

**DESTROYING A PHARMACEUTICAL
PATENT FOR SAVING LIVES?: A CASE
STUDY OF *SANOFI-SYNTHELABO V.
APOTEX, INC.***

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I. INTRODUCTION

The Abbreviated New Drug Application (“ANDA”) is a short path to drug approval. It was designed to allow a generic drug company to introduce a “bioequivalent” version of a currently-approved, brand-name drug.¹ Particularly, in the ANDA procedure, if a generic drug company challenges the validity of patents protecting a brand-name drug in its application, it could gain a privilege after its application is approved, where it could exclusively share the market of such brand-name drug with the pioneer drug company for 180 days.² But, the privilege is mainly conditioned on whether the pioneer drug company will sue the generic drug company for patent infringement and on whether the generic drug company could succeed in such litigation.³

Plavix®, also known as clopidogrel, is a prescribed drug for preventing heart diseases, such as heart attacks and strokes.⁴ It functions “by preventing disc-shaped elements of the blood called platelets from sticking together.”⁵ In 1972, a French drug company, Sanofi-Synthelabo began to develop Plavix®.⁶ The drug was approved by the U.S. Food and Drug Administration (“FDA”) in 1997.⁷ In the United States, Plavix® is sold by Bristol-Myers Squibb.⁸ The sale of Plavix® brings a huge income to Bristol-Myers Squibb.⁹ Plavix® reached sales of about \$4.9

¹ See Wansheng Jerry Liu, *Balancing Accessibility and Sustainability: How to Achieve the Dual Objectives of the Hatch-Waxman Act While Resolving Antitrust Issues in Pharmaceutical Patent Settlement Cases*, 18 ALB. L.J. SCI. & TECH. 441, 447–48 (2008).

² See *id.* at 449–50.

³ See *id.* at 450.

⁴ See Stephanie Saul, *Marketers of Plavix Outfoxed on a Deal*, N.Y. TIMES, Aug. 9, 2006, <http://www.nytimes.com/2006/08/09/business/09drug.html>.

⁵ Reuters, *Risks with Heart Drug*, N.Y. TIMES, Feb. 6, 2008, <http://query.nytimes.com/gst/fullpage.html?res=9B0CE6D91F3DF935A35751C0A96E9C8B63>.

⁶ Andrew Ross Sorkin, *Sanofi Makes Its Bid for Aventis; It Is Quickly Rejected as ‘Inferior’*, N.Y. TIMES, Jan. 27, 2004, <http://www.nytimes.com/2004/01/27/business/sanofi-makes-its-bid-for-aventis-it-is-quickly-rejected-as-inferior.html>; see *Sanofi-Synthelabo v. Apotex Inc. (Sanofi III)*, 492 F. Supp. 2d 353, 356, 358 (S.D.N.Y. 2007).

⁷ *Sanofi III*, 492 F. 3d at 356.

⁸ See Associated Press, *Bristol-Myers and Wyeth Report Big Gains in Profit*, N.Y. TIMES, July 24, 2009, <http://query.nytimes.com/gst/fullpage.html?res=9907E3DC1639F937A15754C0A96F9C8B63>.

⁹ See Associated Press, *2 Drug Makers See Slowdown, With Mixed Outlooks for Year*, N.Y. TIMES, July 27, 2007, <http://www.nytimes.com/2007/07/27/business/27drug.html>.

billion in 2008,¹⁰ and is the second-best-selling drug in the world.¹¹ Of course, Plavix® is expensive.¹²

Apotex, Inc. (“Apotex”), a Canadian company, submitted to the FDA an ANDA for a generic version of Plavix® in November 2001.¹³ After Apotex submitted its ANDA, the patent holders (hereinafter “Sanofi”) of Plavix® brought a suit against Apotex.¹⁴ After six years of the fight, the patentees won the suit and succeeded in defending the validity of the patent of Plavix® in 2008.¹⁵

