacturers to sustain high prices.¹⁷⁵

For example, according to the U.S. Congressional Budget Office, this is exactly what happened in the case of Prozac:

When Prozac was introduced into the antidepressant market in 1988 it offered a new treatment with fewer side effects than many of the older antidepressants. The result was that Prozac became one of the five most widely prescribed drugs in the United States, enjoying worldwide sales of \$1 billion in 1992. Such a market was a tempting target for other companies. Within five years, three lower-priced drugs, all using some variant of the same treatment, were on the market in the United States. Four other drugs are being sold in Europe and await FDA approval for U.S. sale. Because there are several close rivals, manufacturers of antidepressant drugs are being forced to offer discounts, even though their patents last until after the year 2000, when generic versions will be permitted to enter the market.¹⁷⁶

Of course, those accusing the pharmaceutical industry of horizontal price-fixing are quick to point out that the market shares and prices of some pharmaceutical products do not decline significantly when competitors are introduced, even after a patent expires. There are two possible explanations for this, one malignant, one more benign. The malignant explanation is that pharmaceutical companies possess a monopoly of information which they distribute to physicians and hospitals. Generic makers do not possess the revenue to advertise and thus physicians, and by definition, patients, remain uninformed. Consequently, physicians remain loyal

175. *Id.* at 107.

176. CBO 1994 Reports, *quoted in* SCHWEITZER, *supra* note 29, at 107.

to branded pharmaceuticals even after a patent expires. Such an argument might have been plausible decades ago, it is less so now given advances in technology and the information ‘super highway.’ The reason is straightforward: “Physicians have access to information about all competitive products in a therapeutical area, so brand loyalty, resulting in part from imperfect information, can no longer support the thesis of monopolistic structure of the pharmaceutical industry.”¹⁷⁷

The more benign reason stems from the fact that some consumers value brands that they are familiar with and do not trust generics. As Scherer notes:

[W]hen generic substitutes exist, the world of drug buyers consists of two quite different groups—those who are price-sensitive and those who are not. . . . [O]nce generic substitutes enter at much lower prices, the market is bifurcated, and the incumbent branded seller commonly finds it more profitable to desert the price-sensitive market than to reduce the prices quoted to price-insensitive customers.¹⁷⁸

Simply put, some consumers are willing to pay a higher price for products they know and trust. The reason that in some branded drugs we do not see a significant decline in prices or market share is brand loyalty and the goodwill or trust that consumers attach to certain companies and products. Numerous studies have found that the maintenance of market share and price levels “appear to come on the demand side from the accumulated goodwill assets of branded producers and any concerns about quality differences between branded and generic drugs.”¹⁷⁹ And that the period of market exclusivity “provided ample time for identification of the drug with a specific brand name and the development of brand loyalty.”¹⁸⁰ The point, however, is that there is extensive competition and consumers have a choice to buy the branded product at a higher price or the generic product at a lower price. Overall,

177. SCHWEITZER, *supra* note 29, at 108.

178. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, *supra* note 80, at 101.

179. Caves, et al., *supra* note 163, at 10-11.

180. COMPETITIVE STRATEGIES IN THE PHARMACEUTICAL INDUSTRY 150 (Meir Statman & Robert B. Helms eds., 1996).

though, the evidence suggests that the pharmaceutical industry is a highly competitive one.

Interestingly, even under the restrictive (and false) assumption that price differences between countries are based exclusively on the price discriminating behavior of pharmaceutical companies, research suggests that allowing patent holders control over parallel imports might actually increase overall world welfare (including both producers and consumers). Malueg and Schwartz note the importance of including producer surplus as well as consumer surplus in the analysis. As they argue, “manufacturers of products prone to parallel imports also are predominantly from richer (more industrialized) countries, and those manufacturers would gain from discrimination. Thus, allowing complete international price discrimination need not systematically reduce the national welfare of industrialized countries.”¹⁸¹

Critics such as Abbott maintain that studies such as those conducted by Malueg and Schwartz are flawed. In his own words, “Most importantly, they (Malueg and Schwartz) do not consider the effects of an international price discrimination system on the international allocation of resources.”¹⁸² The problem with this assertion is that Abbott appears to only be taking into account consumer welfare as opposed to the welfare of consumers and producers (Marshallian welfare). It also reflects Abbott’s belief that IP protection should be subordinate to other trade considerations. The strength of the Malueg and Schwartz analysis is that it looks at price discrimination as the sole cause of parallel imports, an assumption that clearly does not hold in the real world. Based on this restrictive assumption, however, Malueg and Schwartz conclude that: “our analysis casts doubt on the view that world welfare would be enhanced by encouraging unrestricted parallel imports in

181. David Malueg and Marius Schwartz, *Parallel Imports, Demand Dispersion, and International Price Discrimination*, ECONOMIC ANALYSIS GROUP, ANTITRUST DIVISION, U.S. DEPARTMENT OF JUSTICE, PAPER 93-6, (August 25, 1993), p. 19.

