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Recent Development

In Search of an Elixir: What Ails the Pharmaceutical Industry in Europe and How to Use the Competition Laws to Cure It

Jonathan A. Hareid*

I. INTRODUCTION

On November 28, 2008, the European Commission released its preliminary findings in a study investigating a perceived lack of competitiveness in the pharmaceutical industry in Europe.¹ The study found, among other things, that brand-name drug manufacturers (which the report terms “originator companies”) engage in a variety of tactics to delay the entry of generic drugs onto the market.²

The Commission’s study comes on the heels of its 2005 decision against AstraZeneca.³ In that matter, the Commission found that AstraZeneca, a brand-name drug company, had violated Article 82 of the European Community Treaty and Article 54 of the European

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1. COMPETITION DIRECTORATE-GENERAL, EUROPEAN COMM’N, PHARMACEUTICAL SECTOR INQUIRY PRELIMINARY REPORT: EXECUTIVE SUMMARY (2008), *available at* http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf [hereinafter COMPETITION DIRECTORATE-GENERAL].

2. *Id.* at 7–10.

3. Commission Decision 2006/857, art. 82 and art. 54, 2006 O.J. (L332) 24 (EC and EEA)(summary of the decision; the full text of the decision is *available at* <http://ec.europa.eu/competition/antitrust/cases/decisions/37507/en.pdf> [hereinafter Commission Decision].

Economic Area (“EEA”) by a pair of practices relating to patent extension and regulatory marketing authorization for the company’s proton-pump inhibitor drug, Losec.⁴ The Commission found that AstraZeneca’s practices were aimed at keeping generic competitors from entering the marketplace.⁵

In the United States the Hatch-Waxman Act governs the relationship between brand-name and generic drug manufacturers and has been subject to various abuses by both camps. The intellectual property and regulatory framework is similar to the Hatch-Waxman Act in Europe, although with some differences. The *AstraZeneca* decision and the European Commission’s recent report suggest that just as the basic legal framework is similar in the United States and Europe, abuses of the framework, with anti-competitive consequences, are another common element on both sides of the Atlantic.

The *AstraZeneca* decision provides precedent for applying the competition laws to restrain these abuses, and rightly so. However, while the Commission’s report seems to fault brand-name manufacturers for most of the problems, the true situation is likely more complex. Generic manufacturers are likely parties to some anti-competitive practices too. Moreover, the entire pharmaceutical industry is facing unique challenges in today’s economic and regulatory climate. Hence, this paper argues that the competition laws should be applied with care and attention to the true situation the industry faces. A complete solution involves a package of legal and regulatory overhaul of which judicious application of the competition laws is only a part.

II. BACKGROUND

A. THE LEGAL LANDSCAPE FOR PHARMACEUTICAL PRODUCTS IN THE UNITED STATES

Under the Federal Food, Drug, and Cosmetic Act (“FDCA”)⁶, a drug maker must obtain approval from the Food and Drug Administration (“FDA”) before a new drug is

4. *Id.* at 198.

5. *Id.* at 195.

6. 21 U.S.C. §§ 301–399 (2006).

introduced into interstate commerce in the United States.⁷ Approval requires submission of extensive preclinical and clinical studies demonstrating the drug's safety, efficacy, and pharmacological properties.⁸ Hence, obtaining FDA approval is quite time-consuming as well as expensive. The total time required for drug testing and approval is between three and twenty years, with an average of about eight and a half years.⁹ Estimates of the total cost of drug approval vary, but at the high end the total cost could be over \$800 million.¹⁰

To capture the most economic value from an approved drug, a drug company must obtain one or more patents on the drug. A patent gives the patentee the right to prevent others from making, using, selling, or importing the invention into the United States.¹¹ This right generally lasts for twenty years from the date of filing of the patent application.¹² The patent thus gives the patentee a limited monopoly in the invention.

A drug company must obtain a patent shortly after discovery of the drug; excessive delay results in the company being statutorily barred from obtaining a patent.¹³ However, the long process of getting FDA approval means that a large portion of the patent term will have run before the drug company gets FDA approval, and without FDA approval, the company cannot market the drug commercially. On the other hand, a competitor seeking to manufacture a generic version of the drug has to get FDA approval too, and any sort of testing would ordinarily be an infringement of the drug patent. So even after the drug patent expired, there would be a delay before any generic version could come on the market because only then could a generic drug maker begin to work on FDA approval. Thus,

7. *Id.* § 355(a).