However, Sanofi did not have a “happy” ending. During the litigation, both parties were trying to settle the dispute.¹⁶ The settlement would restrict the competition between both parties in the drug market, and therefore was subject to both state and federal antitrust agencies’ approvals.¹⁷ The agencies did not approve the settlement.¹⁸ Although Apotex’s ANDA was approved by the FDA, Apotex did stop launching its generic version of Plavix® for a period of time because of the on-going settlement negotiation.¹⁹ As a result, in 2009, the former vice president of Bristol-Myers Squibb (one of the patent holders), Dr. Andrew G. Bodnar, pled guilty to an antitrust charge, because he made a false statement to the Federal Trade Commission (“FTC”) about the settlement of patent litigation related to Plavix®.²⁰ Interestingly, he was merely sentenced to write a book.²¹

¹⁰ Natasha Singer, *Judge Orders Former Bristol-Myers Executive to Write Book*, N.Y. TIMES, June 9, 2009, <http://www.nytimes.com/2009/06/09/business/09bristol.html>.

¹¹ Natasha Singer, *F.D.A. Panel Approves Lilly Drug for Clotting*, N.Y. TIMES, Feb. 4, 2009, <http://query.nytimes.com/gst/fullpage.html?res=9E0DE4DD1430F937A35751C0A96F9C8B63&sec=&spon=&pagewanted=all>.

¹² Gardiner Harris, *Study Raises Questions on Plavix Safety*, N.Y. TIMES, Jan. 20, 2005, <http://www.nytimes.com/2005/01/20/health/20drugs.html>.

¹³ *Sanofi-Synthelabo v. Apotex, Inc. (Sanofi IV)*, 550 F.3d 1075, 1078 (Fed. Cir.2008); *see also*, About Apotex, APOEX.COM, <http://www.apotex.com/global/about/default.asp> (last visited Dec. 19, 2010).

¹⁴ *Sanofi-Synthelabo v. Apotex, Inc. (Sanofi I)*, 488 F. Supp. 2d 317, 322 (S.D.N.Y. 2006).

¹⁵ *Sanofi IV*, 550 F.3d at 1078.

¹⁶ *Sanofi I*, 488 F. Supp. 2d at 323–24.

¹⁷ *Id.* at 324.

¹⁸ *Id.*

¹⁹ *Id.* at 323–24.

²⁰ *See* Stephanie Saul, *Drug Executive is Indicted on Secret Deal*, N.Y. TIMES, Apr. 24, 2008, <http://www.nytimes.com/2008/04/24/business/24bristol.html>; Plea Agreement, United States v. Andrew Bodnar, No. 1:08-00115 (D.D.C. 2009), *available at* <http://www.justice.gov/atr/cases/f244500/244552.pdf>.

²¹ *See* Natasha Singer, *Judge Orders Former Bristol-Myers Executive to Write*

ANDA is designed for making medicines “cheaper and more affordable to the public.”²² ANDA is supposed to encourage drug companies’ competition in the market of a generic drug.²³ Specifically, ANDA is intended to induce a generic drug company to challenge a pioneer drug company in the market of such pioneer drug company’s brand-name drug.²⁴ But, the story of *Sanofi-Synthelabo v. Apotex, Inc.* reveals that ANDA’s objectives are not always fulfilled.²⁵ That is, the generic drug company failed in its patent challenge, and the pioneer drug company committed an antitrust crime during the ANDA fight between these two companies.²⁶

This essay reviews and criticizes the current ANDA system, and proposes a modification of the system. The essay examines the ANDA system by using *Sanofi-Synthelabo v. Apotex, Inc.*, as an example of how it works. Part II presents the factual background of the case, including the technology, disputed patent, procedural history, legal issues, and antitrust charge. Part III describes ANDA by focusing on the statutory provisions related to the challenge against a brand-name drug patent. Part IV discusses what is learned from *Sanofi-Synthelabo v. Apotex, Inc.* by examining the policy reasons supporting ANDA and the policy criticisms against it and offering ideas for improving the system to strike a better balance between drug innovation and drug affordability.

II. FACTUAL BACKGROUND OF SANOFI-SYNTHELABO V. APOTEX, INC.

A. Drug at Issue-Plavix®

1. Therapeutic Effects of Plavix®

Plavix® is an agent which inhibits platelet aggregation (or blood clotting).²⁷ The platelet aggregation increases the

Book, N.Y. TIMES, June 8, 2009, <http://www.nytimes.com/2009/06/09/business/09bristol.html>.