182. Abbott, *First Report (Final) To The Committee on International Trade Law Of The International Association On The Subject Of Parallel Importation*, *supra* note 154, at 620.

order to undermine price discrimination.”¹⁸³

5. The Politics of Pharmaceutical Pricing

It is important to point out that the above discussion is based on an assumption; that is, that price differentials in the pharmaceutical industry are based solely on the decisions of pharmaceutical companies. While studies do show that price discrimination takes place,¹⁸⁴ the reality is that price differentials are determined by a host of other factors outside of demand differences and pricing to market strategies by pharmaceutical companies. These factors are often beyond the control of pharmaceutical companies but are important to discuss. The reason is that a doctrine of international exhaustion will have little impact on consumer welfare because other factors (largely governmental interventions) will overwhelm the pricing strategies of pharmaceutical manufacturers. Indeed, there is a danger in making consumer welfare conclusions based solely on price differentials between countries. Such studies are fraught with problems. As Danzon notes, “a comparison of prices alone, even if undertaken with the best feasible methods, does not provide a valid basis for policy prescriptions about pharmaceutical regulation because of other effects on costs, product availability, and consumption patterns.”¹⁸⁵

183. Malueg and Schwartz, *supra* note 181, at 20. They suggest offering lower prices to LDCs to increase welfare, because their demand elasticities are much higher than those of industrialized countries due to vastly lower per capita incomes. Once again, however, they offer no practical way this could be accomplished through public policies—and confine themselves to noting that private suppliers (pharmaceuticals) are responding to this reality by correlating their prices somewhat to per capita incomes.

184. Schut and Van Bergeijk, found “[a] strong positive relationship between price level and per capita GDP” with “a 10% increase in per capita income being associated with on average 8% higher drug prices.” Schut and Van Bergeijk, *supra* note 169, at 1141. This suggests “that the pharmaceutical industry charges what the market ‘will bear.’” *Id.*

185. Patricia M. Danzon, *The Uses and Abuses of International Price Comparisons*, in *COMPETITIVE STRATEGIES IN THE PHARMACEUTICAL INDUSTRY* 85-86 (Robert B. Helms ed., 1996). The reasons are manifold as Danzon continues, on pp. 88-89. Specifically:

There are several indices one could use to measure the impact of price differentials on consumer welfare but certain restrictive assumptions apply. Those assumptions include: identical consumer preference structures in the two circumstances under comparison; identical range of products and

The factors that influence pharmaceutical prices are manifold. First, there is often variation in the exchange rate between countries, of which parallel importers will attempt to take advantage. An extensive literature documents that parallel imports surge when a country's exchange rate appreciates because import prices do not decrease in the same proportion as the depreciation of the other country's currency.¹⁸⁶ The ability of companies to respond to these differences is limited as well. As Rothnie points out, "The role of currency movements in causing sharp increases in the volumes of parallel imports may indicate that firms do make some effort, albeit apparently unsuccessful, to ensure that price differences between markets are kept within some bounds."¹⁸⁷

Second, intellectual property rights regimes vary significantly by country. Patents are current in some countries but not in all. As such, generic competition can lead to downward price pressures in some countries. The TRIPS Agreement, while an important step in the right direction, does not lead to an approximate harmonization of IPR regimes; instead, it provides only a minimum set of stan-

product qualities available; control for all relevant substitutes and complements; and informed consumer choice in competitive markets. For international drug price comparisons, all the assumptions necessary for welfare conclusions are violated. Consumer preferences probably differ cross-nationally, and the range of available products certainly differs. Actual drug consumption patterns do not reflect the choices of informed consumers in competitive markets; rather, they reflect medical norms, subject to the incentives and constraints of insurance and reimbursement systems and regulatory regimes. Indexes that focus only on drug prices fail to control for prices or quantities of other medical services that are important substitutes and complements for drugs, such as patient time and the price of a physician office visit. These violations of standard assumptions imply that index numbers cannot be used to justify conclusions about consumer welfare.

Id. at 88-89.

186. A cottage industry of research sprang up during the late 1980s analyzing the connection between currency fluctuations, particularly the wide swings in the dollar, and grey market imports. See, for example: Robert Feenstra, *Symmetric Pass-Through of Tariffs and Exchange Rates Under Imperfect Competition: An Empirical Test*, 27 J. WORLD COMPETITION 25 (1989); Rudiger Dornbusch, *Exchange Rates and Prices*, 77 AM. ECON. REV. 93 (1987); Alberto Giovanni, *Exchange Rates and Traded Goods Prices*, 24 J. INT'L ECON. 45 (1988); and Kenneth Kasa, *Adjustment Costs and Pricing-to-Market: Theory and Evidence*, 32 J. INT'L ECON. 1 (1992). See also ROTHNIE, *supra* note 33, at 587.

187. ROTHNIE, *supra* note 33, at 587.

dards. It leaves the implementation of the rules to governments subject to multilateral review. This leads to particular problems for countries that choose to extend the life of patents, as is their right. As Harvey Bale points out: "If parallel trade were permitted, the purpose of extending the life of patents in countries which extend patent rights would be compromised by the competition of the innovator's own product coming from other markets where generic versions exist."¹⁸⁸