8. *Id.* § 355(b)(1); 21 C.F.R. §§ 314.50(c)(2)(ii), (v) (2008).

9. Michael Dickson & Jean Paul Gagnon, *Key Factors in the Rising Cost of New Drug Discovery and Development*, 3 NATURE REV. DRUG DISCOVERY 417, 418 fig.1 (2004). The Pharmaceutical Research and Manufacturers of America (PhRMA) maintains that the average time is 14.2 years in recent decades. *Id.*

10. *Id.* at 424-26.

11. 35 U.S.C. § 154(a)(1) (2006).

12. *Id.* § 154(a)(2).

13. *Id.* § 102(b).

the regulatory process effectively distorts the commercial exclusivity associated with drug patents, both at the front end and the back end of the patent term.¹⁴

Congress sought to solve these problems by passing the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act.¹⁵ The law amended the Patent Act and the FDCA in several respects. First, it enabled a drug manufacturer seeking approval of a generic version of an already-approved drug to file an abbreviated new drug application (“ANDA”), which would piggyback on the safety and effectiveness data submitted by the original manufacturer and thus streamline approval for generic drugs.¹⁶ This eliminated the necessity for generic manufacturers to do all the same testing on the same drug that the original manufacturer did, which seemed like wasteful duplication. Second, the law enabled patent term extension for products subject to FDA approval to enable the original manufacturer to regain some of the patent term lost during the FDA approval process.¹⁷ Third, the law created a safe harbor from patent infringement for uses of patented inventions to develop information for submission to the FDA for approval of a product, which enabled generic manufacturers to do the research and testing required for FDA approval while a brand-name drug is still under patent.¹⁸

Finally, the law included provisions to expedite patent litigation over generic drugs and incentivize generic manufacturers to challenge drug patents. Specifically, the law provides that an ANDA filer must certify that (1) the original drug patent information has not been filed, (2) the patent has expired or will expire and the ANDA filer will not begin commercial marketing until after expiration, or (3) the patent is invalid or will not be infringed.¹⁹ If the ANDA filer asserts that the patent is invalid or will not be infringed

14. See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669–71 (1990).

15. The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in 21 U.S.C. § 355 (2006), 35 U.S.C. §§ 156, 271, 282 (2006)).

16. 21 U.S.C. § 355(j).

17. 35 U.S.C. § 156(a), (f).

18. *Id.* § 271(e)(1).

19. 21 U.S.C. § 355(j)(2)(A)(vii).

(known as a Paragraph IV certification), this assertion is considered a technical act of patent infringement, and the brand-name drug company (the patentee) has forty-five days to bring a patent infringement suit against the ANDA filer; if no suit is brought, the FDA may approve the ANDA immediately.²⁰ If the patent holder does file suit, the FDA may not approve the ANDA for thirty months²¹ or until a court declares the patent invalid.²² This enables patent disputes to go directly to court without waiting for the generic company to actually begin manufacture or file a declaratory judgment action. Moreover, to encourage Paragraph IV certifications, the first ANDA filer to successfully use a Paragraph IV certification gets a 180-day period of marketing exclusivity during which the FDA cannot approve other ANDAs.²³ This incentivizes generic drug makers to challenge brand-name drug patents and presumably enhances the general availability of generic drugs, which are cheaper and benefit consumers.

The ANDA provisions have been subject to a variety of practices with potential anti-competitive effects. Many of these practices are attempts by brand-name drug makers to delay the availability of generic versions of their drugs.²⁴ While some of these strategies are legitimate business tactics, others undoubtedly rise to the level of abuse of the Hatch-Waxman provisions or violation of the antitrust laws. For example, some brand-name manufacturers have obtained additional patents on their drugs in order to trigger additional thirty-month stays.²⁵ One brand-name manufacturer tried unsuccessfully to assert copyright infringement against the ANDA filer because the generic manufacturer is required to use the same labeling as the original manufacturer.²⁶ Sometimes brand-name

20. *Id.* § 355(j)(5)(B)(iii).

21. *Id.*

22. *Id.* § 355(j)(5)(B)(iii)(I).

23. *Id.* § 355(j)(5)(B)(iv).

24. For an in-depth case study of two brand-name companies' strategies to delay the onset of generic competition to their blockbuster drugs, see Daniel Gorlin, *Staving Off Death: A Case Study of the Pharmaceutical Industry's Strategies to Protect Blockbuster Franchises*, 63 FOOD & DRUG L.J. 823 (2008).