²² See Liu, *supra* note 1, at 443.

²³ See *id.*

²⁴ See *id.* at 447–48.

²⁵ *Id.* at 443, 479–80.

²⁶ *Id.* at 479–80.

²⁷ *Sanofi-Synthelabo v. Apotex, Inc. (Sanofi II)*, 470 F.3d 1368, 1372 (Fed. Cir. 2006); see Corey Schaecher, Comment, “Ask Your Doctor If this Product is

probability of heart attack and stroke, because aggregates block arteries and ischemia (a restriction in blood supply) follows the blockage.²⁸ Additionally, strokes also result from “blockages of cerebral arteries or carotid arteries [which feed] blood to the brain.”²⁹ Because Plavix® can prevent blood clotting, it could reduce heart attacks and strokes.³⁰ However, Plavix® has been alleged to cause a brain hemorrhage of a patient who took Plavix® after a cardiac catheterization and stenting procedure.³¹

2. Development of Plavix®

Plavix® has its grandma version which is “Ticlid,” the brand name of Ticlopidine.³² The idea of developing Ticlopidine came from a drug, tinoridine, which has anti-inflammatory properties.³³ “Ticlopidine is a member of a class of chemical compounds known as thienopyridines.”³⁴ Therefore, Sanofi organized a team to synthesize member compounds of thienopyridines.³⁵ During 1972 and 1973, Sanofi tested several compounds, and eventually found ticlopidine had anti-platelet-aggregation properties.³⁶

Ticlopidine was first used as a drug in France in 1978 and in the United States in 1991.³⁷ However, Sanofi found that “Ticlid” had some side effects, for instance, blood disorders known as neutropenia and thrombotic thrombocytopenic purpura (“TTP”).³⁸ The FDA also asked Sanofi to attach a warning to Ticlid products.³⁹

Since Ticlopidine was invented, Sanofi had improved it by synthesizing new derivatives.⁴⁰ Sanofi finally developed a new

Right for You”: Perez V. Wyeth Laboratories, Inc., Direct-To-Consumer Advertising and the Future of the Learned Intermediary Doctrine in the Face of the Flood of Vioxx(R) Claims, 26 ST. LOUIS U. PUB. L. REV. 421, 452 (2007).

²⁸ See Schaecher, *supra* note 27, at 452.

²⁹ *Id.*

³⁰ See Saul, *supra* note 4.

³¹ See, e.g., Allison Torres Burtka, *Lawsuits Question Safety and Efficacy of Plavix*, 43 TRIAL 74, 74 (2007).

³² *Sanofi III*, 492 F. Supp. 2d. at 358–59.

³³ *Id.* at 358.

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.* at 359–62.

compound named as PCR 4099.⁴¹ Because PCR 4099 was not an appropriate drug format, Sanofi continued to discover a right crystalline salt of PCR 4099.⁴² Luckily, Sanofi found the bisulfate salt of PCR 4099 was a highly suitable pharmaceutical formulation.⁴³ While doing research about PCR 4099, Sanofi also found clopidogrel, which is another format of PCR 4099.⁴⁴

After a series of tests, clopidogrel bisulfate was shown to be better than the bisulfate salt of PCR 4099.⁴⁵ As a result, Sanofi stopped the project of PCR 4099, and went on with clopidogrel.⁴⁶ Later, clopidogrel bisulfate was launched in the drug market as Plavix®.⁴⁷ It started to replace Ticlopidine.⁴⁸

3. Drug Market of Plavix®

Plavix® is a very successful drug. The records for the total U.S. net sales in 2005, 2006, 2007, and 2008 are 3,235,000,000 USD, 2,655,000,000 USD, 4,060,000,000 USD, and 4,920,000,000 USD, respectively.⁴⁹ In 2008, Plavix® represented 92.5 percent of the U.S. market for blood-thinning pills.⁵⁰ Doubtlessly, Plavix® provides a huge income to Bristol-Myers Squibb.