The third and most important factor explaining why pharmaceutical companies have little control over and accounts for differences in prices are the different regulatory regimes in different countries.¹⁸⁹ This wide variance in market harmonization in the health industry between nations, even within the EU, should give considerable pause to those advocating a doctrine of international exhaustion for patent holders. As Danzon argues, "parallel trade in pharmaceuticals does not yield the normal efficiency gains from trade because countries achieve low pharmaceutical prices by aggressive regulation, not through superior efficiency. In fact, parallel trade reduces economic welfare by undermining price differentials between markets."¹⁹⁰ It does so because it "exploits regulated price differences that do not reflect real cost difference, [therefore] such trade can actually increase societal costs because of additional transportation and administrative costs, yet still be profitable for the trader."¹⁹¹ For this reason, even some proponents of parallel importation acknowledge the special case of pharmaceuticals, in light of the variation in national health policies.¹⁹²

188. Bale, *supra* note 41, at 643.

189. See F.M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, *supra* note 80, at 109-7.

190. Patricia M. Danzon, *The Economics of Parallel Trade*, *supra* note 6, at 293.

191. See *id.* Burstall and Senior concur, noting that: "parallel trade represents a market distortion and not a market correction . . ." In some cases the product has been transported twice in order to end up being consumed in the country where it was made. The absurdity of this is clear. In a properly working market redundant activities such as double transporting would disappear. Burstall and Senior, *supra* note 31, at 16-17.

192. Frederick Abbott, for example, argues that:

One can envisage an exception to an open international parallel importation rule based upon government price controls directed at a specific industry,

C. *The Benefits of Territorial Vertical Restraints in the Pharmaceutical Industry*

1. How Parallel Trade Would Undermine Pharmaceutical R&D

This section lays out the economics of the pharmaceutical innovation process and describes the negative impact of parallel imports on the ability of drug firms to support the long-term R&D vital to that process. As noted above, today, U.S. pharmaceutical firms are spending about 20 percent of total sales on R&D. However, if all costs including R&D, production, distribution, marketing and administrative costs are expressed in discounted present value at the time drugs are launched, R&D accounts for approximately 30 percent of total costs (manufacturing and distribution, 29 percent; marketing, 24 percent).¹⁹³ There are several reasons for the high R&D costs, including the large number of ‘dry holes,’ (compounds investigated and then abandoned before commercialization) and foregone interest (capital costs) because of the long lag (as long as fifteen years) between commitment of R&D and the successful launch of a product.

A major problem in pricing for pharmaceuticals arises from the fact that the large R&D share of total costs is in reality what is termed a global joint cost, that is the cost is the same no matter how many consumers or countries utilize a drug. This means that it is impossible to allocate to particular users or countries portions of the joint global cost. Further, there are also some aspects of

for example, the pharmaceutical industry. By setting a non-market price, the government subsidizes exports at the expense of the manufacturer. Parallel imports of products ‘specifically’ subsidized in this manner might be regulated in light of long-standing WTO policy regarding export subsidies.

Abbott, *First Report (Final) To The Committee on International Trade Law Of The International Association On The Subject Of Parallel Importation*, *supra* note 182, at 623.

193. See Danzon, *The Economic of Parallel Trade*, *supra* note 6, at 295-96; Danzon, PHARMACEUTICAL PRICE REGULATION, *supra* note 28, at 7-9 (note: Danzon’s estimates assume a 46 percent corporate tax rate and 10 percent cost of capital.)

production and distribution which also are in effect global joint costs as, for example, when a single plant supplies a number of drugs to multiple countries. The difficulty of pricing to cover joint costs is exacerbated by the reality that most of these costs are already sunk by the time the product is launched and price negotiations ensue. As Danzon explains:

The cost structure of the research-based pharmaceutical industry is markedly different from that of most other industries because of the significance of joint costs, some of which cannot meaningfully be attributed to any single product, and certainly not to a specific dosage form sold to a specific market segment in a particular country. Most of the costs of research and development, including the cost of the many compounds that never make it to market, are joint costs to all users. Those costs of obtaining information are a pure public good: they are the same whether one patient or millions of patients use the drug.¹⁹⁴

Danzon estimates that true short-term marginal costs—secondary production, processing, packaging and some promotion—account for roughly 30 percent of the total cost. The temptation and danger for the pharmaceutical companies is that users and government regulators have a great incentive to free ride by attempting to drive the price down to a level that covers only short-term marginal costs. If all users drove this bargain, then revenue shortfall could be as high as 70 percent; if prices covered all costs except R&D, the shortfall would be roughly 30 percent.¹⁹⁵

Whatever the individual circumstances, the basic economic fact is that over the long haul if a firm is to survive the average costs across all units of production in all markets must be sufficient to cover the average total cost, including the sunk joint costs.

This reality is one important foundation for the patent system, which grants limited market exclusivity as a means of enabling the patent holders, for a fixed period of time, to price above marginal costs and generate the revenue for R&D and other global joint

194. Patricia M. Danzon, *The Uses and Abuses of International Price Comparisons*, *supra* note 185, at 100.

195. See Danzon, *Economics of Parallel Trade*, *supra* note 6, at 295-97.

costs.