25. See, e.g., *Mylan Pharm. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001).

26. See *SmithKline Beecham Consumer Healthcare v. Watson Pharm.*,

manufacturers have tried to use an FDA procedure known as the citizen's petition to prevent approval of an ANDA.²⁷ Brand-name manufacturers may suddenly withdraw their marketing authorization for particular dosage forms of a drug just before a generic manufacturer is about to obtain ANDA approval for that dosage form, thereby preventing the ANDA from being approved because there is no original application for the ANDA to piggyback on.²⁸

Finally, many patent infringement suits triggered by ANDAs are settled with a payment from the brand-name manufacturer to the generic company.²⁹ Such a payment, called a "reverse" payment because it flows in the opposite direction a normal patent settlement payment would (i.e., from accused infringer to patentee), is frequently accompanied by settlement provisions that involve the generic manufacturer refraining from manufacturing the drug for a certain period of time. This raises antitrust scrutiny because the effect of such agreements is to reduce competition in the drug market. Courts and scholars have differed over how to approach the legality of reverse payments in light of the antitrust laws.³⁰

The abuses have not gone unnoticed by Congress or the Federal Trade Commission. In the Medicare Modernization Act of 2003, Congress amended the Hatch-Waxman provisions to curb some of the abusive practices, including limiting brand-name companies to one thirty-month stay per ANDA.³¹ The law mandates Federal Trade Commission

Inc., 211 F.3d 21 (2d Cir. 2000).

27. See S. REP. NO. 109-266, at 136-47 (2006) (report for an appropriations bill noting a sharp increase in the occurrence of citizen petitions and attributing many of these petitions to attempts to delay the marketing of a generic version of an existing drug).

28. See *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 414-18 (D. Del. 2006).

29. See, e.g., *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056 (11th Cir. 2005); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

30. For an excellent up-to-date summary of various approaches courts and scholars have taken to the reverse payment question, see Erica N. Andersen, *Schering the Market: Analyzing the Debate over Reverse-Payment Settlements in the Wake of the Medicare Modernization Act of 2003 and In re Tamoxifen Citrate Litigation*, 93 IOWA L. REV. 1015 (2008).

31. Medicare Prescription Drug, Improvement, and Modernization Act

review of agreements between brand-name and generic manufacturers, and between different generic manufacturers, that are the result of ANDA filings with Paragraph IV certifications.³²

B. THE LEGAL LANDSCAPE FOR PHARMACEUTICAL PRODUCTS IN EUROPE

As in the United States, a drug manufacturer must obtain regulatory approval to market a pharmaceutical product in Europe. This is done in one of two ways. First, a drug maker may apply with the European Medicines Agency (“EMA”) for an authorization that covers all member states.³³ Second, the drug maker may obtain approval from an individual member state and later obtain authorization from all the others through the Mutual Recognition Procedure (“MRP”).³⁴

As in the United States, a company may also seek patent protection on its drug to obtain the economic benefits of a limited monopoly right. However, there is no single European Community patent. The European Patent Office handles patent applications in a centralized way, but after the patent issues, the rights afforded are defined by national patent laws and must be enforced separately in each member state.³⁵

The European Community has adopted some, but not all, of the features of the Hatch-Waxman regime governing generic drug approval in the United States. As in the United States, it is possible for a company seeking approval of a generic drug to piggyback on the safety and effectiveness data submitted by the original manufacturer.³⁶ Also, the original manufacturer can get a patent term extension, called a Supplementary Protection Certificate (“SPC”), to recoup some of the patent term lost during regulatory approval.³⁷

Originally, the patent laws of some European countries

of 2003, Pub. L. No. 108-173, § 1101, 117 Stat. 2066, 2448–2457 (2003).

32. *Id.* §§ 1111–1118.

33. Council Regulation 726/2004, 2004 O.J. (L136) 1 (EC).

34. Council Directive 2001/83, 2001 O.J. (L311) 67 (EC).

35. COMPETITION DIRECTORATE-GENERAL, *supra* note 1, at 6.

36. Council Directive 2004/27, 2004 O.J. (L136) 35 (EC).

37. Council Regulation 1768/92, 1992 O.J. (L182) 1 (EC).

did not exempt testing and other activities by generic drug companies for obtaining regulatory approval, and the European Court of Justice had upheld injunctions against generic companies based on patent infringement theories.³⁸ However, the European Parliament and Council recently enacted a Community-wide analogue to the safe harbor provision in the United States that permits generic drug testing during the patent term for purposes of obtaining regulatory approval.³⁹ However, as yet there are no analogous provisions to those in the United States providing an immediate route to the courts upon ANDA filing, Paragraph IV certifications, thirty-month stays, or 180-day marketing exclusivity for successful generic challengers.

C. THE *ASTRAZENECA* DECISION

It is natural to ask whether the various abuses aimed at keeping generic drugs off the market, well-documented in the United States, have occurred in Europe as well. A clear answer came in 2005, when the European Commission fined the pharmaceutical company AstraZeneca sixty million euros for abuse of a dominant position, in violation of Article 82 of the European Community Treaty and Article 54 of the EEA, relating to the company's conduct in relation to its blockbuster drug Losec (generic name omeprazole, which is sold as the blockbuster drug Prilosec in the United States).⁴⁰ The conduct was aimed at preventing other companies from manufacturing generic versions of Losec, a proton-pump inhibitor drug.⁴¹

First, the Commission had to define the relevant market. The Commission noted that in the pharmaceutical sector price competition is less important than non-price competition for two reasons.⁴² First, the price of drugs, even patented drugs, is largely controlled by national health authorities who are the sole buyers in each country (i.e.,

38. See Case C-316/95, *Generics BV v. Smith, Kline & French Labs. Ltd.*, 1997 E.C.R. I-3929 (upholding injunction against generic drug company against various challenges based on European Community Treaty provisions).

39. Council Directive 2004/27, *supra* note 36, art. 10 at 39.

40. Commission Decision, *supra* note 3, at 198.

41. *Id.* at 195.

42. *Id.* at 86-88.

monopsony buyers).⁴³ Second, the one who chooses a drug is not the payer but the doctor or other health care professional.⁴⁴

Thus, the Commission relied on product characteristics as well as price pattern substitutability to define the relevant market and determined that the relevant product was Losec itself, since omeprazole is a one-of-a-kind drug with a unique mechanism of action.⁴⁵ As for price pattern substitutability, the Commission noted that in the pertinent timeframe a similar class of drugs, the histamine H2 receptor blockers, ostensibly exerted no competitive pressure on Losec because the latter's market share kept growing in spite of the fact that it generally cost more than the H2 blockers.⁴⁶ Therefore, the relative product market was that for Losec itself.⁴⁷

The Commission held that the relevant geographic market was each nation in which the drug was sold, since the different purchasing policies of each national health authority tended to define markets of national scope.⁴⁸

The Commission decided that AstraZeneca held a dominant position in the relevant markets because omeprazole was the first drug of its kind so the company enjoyed a first mover advantage.⁴⁹ For this reason, and because of AstraZeneca's patent rights, it had a strong bargaining position even against monopsony buyers.⁵⁰

The first abuse involved submission of misleading information by AstraZeneca to national patent offices and authorities of various member countries for purposes of obtaining SPC protection to which the company was not entitled.⁵¹ The Commission held that this was abuse of a dominant position because it was aimed at delaying the availability of generic versions of Losec.⁵²

The second abuse involved the selective de-registration

43. *Id.* at 86.

44. *Id.*

45. *Id.* at 89–90.

46. *Id.* at 94–95.

47. *Id.* at 114.

48. *Id.* at 113.

49. *Id.* at 120–21.

50. *Id.* at 123–24.

51. *Id.* at 135.

52. *Id.* at 166–67.

of marketing authorization of a particular formulation of Losec, specifically a capsule, and the simultaneous registration of a different formulation in tablet form.⁵³ While AstraZeneca argued that it was merely making a business decision to switch dosage forms, the Commission relied on documents from the company premises to determine that there was no purpose for the switch other than to delay the market entry of generic versions of Losec, some of which were poised to gain marketing authorization of a capsule version of omeprazole.⁵⁴ The Commission was swayed in part by the fact that AstraZeneca had only made this switch in countries where it was likely to delay the onset of generic competition.⁵⁵ Hence, the Commission determined that the selective de-registration was also abuse of a dominant position.⁵⁶

D. THE RECENT COMPETITION DIRECTORATE-GENERAL PHARMACEUTICAL SECTOR INQUIRY

The Competition Directorate-General, a branch of the European Commission, plays a role parallel to that of the Federal Trade Commission in the United States: to enforce the competition laws, analogous to the antitrust laws in the United States, in order to promote competition and efficient markets in the European community for the benefit of the economy and consumers.⁵⁷ The Competition Directorate-General is currently investigating the competitiveness of the pharmaceutical industry in Europe. Preliminary findings were made public on November 28, 2008.⁵⁸ A final report is expected to be ready in summer 2009.⁵⁹

The investigation was motivated by perceptions that the number of novel drugs on the market was declining and

53. *Id.* at 170.