The global nature of the pharmaceutical industry and the drugs it produces, combined with the high ratio of sunk R&D joint costs, renders the industry particularly vulnerable to the negative long-term effects of parallel trade. Economic theory, however, for some years has offered a plausible strategy for achieving both high consumer welfare results and revenue sufficient to cover joint costs: so-called Ramsey pricing.¹⁹⁶

First utilized for regulated utility (air flight, electricity) pricing, Ramsey pricing requires that customers be charged according to their sensitivity to prices. Thus, the mark-up of price over marginal cost will be greater for consumers who are relatively price insensitive (inelastic demand) than for those who are more price sensitive (elastic demand). The more efficient outcome stems from the fact that price differential lead both the price sensitive and the price insensitive consumers to reduce their demand by an equal amount relative to the hypothetical price equal to marginal cost. With a uniform price, price sensitive users will reduce their consumption more and will have their economic welfare reduced by more than price insensitive users. They may drop out of the market entirely, though they might have been willing to pay an intermediate price that still covered the marginal cost of serving them.

For this article, it is also important to note that with differential pricing, total revenue is higher because the price insensitive consumers pay more and more of the price sensitive consumers stay in the market. Over time, the higher flow of revenue will pay for a higher rate of R&D investment. Thus, we agree with Stefan Szymanski who has argued that:

Exhaustion [of patent rights] reduces the incentive to innovate because the expected profitability of innovation is reduced. Even if innovation occurs, exhaustion may well limit the diffusion of the benefits because it limits the incentive of IPR holders to serve consumers in low valuation

196. See F. P. Ramsey, A Contribution to the Theory of Taxation, *ECON. J.* 47-61 (1927). For a more contemporary analysis, see Tirole, *supra* note 161. Danzon, also explains the theory behind Ramsey pricing as it relates to pharmaceuticals in *Economics of Parallel Importing*, *supra* note 6, at 297-98.

markets. These potential costs should weigh heavily with policy makers. Innovation and creativity are central to the process of economic development and should be highly prized both in rich and poor countries. Policies that tend to undermine these activities must be seen to produce significant and substantial countervailing benefits if they are to be adopted.¹⁹⁷

2. Implications for Consumer Economic Welfare

Even if one ignores producer surplus and focuses only on consumer economic welfare, there are strong reasons to believe that parallel imports will help consumers in neither developed nor developing countries.¹⁹⁸ Consumers in developed countries would suffer over the long-term as declines in R&D would bring fewer new therapies to the market. Moreover, given extensive government involvement in pricing, parallel imports will do little to help patients. With this in mind, Burstall and Senior point out that: “Doctors and patients may not profit from parallel trade but the distributors—the wholesalers, the dispensers in the high street or in hospitals, and, of course, the traders themselves—very definitely do.”¹⁹⁹ While empirical evidence is difficult to come by, one of the most comprehensive studies on this matter conducted by those at the National Economic Research Associates found similarly that: “the major beneficiaries of parallel trade are the parallel traders who, on average, claim about 70 percent of the price difference between a parallel import product and the local price. Other direct beneficiaries are pharmacists and, to a much lesser extent, payors. The consumer hardly benefits at all.”²⁰⁰

197. Szymanski, *International Exhaustion*, at 13-14.

198. See Danzon, *The Economics of Parallel Trade*, *supra* note 6, at 304.

199. Burstall and Senior, *supra* note 31, at 22.

200. National Economic Research Associates (NERA), *Survey of Parallel Trade*, *supra* note 25, Key Conclusions.

The most negative impact of parallel trade, though, would be on consumers in the developing world, because the convergence of prices would “inflict a tragic loss on poorer countries that could no longer afford innovative therapies.”²⁰¹ Pharmaceutical companies “have an incentive to set lower prices in low-income countries as long as parallel trade does not exist, so developing countries pay lower prices compared to high-income countries.”²⁰² For example, pharmaceutical companies have reduced by 50 to 75 percent the prices of HIV/AIDS drugs destined for developing countries. Conversely, though, the threat of parallel trade takes away any incentives of pharmaceutical patent holders to make significant concessions to poorer countries.²⁰³

The evidence on whether pharmaceutical companies would not supply drugs to low-priced markets where the threat of parallel importation is high is mixed, and often depends on the type of drug. In some cases, for non-essential drugs, pharmaceutical companies have been reluctant to supply markets. In France, for example, Glaxo-Wellcome’s “refusal to accept a relatively low price for its new migraine drug Imigran has delayed launch for several years despite marketing approval.”²⁰⁴ Other companies have also apparently delayed releasing some drugs, or adopted a uniform price as Merck did when it released Crixivan in the EU in 1996.²⁰⁵ For most drugs, however, “the major firms have been very reluctant to take such steps. Commercial judgments have played their part, but so have ethical considerations. To deny the sick medicines is not the way they act.”²⁰⁶

Outside of the economic rationale, however, there are other important reasons why patent holders should have control over parallel importation through the use of territorial vertical restraints. First, as discussed above on a theoretical level, territorial vertical restraints give an incentive to distributors “to provide extensive

201. Danzon, *The Uses and Abuses of International Price Comparisons*, *supra* note 185, at 102.

202. Rozek and Berkowitz, *supra* note 173, at 215-16.

203. See Bale, *supra* note 41.

204. DANZON, PHARMACEUTICAL PRICE REGULATION, *supra* note 28, at 87.

205. See Danzon, *The Economics of Parallel Trade*, *supra* note 6, at 300.

206. Burstall and Senior, *supra* note 31, at 66.

services for pharmacies (including hospital pharmacies) that they supply exclusively.”²⁰⁷ They would be less willing to do so, however, if there were a credible threat that unauthorized distributors could free-ride on the services and not incur the costs. As Rozek and Rapp suggest:

In order for a pharmaceutical distributor to furnish health care providers with the information that generates sales of a product and to monitor the experience of the product in a country, the distributor must have the proper incentive. Namely, the distributor must be allowed to make the sales of the product associated with its disseminating information about the product and monitoring reactions and product quality. If a parallel trader does not provide the information or service, but rather rides free on the authorized pharmaceutical distributor, the authorized distributor will eventually stop providing the information and service.²⁰⁸

One would be hard pressed to argue that consumer welfare would benefit under such a regime. Indeed, as noted above in the theoretical discussion, there is reason to believe that vertical territorial restraints actually have a procompetitive impact because they promote interbrand competition. Critics of the argument advanced here often ignore this point. Abbott, for example, likens price discrimination supplied through territorial vertical restraints as “quotas” which limit the supply of a good in a particular market. In his own words:

The theory of beneficial price discrimination seems to be fundamentally at odds with the theory of comparative advantage and the underlying economic premise of the GATT-WTO trading system. Since quotas are as a general proposition prohibited by the GATT 1994, business enterprises are in general precluded from engaging in overt price discrimination between markets, except to the extent that transport and related costs allow some price differentials to exist.²⁰⁹

207. Caves et al., *supra* note 163, at 9.

208. Rozek and Rapp, *supra* note 152, at 190.

209. Abbott, *Discussion Paper for Conference on Exhaustion of Intellectual Property Rights and Parallel Importation in World Trade*, *supra* note 19, at 10.

Holding territorial vertical restraints synonymous with quotas is categorically wrong. In the first place, quotas are supplied by governments, in this case, it is the pharmaceutical manufacturer making the decision. Second, quotas apply to overall goods, not specific brand names. This point is crucial because it again reflects the narrowness with which some think of contestable markets. Patent holder control over parallel imports while restricting intrabrand competition does nothing to limit, much less impose a quota, on interbrand competition.

Indeed, as discussed above on a theoretical level, territorial vertical restraints actually make markets more contestable by promoting interbrand competition. When distributors are secure that their marketing and dissemination of information on therapies will not be taken advantage of by unauthorized distributors, they will be able to introduce more effectively new products. As Rozek and Rapp continue, this will actually serve to increase consumer economic and physical welfare in the pharmaceutical industry:

Restraints on intrabrand competition—in the form of parallel imports—will tend to enhance interbrand, therapeutic competition. Absent free riding, distributors can reap the full benefits of their market development efforts. They will efficiently promote their products in competition with other brands available in the country. Consumers benefit from competition in the form of the number of options available to treat a given problem at competitive prices.²¹⁰

This debate at the international level mirrors that which takes place in a domestic context. Theoretically, the issue is the same given that “the ‘free-rider’ problems that give rise to exclusive distribution arrangements are no less important in international commerce than in domestic commerce. Just as domestic suppliers utilize vertical restraints on domestic distributors, many domestic suppliers utilize vertical restraints on foreign distributors as well. For this reason, as Malueg and Schwartz argue, the efficiencies of territorial restraints “are likely to be at least as great in the international context as within countries, given that substantial country-

210. Rozek and Rapp, *supra* note 152, at 192.

specific investments are often required to introduce new products and that such investments are often best elicited by awarding sole-import distributorships.”²¹¹

3. Health and Safety Concerns

Parallel trade in pharmaceuticals raises safety concerns as well. The distribution chain in the pharmaceutical industry is critical to maintaining the quality and safety of drugs. For example, some drugs must be stored within a particular temperature range. In a world where patent holders could not control parallel imports, it would be very difficult to monitor, much less enforce these requirements. Parallel imports also can overburden customs officials who would have a difficult time distinguishing between legitimate parallel imports and counterfeit products. The packaging varies not only in language but in the number of units in a box, the amount of active ingredient, etc., which is a reflection of doctors’ and patients’ preferences and national regulations. For a variety of reasons then, Danzon argues that:

[C]onsumers may face increase in health risk, if the parallel imports include counterfeit products of inferior quality, if repackaging makes it harder to trace specific batches in the event of a recall or if consumers misuse the product because the labelling is literally in Greek. Although parallel importers are required to obtain a license, chemical testing for equivalence is not performed, and instances of counterfeit production have occurred.²¹²

Empirically, for example, the NERA study of parallel importation in Europe found “a number of parallel import products whose repackaging by the parallel importer did not conform to legal requirements” and that some had an “inaccurate description of the active ingredient.” Specifically, the report cited “numerous examples of faulty batch-numbering such as different batch numbers on the blister and the box which could become dangerous in the event of recall; adaptation of original batch numbers to those of the im-

211. Malueg and Schwartz, *supra* note 181, at 20.

212. Danzon, *Economics of Parallel Trade*, *supra* note 6, at 299.

porter; and absence of leaflets.”²¹³

Government officials in both developed and developing countries have voiced their concern over the health risk of parallel imports as well for several reasons. First, it would foster the growth of counterfeit drugs of questionable safety. Customs officials would find it very difficult to distinguish between counterfeit and legitimate products traded in a parallel fashion. Second, the proper storage and handling of legitimate pharmaceuticals cannot be guaranteed. With these and other considerations in mind, one drug regulatory official in Kenya observed that:

[T]he reality of parallel imports raises a number of additional problems from a regulatory standpoint: 1) the application of double standards for approved packaging and labeling; 2) required cooperation of manufacturers and distributors in determining counterfeit products; 3) patient confusion due to multiple presentations of the same product; 4) the persistent threat of intellectual property infringement challenges; 5) the inability of the Pharmacy and Poisons Board to ascertain that the parallel import was manufactured with GMP (Good Manufacturing Practice) standards; and 6) in the event of quality control problems there was an inability to implement necessary product recall policies.²¹⁴

B. *Public vs. Private Enforcement of Territorial Vertical Restraints*

Interestingly, some acknowledge the logic of the argumentation presented above, but are nervous about who imposes or helps to enforce the contract establishing the territorial vertical restraint. Some argue that the vertical territorial allocation of distribution of IPRs owners can be accomplished by significantly less trade restrictive means, i.e., by private contract establishing exclusive sales

213. National Economic Research Associates (NERA), *Survey of Parallel Trade*, *supra* note 30, at 18.

214. Letter from Director, National Quality Control Laboratory, Nairobi, Kenya to Director, Medicines Control Council, Cape Town, South Africa, October 14, 1997. Quoted in, Bale, *supra* note 41, at 651.

territories for authorized sellers.”²¹⁵

Contrary to this assertion, there is overwhelming empirical evidence that private court ordering is not efficacious; indeed, in many cases it is near impossible. Even those skeptical of the argument advanced here claim that manufacturers “obviously find it difficult to impose contractual limitations on domestic importers.”²¹⁶ There are two reasons why national governments and international agreements such as TRIPS should codify the legality of restrictions on parallel imports rather than rely on private contractual enforcement of contractual vertical restraints. The first is that the legal structures of some developing countries make it difficult, and in some cases impossible, to enforce contracts privately. As Chard et al. note: “a number of developing countries have laws concerning licensing arrangements that prevent rights-owners from enforcing contractual restraints on exports Thus, rights-owners may find it particularly difficult to restrain parallel imports from these countries if the principle of exhaustion is extended internationally.”²¹⁷

The second reason is that “even if enforcement of contractual restraints on parallel exports is legal under national laws, there may be problems in tracing the source of parallel imports and hence the party who is in breach of contract.”²¹⁸ Put differently, the transaction costs of monitoring and enforcing vertical restraints are too high to realistically enforce privately at this time. Thus, thinking of restrictions on parallel imports in the same way as protection like the imposition of a quota as Abbott does confuses government enforcement of property rights with government protection and ignores that governments have an enormous cost advantage over world-wide policing by manufacturers.

Some still advocate that a private solution is possible is the belief that the world is moving to one uniform market and that increasingly firms will be able to adopt a single pricing policy in all

215. Abbott, *Discussion Paper for Conference on Exhaustion of Intellectual Property Rights and parallel Importation in World Trade*, *supra* note 19, at 635.

216. DEMARET, *supra* note 140, at 76.

217. John Chard, et al., *International Exhaustion of Intellectual Property Rights 95*, (A Report to the Department of Trade and Industry, November 1988).

218. *Id.*

markets. While it is true that the economies of different nations are becoming increasingly integrated, it is wrong to think that we are at a point where a universal and uniform global market exists. Some argue that a single pricing policy would eliminate the parallel import problem, but it would also eliminate the efficiencies realized through strategic pricing. Moreover, it reflects a naive understanding of marketplace realities given that price variations stem from a number of causes including differences in local demand, local ability to pay, local taxes, local regulations and international treaty obligations, local manufacturing and distribution costs, and local infrastructure.

Interestingly, proponents of removing restrictions on parallel imports often acknowledge that vertical restraints serve a pro-competitive role. Ruff, for example, argues that government restrictions on parallel imports are unnecessary because the private sector can eliminate them through vertical restraints. In his own words: “separate restrictions on parallel imports contribute nothing to efficiencies produced through combined vertical restraints. By the time a manufacturer has instituted a dynamic system to provide quasi-rents, she will have controlled for the kind of price competition represented by parallel imports.”²¹⁹ Similarly, Abbott in likening patents to copyright, argues that territorial vertical restraints might be efficiency enhancing but, “while this argumentation may indeed support contractual vertical territorial restraints on the international plane, it does not make the case against the market policing function of parallel imports.”²²⁰

This leads to the interesting question of whether it is the vertical arrangement itself that is the problem, or the supplier (i.e., the government of the patent owner herself through private contract) of the vertical arrangement that poses the problem. Theoretically, vertical restraints contracted privately should also result in similar types of abusive price discrimination as vertical restraints imposed by the government. Both Ruff and Abbott express concern about abusive and anti-competitive price discrimination. But if this is

219. Andrew Ruff, *Releasing the Grays: In Support of Legalizing Parallel Imports*, 11 UCLA PAC. BASIN L. J. 119, 149 (1992).

220. Abbott, *Discussion Paper for Conference on Exhaustion of Intellectual Property Rights and parallel Importation in World Trade*, *supra* note 19, at 627.

their concern, then they should oppose abusive vertical restraints regardless of whether it is imposed by government allowances of private contractual restraints or directly by the private sector itself.