54. *Id.* at 168-72.

55. *Id.* at 172.

56. *Id.* at 186.

57. Directorate General for Competition, http://ec.europa.eu/dgs/competition/index_en.htm (last visited Apr. 17, 2009).

58. COMPETITION DIRECTORATE-GENERAL, *supra* note 1.

59. Pharmaceuticals Sector Inquiry, <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html> (last visited Apr. 13, 2009).

that there was often a delay between patent expiration on a pioneer drug and the availability of a generic version.⁶⁰ The findings confirmed that both perceptions are accurate.⁶¹ The research revealed that brand-name drug manufacturers (or originator companies, as the report refers to them) engage in a variety of tactics to delay the entry of generic drugs into the marketplace, including accumulating multiple patents (“patent clusters”) on the same drug (1300 patents on a single drug in one case), suing generic drug companies for patent infringement, making settlement agreements in patent infringement suits that have the effect of delaying generic entry, and intervening in regulatory procedures for the approval of generic drugs.⁶²

The investigation calculated that generic entry lagged behind patent expiration by an average of seven months for the drugs studied.⁶³ The investigators estimated that generic drugs were initially priced twenty-five percent lower than the brand-name drugs they replaced and that within two years the average price of a generic drug was forty percent lower than that of the originator drug on average.⁶⁴ The researchers further estimated that payers would have saved three billion Euros, or more than five percent of the cost of the medicines, if generic versions had been available immediately upon patent expiration.⁶⁵

In the United States, the Hatch-Waxman regime encourages patent litigation over brand-name drugs by granting 180 days of marketing exclusivity to a generic company that makes a Paragraph IV certification and successfully challenges a brand-name drug patent and by enabling the brand-name manufacturer to sue the generic company for patent infringement upon making the Paragraph IV certification.⁶⁶ This system has had the unintended consequence of encouraging settlements in these patent suits that often involve a delay before the generic company begins marketing and a reverse payment

60. COMPETITION DIRECTORATE-GENERAL, *supra* note 1, at 3.

61. *Id.*

62. *Id.* at 7–10.

63. *Id.* at 6.

64. *Id.*

65. *Id.*

66. *See supra* Part II.A.

from the brand-name company to the generic company.⁶⁷ These settlements have drawn scrutiny and lawsuits from the Federal Trade Commission and a vigorous debate among courts and scholars about how to analyze the settlements under antitrust laws.⁶⁸ Although the European countries do not have analogous provisions, patent litigation over drugs abounds in Europe; the Competition Directorate-General's findings noted close to 700 patent cases involving the drugs included in the study.⁶⁹ Although generic companies won sixty-two percent of the cases that came to a final judgment,⁷⁰ the average duration of the suits studied, 2.8 years,⁷¹ suggests the potential for these suits to delay generic entry. Also, the research revealed that these patent lawsuits often ended in settlement agreements with anti-competitive consequences, as happens in the United States. Specifically, of about 200 settlement agreements scrutinized, forty-eight percent included restrictions on the generic's ability to market.⁷² Reverse payments occurred in more than twenty of these settlements, and the total value of these reverse payments was over 200 million Euros.⁷³

The investigators described the legal framework for pharmaceutical products in Europe and how it might be reformed. It was noted that both originator and generic companies favor the creation of a single Community patent and a specialized patent judiciary, changes in the regulatory framework, and changes in pricing and reimbursement rules.⁷⁴

67. See *supra* Part II.A.

68. See *generally* Andersen, *supra* note 30.

69. COMPETITION DIRECTORATE-GENERAL, *supra* note 1, at 8.

70. *Id.*

71. *Id.*

72. *Id.* at 9.

73. *Id.*

74. *Id.* at 13.

III. ANALYSIS

A. THE *ASTRAZENECA* DECISION: APPLYING COMPETITION LAW TO CURB ABUSE BY ORIGINATOR COMPANIES

The Commission's decision in *AstraZeneca* is a seminal one in several respects.⁷⁵ The upshot of the decision is that it puts the competition laws to service in policing abuses of the drug regulatory framework.