There is an important reason to distinguish between vertical arrangements sanctioned by the government versus those contracted for in the private sector—but the distinction is one that ultimately makes the case for why legal rules are crucial. There is a strong case to be made for market failure in protecting intellectual property rights, particularly at the international level. As Alden Abbott observes:

The key principle that emerges from this discussion is that it is much more difficult to arrange privately for the protection of intangible knowledge goods than for that of tangible goods. While purely private methods of protecting intellectual property should be allowed, innovators should also have an opportunity to avail themselves of guaranteed protection under intellectual property law—a form of protection that may often prove more conducive to desirable innovation than strictly private approaches that enjoy no legal protection.²²¹

221. Alden F. Abbott, *supra* note 55, at 322. Ironically, to the extent that it is vertical restraints that indeed are the problem, some suggest that fears of price discrimination might actually *increase* in a world devoid of public enforcement of intellectual property rights. Abbot observes that the unintended consequence in such a world would be that privately contracted vertical restraints would overcompensate, thereby fostering price discrimination. *Id.* at 321. Private mechanisms are “less than ideal Indeed they may lead innovators to devise distribution schemes that are more restrictive, and thus more socially costly, than those used when intellectual property protection exists.” *Id.* at 321.

CONCLUSION

It is interesting to note the language used to couch debates over intellectual property and international trade. Do intellectual property rights grant a monopoly, a term which has negative connotations, or is it better to conceptualize intellectual property rights as any other private property right, albeit only temporary? Are pharmaceutical patent holders controlling the flow of their products or are they restricting free trade? This choice of words clearly reflect the tensions and deep divisions within the international trading community. As always, it is necessary to balance goals. In the case of intellectual property, as Rothnie argues: "There is no point in railing at intellectual property rights because they distort the operation of market forces; that is, the point of adopting intellectual property laws. On the other hand, it is necessary to recognize that not every use made of intellectual property rights should be accorded immunity."²²²

In achieving this proper balance and reconciling these tensions, it is important to look at circumstances unique to particular forms of intellectual property, as well as the unique characteristics of particular industries. We firmly believe that the research-based pharmaceutical industry represents a case where a doctrine of international exhaustion permitting parallel trade would have a negative impact on global welfare. This article emphasizes global welfare because proponents of parallel trade too often only consider the short-term welfare implications of consumers in particular locales. It is noteworthy too that the available evidence of the European Union suggests that consumers in the more developed countries of Europe have seen little of the price reduction due to parallel trade—instead, parallel traders and some unauthorized distributors have realized most of the gains. These short-term gains to middlepersons, however, come at a considerable cost.

This article has attempted to document the central role of the patent system in fostering and maintaining a stream of innovative

222. ROTHNIE, *supra* note 33, at 593.

drugs from the pharmaceutical industry. There is a growing consensus among economists that, particularly with regard to the pharmaceutical industry, the symbiotic relationship between the 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. Moreover, an effective distribution system is critically important for pharmaceutical manufacturers to realize profits on a very few products in a very short period of time. Consequently, if one looks at global welfare, however, as Danzon argues: "The welfare maximizing set of prices to cover joint costs requires charging different prices to users who differ in their price elasticities of demand for innovative medicines."²²³ In a world of parallel trade, though, legitimate forms of price of discrimination would not be allowed.

Of course, as discussed above, the price differentials of pharmaceuticals across markets often have little to do with the pricing strategies of pharmaceutical firms; rather, it is based on government intervention. The result is that parallel trade is doing very little to create a uniform market as hoped for by proponents of a doctrine of international exhaustion. Nowhere is this more evident than in the European Union, which has a doctrine of internal or regional exhaustion for member states. Interestingly, in his exhaustive survey of several industries, Rothnie concludes with regard to the pharmaceutical industry that: "More than the other aspects of the study, the examination of the pharmaceuticals industry shows both the fallacy and danger of a doctrine of international exhaustion."²²⁴ A fallacy in the sense that the EU is not a uniform market; a danger in the sense that a burgeoning parallel trade industry in pharmaceuticals could leave some markets unserved and risk the health and safety of consumers through faulty packaging and counterfeiting. For this reason, as Bale concludes, the EU is an example of what not to do: impose parallel trade for a sector on a system of existing national price controls and the continuation of gross differences in IPR protection.²²⁵

223. Danzon, *The Economics of Parallel Trade*, *supra* note 6, at 304.

224. ROTHNIE, *supra* note 33, at 587.

225. See Bale, *supra* note 41.

Again, as critics of the argument advanced here point out, this does not mean that intellectual property should be the only lens through which we observe the issue. There are legitimate concerns that consumer welfare could suffer unduly if firms were engaging in abusive price discrimination. The authors acknowledge the theoretical possibility of abusive price discrimination in any industry. The work on this subject, though, overwhelmingly shows that it is most likely to occur in industries which are heavily concentrated where only a few firms dominate because collusion and cartels are much easier to maintain. This is not the case, however, in the research-based pharmaceutical industry, where the top firm does not even have a 5 percent market share. Moreover, the increasingly shortened periods of market exclusivity for a particular therapeutic drug suggest that competition is alive and well in the industry. Given the number of competitors, pharmaceutical manufacturers have little incentive, much less ability, to price discriminate in an abusive fashion—doing so would only encourage entry by others.