Doctrinally, the case holds that the relevant market for a successful blockbuster drug includes only that particular drug, at least where the drug has unique attributes like omeprazole that render it relatively insensitive to price competition with similar drugs. If so-called "me-too" drugs are available, that is, other drugs of the same class with very similar pharmacological properties, perhaps these drugs would have to be included in the relevant product definition. But where a drug is the only one of its kind, it should be relatively easy to show that the manufacturer is in a dominant position after *AstraZeneca*. Moreover, even though the buyer may be in a monopsony position because of nationalized health care, the maker of a one-of-a-kind drug has plenty of bargaining power if the drug has an important function. Because no one can force a company to manufacture a drug, the maker of a blockbuster drug probably has the upper hand. Thus the Commission was probably correct that *AstraZeneca* was in a dominant position.

The more important question is whether the company abused its dominant position. Article 82 provides some examples of abuse of a dominant position:

Such abuse may, in particular, consist in:

- (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- (b) limiting production, markets or technical development to the prejudice of consumers;
- (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no

75. For an excellent analysis of the *AstraZeneca* case, see Matteo Negrinotti, *Abuse of Regulatory Procedures in the Intellectual Property Context: The AstraZeneca Case*, 29 EUR. COMPETITION L. REV. 446 (2008).

connection with the subject of such contracts.⁷⁶

Neither of AstraZeneca's practices, the misleading information to obtain SPCs and the selective de-registration, seem to fit into these pigeonholes. However, Article 82 indicates that abuse "may" consist of these practices, suggesting that the listed abuses are not exclusive.⁷⁷ The Commission decision makes clear that "abuse" is not confined to the listed examples.

Moreover, American antitrust law has condemned practices similar to the ones at issue. For instance, fraudulent procurement of a patent is a violation of section 2 of the Sherman Act if the other elements of monopolization are present.⁷⁸ Also, the Federal Trade Commission has determined that brand-name drug companies that improperly list patents for purposes of obtaining thirty-month stays and delaying generic entry violate section 5 of the Federal Trade Commission Act.⁷⁹ Thus, to the extent that AstraZeneca did mislead patent officials to obtain patent extensions to which it was not entitled, the abuse would likely violate the American antitrust laws.

As for the selective de-registration of Losec, a similar case in the United States involved a brand-name company switching approved formulations in anticipation of a generic entry.⁸⁰ The court held that this could be a violation of section 2 of the Sherman Act, subject to a rule of reason analysis.⁸¹ Under a rule of reason analysis, a court weighs all the circumstances of a case to determine if a particular practice is an antitrust violation, including such factors as information about the relevant business; the practice's nature, effects, and history; and the presence of market

76. Consolidated Version of the Treaty Establishing the European Community, art. 82, Dec. 24, 2002, O.J. (C 325) 65.

77. *Id.*

78. *See* Walker Process Equip. Co. v. Food Mach. & Chem. Corp., 382 U.S. 172, 175 (1965).

79. *See* Bristol-Myers Squibb Co., 135 F.T.C. 444 (2003); Biovail Corp., 134 F.T.C. 407 (2002).

80. *See* Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d. 408, 416-17 (D. Del. 2006).

81. *Id.* at 420-24.

power.⁸² This analysis is to determine if the practice is pro-competitive or anti-competitive.⁸³

It is evident, then, that antitrust law in the United States has been applied to practices such as those AstraZeneca used, so the Commission's application of the competition law had foreign precedent. Indeed, the Commission's use of Article 82 is a step toward harmonization of American and European law regarding efforts to forestall generic drug entry.

It is important for courts to be able to distinguish legitimate business strategies from illegitimate ones. Obtaining SPCs or switching approval for drug formulations could certainly be part of legitimate business strategies. The Commission Decision seemed to recognize this in that it noted that a change in market authorization for a formulation would not normally be considered an abuse.⁸⁴ Critically, the Commission based its conclusions on both practices on the fact that they were aimed at delaying generic entry into the marketplace.⁸⁵

To determine exactly where the line is between a legitimate business practice and abuse of a dominant position, it is instructive to examine another recent case, *SYFAIT v. GlaxoSmithKline*.⁸⁶ In that 2005 case the European Court of Justice held that a refusal by a large pharmaceutical company to fill orders from a wholesaler was not necessarily abuse of a dominant position.⁸⁷ The Court noted the unique aspects of the pharmaceutical industry, including the large framework of legal regulation, the economics of the industry, and the consequences of parallel trade for consumers.⁸⁸ The Court held that a restriction on parallel trade based on a refusal to supply to a wholesaler beyond its specific needs was not an abuse if it was "reasonable and proportionate."⁸⁹ The Court

82. See *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 127 S.Ct. 2705, 2712-13 (2007).

83. *Id.* at 2713.