This does not mean that pharmaceutical manufacturers or their distributors are completely off the hook. Price fixing behavior through a cartel by manufacturers or distributors is illegal—and should be. Fortunately, countries have a body of anti-trust laws to deal with such illegal and anti-competitive behavior. Undermining the efficient and pro-competitive benefits of territorial vertical restraints, however, as Chard et al., conclude, “risks throwing out the baby with the bath water. Competition policy is the most appropriate policy for dealing with those relatively infrequent situations where the use of intellectual property rights to prevent parallel importation has detrimental effects.”²²⁶ Such competition provisions “would ensure that the economic functions of the intellectual property rights are adequately protected (while under an exhaustion rule, they are not) and, at the same time, it would provide for appropriate control of any abuses of intellectual property rights.”²²⁷ It was with this in mind that Posner concluded that vertical restraints should be legal *per se*. While speaking to the case of the

226. Chard et al., *supra* note 217, at 92.

227. Chard et al., *supra* note 217, at 90.

U.S., his analysis would apply equally to the international level. As he notes, “cases in which dealers or distributors collude to eliminate competition among themselves and bring in the manufacturer to enforce their cartel, or in which vertical restrictions are used to enforce a cartel among manufacturers, can be dealt with under the conventional rules applicable to horizontal price-fixing conspiracies.”²²⁸

Specifically with regard to the current situation in the TRIPS Agreement, where Article 6 merely records a standoff between those opposing and those favoring restrictions on parallel imports, we believe that there is a great danger that in the near future bilateral and even regional conflicts will erupt that could undermine legitimacy of the TRIPS itself. It is, therefore, imperative that the WTO move quickly to fill the gap concerning restrictions on parallel imports. Given the arguments advanced in this article, our first preference would be for a rule allowing IPRs holder to block parallel imports. Failing this, at a minimum to take care of the special problems presented for the pharmaceutical industry, a new rule for exhaustion should allow restrictions by patent holders on parallel imports that come from countries that maintain price controls, or other market restricting practices. As we have argued elsewhere, the authors also recommend that a future regime on parallel trade include a competition policy test that takes into consideration market structure and the potential ability for putative collusive behavior. In countering such collusion governments should have the ability to apply competition rules.²²⁹

In conclusion, the authors reiterate that the debate on parallel trade is part of the larger debate on deeper integration and the globalization of the world economy. And while elsewhere we have argued vociferously in favor of free trade, our analysis suggests, in agreement with Danzon, that: “The first best policy option would be to exempt pharmaceuticals from parallel trade.”²³⁰ The world is not yet a uniform market where consumers have similar tastes, regulatory policies are harmonized, and all countries have

228. Posner, *supra* note 130, at 22.

229. See Barfield and Groombridge, *supra* note 5.

230. DANZON, PHARMACEUTICAL PRICE REGULATION, *supra* note 28, at 89.

strong regimes to protect intellectual property. At this time, as court ordering through private contract is not feasible given different legal regimes and the inordinately high transaction costs, government rules are necessary. Government rules allowing pharmaceutical patent holders to control parallel trade are vital not only to promoting innovation, but to enhancing consumer economic and physical welfare in both the developed and developing world.

APPENDIX

WORLD MARKET SHARE OF TOP 20 PHARMACEUTICAL
CORPORATIONS²³¹

Corporation NAME	MARKET SHARE IN 1993 (PERCENT AGE / RANK)	MARKET SHARE IN 1996 (PERCENTAGE / RANK)	MARKET SHARE IN 1997 (PERCENTAGE / RANK)
Merck & Company	3.5% / #4	4.2% / #3	4.6% / #1
Glaxo Well- come	4.8% / #1	4.6% / #1	4.5% / #2
Novartis	4.7% / #2	4.4% / #2	4.3% / #3
Bristol-Myers Squibb	3.5% / #5	3.5% / #4	3.7% / #4
Johnson & Johnson	2.7% / #9	3.4% / #5	3.5% / #5
Pfizer	2.6% / #10	3.2% / #7	3.4% / #6
American Home	3.4% / #6	3.3% / #6	3.3% / #7
Smithkline Beecham	2.9% / #8	2.8% / #9	3.0% / #8
Hoechst	3.8% / #3	3.2% / #8	2.8% / #9
Lilly	2.2% / #13	2.3% / #12	2.6% / #10
Roche	2.9% / #7	2.6% / #10	2.6% / #11
Abbott	1.8% / #16	2.3% / #11	2.5% / #12
Scherling Plough	1.8% / #15	2.1% / #15	2.3% / #13

231. See IMS Health, Insight for Life, *Global Services: World Review 1997*, This table represents data from 60 countries.

Bayer	2.2% / #12	2.2% / #13	2.2% / #14
Astra	1.4% / #19	2.1% / #14	2.1% / #15
Warner-Lambert	1.5% / #18	1.5% / #20	1.9% / #16
Rhone Poulenc	2.0% / #14	1.9% / #16	1.8% / #17
Pharmacia & Upjohn	2.3% / #11	1.8% / #17	1.8% / #18
Boehringer Ingelheim	1.4% / #20	1.5% / #19	1.5% / #19
Takeda	1.5% / #17	1.5% / #18	1.4% / #20
<i>TOTAL 20</i>	52.9%	54.1%	55.7%