84. Commission Decision, *supra* note 3, at 170-71.

85. *Id.* at 145, 175.

86. Case C-53/03, *Syfait v. Glaxo Smith Klein AEVE*, 2005 E.C.R. I-4609 (opinion of Advocate General Jacobs).

87. *Id.* ¶ 105.

88. *Id.* ¶¶ 75-100.

89. *Id.* ¶ 100.

determined that in the particular case at hand this condition was satisfied because the restriction on parallel trade would be minimal and the company needed to maintain enough supply on hand for orders from other wholesalers.⁹⁰ The Court noted that a refusal to supply might be found to be an abuse of a dominant position if it had anti-competitive effects other than a minimal restriction on parallel trade.⁹¹

The words “reasonable and proportionate” are Delphic; they indicate in appropriate Article 82 cases an analysis is taken similar to the rule of reason that American courts use.⁹² Moreover, the case suggests that courts should consider the unique aspects of the pharmaceutical industry in this analysis.

Viewing *AstraZeneca* through the lens of *SYFAIT*, then, it is difficult to fathom how supplying misleading information to patent offices could qualify as a reasonable and proportionate measure. It seems axiomatic that conduct that is independently wrong or unlawful is not reasonable and proportionate. Changing the marketing authorization for a drug formulation, on the other hand, could easily be regarded as reasonable and proportionate if there was a business justification other than stalling generic competitors. The Commission was heavily swayed by the fact that *AstraZeneca* had only changed its marketing authorization in countries where this move would have the likely effect of preventing impending generic approval. From this fact it might be inferred that *AstraZeneca*’s main motive was to stymie generic competition.

AstraZeneca and *SYFAIT* offer twin lessons to pharmaceutical companies and courts. The first is that in Europe, as in the United States, more or less overt efforts to prevent generic drug approval run afoul of the competition laws. If a particular action seems likely to restrain generic competition, brand-name companies must take care to document the legitimate business reasons for such action. Second, a lesson for the courts is not to treat these cases

90. *Id.*

91. *Id.* ¶ 104.

92. See, e.g., *Standard Oil Co. v. United States*, 221 U.S. 1, 68 (1911).

too superficially. In some cases, such as an attempt to procure patent rights by misleading patent officials, the conduct can be condemned without much ado. But in other cases involving conduct not otherwise wrong or unlawful, courts should determine if there is a legitimate business reason for the conduct and if any anti-competitive effect involved is reasonable and proportionate in light of such a reason.

B. THE PHARMACEUTICAL SECTOR INQUIRY: POLICY IMPLICATIONS

The Competition Directorate-General's pharmaceutical sector inquiry reflects dissatisfaction on the part of policy makers with the state of the pharmaceutical industry today.⁹³ Two questions emerge: (1) what ails the industry, and (2) what can policymakers (including courts) do about it?

In answering the first question, it is important to understand the complexity of the problems. For example, the inquiry made the preliminary findings that the number of new drugs going to market has been declining lately, and that generic approval often lags behind patent expiration on these drugs.⁹⁴ Even putting these two problems side-by-side, however, the preliminary report did not acknowledge that they involve conflicting priorities. Because generic drug approval brings competition to the marketplace and hence reduces the price of a drug, a necessary consequence is that anything that speeds up generic approval tends to reduce incentives for originator companies to discover new drugs.

While the Competition Directorate-General's findings seemed to focus on examples of practices by brand-name drug manufacturers that thwart generic competition,⁹⁵ generic companies are involved in some anti-competitive practices too, such as collusive settlement agreements to patent litigation suits. Brand-name manufacturers face a host of problems of their own: fewer new drugs in the approval pipeline, competition from generics, a less-friendly regulatory environment, and the potential changes in policy the new U.S. presidential administration and Congress could enact such as drug price controls or re-importation of

93. See generally COMPETITION DIRECTORATE-GENERAL, *supra* note 1.

94. See *supra* Part II.D.

95. See *supra* Part II.D.

drugs from Canada.⁹⁶ Many drug companies are directing a larger portion of their drug development efforts and sales toward developing countries such as China and India, in part because of the less favorable legal and regulatory environments in both Europe and the United States.⁹⁷ Optimal policy therefore requires not only setting a proper balance between the brand-name and the generic industries, but also legal and regulatory reforms that make the business environment more favorable for the whole pharmaceutical industry overall.

The inquiry found about 700 patent litigation cases involving the drugs studied.⁹⁸ This suggests that adoption of additional incentives to encourage litigation over drug patents, such as the Paragraph IV certification and 180-day marketing exclusivity for successful generic challengers in the United States, is unnecessary since patent litigation abounds even without these inducements. The inquiry found that generic companies are already testing the limits of patent rights, and successfully; generics won sixty-two percent of the cases in which a final judgment was reached.⁹⁹ As in the United States, the inquiry found that drug patent litigation often ended in settlement agreements involving restrictions on the generic company's ability to market or reverse payments from the brand-name company to the generic company.¹⁰⁰ On the basis of this finding, the Competition Directorate-General should begin to assume the same role in policing these agreements as the Federal Trade Commission in the United States does. While it is not clear to what extent collusive settlement agreements contribute to the lag in generic entry into the marketplace, the situation in the United States indicates that these agreements should be carefully monitored for anti-competitive effects.

To achieve greater savings from generic drugs, the Commission should consider reform to the patchwork of

96. See *Winds of Change*, ECONOMIST, Dec. 13, 2008, at 75-76; *Racing Down the Pyramid*, ECONOMIST, Nov. 15, 2008, at 76.

97. See *Racing Down the Pyramid*, *supra* note 96, at 76.

98. See COMPETITION DIRECTORATE-GENERAL, *supra* note 1, at 8.

99. *Id.*

100. *Id.* at 9.

reference pricing, price caps, and other regulations that set generic prices. Economists believe this system is less effective at producing low generic prices than the free market system in place in the United States.¹⁰¹

As for improving the business climate for pharmaceuticals overall, the preliminary findings from the inquiry identified several areas in which all stakeholders agree reforms are needed: creation of a single European Community patent, regulatory reform, and changes to pricing and reimbursement schedules.¹⁰² There may be limits to what policy reform can accomplish; some of the industry's problems may be the results of the blockbuster business model having outlived its usefulness and the need to adopt new business strategy. However, there is widespread agreement that legal reforms are needed.

Last but not least, there is certainly a role for the competition laws to play in drug policy. The sector inquiry found that various practices with potential anti-competitive effects are common in Europe, just as they are in the United States.¹⁰³ *AstraZeneca* and *SYFAIT* establish the framework for applying the competition laws in the pharmaceutical context.¹⁰⁴ Here as elsewhere, it is important for courts to see the laws not just as a tool for preventing brand-name company abuses but rather as an instrument for maintaining a proper balance between brand-name and generic drug companies and encouraging a favorable environment for the pharmaceutical industry overall. To this end, in considering whether a particular anti-competitive effect is reasonable and proportionate to the business interests involved, a court might consider such broad policy factors as the state of the brand-name industry or the trend in new drug approvals. If the balance seems to have shifted too far in favor of generic drug makers, for example, a court might be less inclined to condemn a particular practice by a brand-name company. Encouraging new drug development and approval is just as important a policy goal as encouraging generic approval. So in applying the competition laws in pharmaceutical cases, courts

101. See *Patently Absurd*, *ECONOMIST*, Dec. 6, 2008, at 82.

102. COMPETITION DIRECTORATE-GENERAL, *supra* note 1, at 13–14.

103. See *supra* Part II.D.

104. See *supra* Part III.A.

should be as mindful of the policy background as *SYFAIT* exhorted them to be of the factual background.

IV. CONCLUSION

The *AstraZeneca* matter and the European Commission's findings both point to the unsatisfactory condition of the pharmaceutical industry in Europe. There is legitimate cause for concern over tactics by brand-name drug manufacturers to delay the entry of generic drugs into the market. However, the woes facing the drug industry are complex and the brand-name companies should not be singled out as the culprits. Rather, policy makers should consider a whole package of legal and regulatory reforms to improve the business climate for both brand-name and generic companies.

One policy lever available to maintain a competitive balance between brand-name and generic manufacturers is the competition laws. As in the *AstraZeneca* case, the competition laws can be used to restrain abuses of patents or regulatory procedures intended to forestall generic competition. However, courts should be mindful of the challenges facing pioneer drug companies too and should take care not to shift the balance too far in favor of generic drug companies. Like the United States antitrust laws, the European competition laws are a flexible instrument with interpretive leeway that courts can bend to different policy objectives as the situation requires. This has the advantage of not requiring new legislation to implement new policy.