⁴¹ *Id.* at 361.

⁴² *Id.* at 367, 371–73, 375.

⁴³ *Id.* at 376.

⁴⁴ *Id.* at 373, 375–76; *see also Sanofi I*, 488 F. Supp. 2d 317, 329 (“The first of the 21 examples in the ‘596 patent is a thienopyridine racemate entitled ‘methyl alpha-5(4,5,6,7-tetrahydro (3,2-c) thienopyridyl)(2-chlorophenyl) acetate.’ Sanofi referred to this compound internally as ‘PCR 4099.’ PCR 4099 was described in the ‘596 patent as a hydrochloride salt. The later patent, that is, the ‘265 patent which is at issue here, claims the “[h]ydrogen sulfate of the dextro-rotatory enantiomer of methyl alpha-5(4,5,6,7-tetrahydro (3,2-c) thienopyridyl)(2-chlorophenyl) acetate. In other words, the ‘265 patent claims the dextrorotatory enantiomer of the racemate PCR 4099, which has been given the generic name ‘clopidogrel,’ prepared as a bisulfate salt.”) (alteration in original) (citations omitted).

⁴⁵ *Sanofi III*, 492 F. Supp. 2d. at 376–77.

⁴⁶ *Id.* at 378.

⁴⁷ *Id.* at 380.

⁴⁸ *Id.* at 380–81.

⁴⁹ *See e.g.*, BRISTOL-MYERS SQUIBB CO., BIOPHARMA: OUR STRATEGY IN ACTION 2008 ANNUAL REPORT 10 (2008), *available at* <http://www.annualreports.com/HostedData/AnnualReports/PDFArchive/bmy2008.pdf>; BRISTOL-MYERS SQUIBB CO., BIOPHARMA THE NEXT GENERATION 2007 ANNUAL REPORT 14 (2007), *available at* <http://www.annualreports.com/HostedData/AnnualReports/PDFArchive/bmy2007.pdf>.

⁵⁰ *See Singer, supra* note 11 (comparing the global market value of Bristol-Myer’s drug Plavix between 2007 and 2008).

B. Patent at Issue- U.S. Patent No. 4,847, 265

1. Technology

Clopidogrel bisulfate is covered by Sanofi's U.S. Patent No. 4,847,265 ("265 patent").⁵¹ The '265 patent was issued on July 11, 1989, and will expire on November 17, 2011.⁵² The '265 patent claims "[h]ydrogen sulfate of dextrorotatory enantiomer of methyl alpha-5(4,5,6,7-tetrahydro(3,2-c) thienopyridyl(2-chlorophenyl) acetate."⁵³ The enantiomers can be divided into two types, dextrorotatory enantiomer and levorotatory enantiomer.⁵⁴ These two kinds of enantiomer are mirror images of each other.⁵⁵ In addition, they have identical physical properties, such as melting temperature, except that when a plane of polarized light is directed through a solution of either of these enantiomers, a dextrorotatory enantiomer rotates the light plane to the right, but a levorotatory enantiomer rotates the light plane to the left.⁵⁶

2. Patent Invalidity Issues

The issues of patent invalidity included novelty, obviousness, double-patenting and inequitable conduct.⁵⁷ Apotex claimed that Sanofi's own patent, U.S. Patent No. 4,529,596 ("596 patent"), anticipated the '265 patent,⁵⁸ that the '265 patent was obvious because the result of the invention was not unexpected,⁵⁹ that the '265 patent was invalid according to "the judicial doctrine of obviousness-type double patenting,"⁶⁰ and that the '265 patent was unenforceable under the doctrine of inequitable conduct because Sanofi failed to list one inventor, made a false statement regarding the unexpected properties of the invention, and failed to disclose a material prior art to the United States Patent and Trademark Office ("USPTO").⁶¹

⁵¹ *Sanofi I*, 488 F. Supp. 2d 317, 321–22 (S.D.N.Y. 2006).

⁵² *Id.* at 322.

⁵³ *Id.* at 329.

⁵⁴ *Id.* at 328.

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.* at 323. Other affirmative defenses include laches and unclean hands.

See *id.* at 346, 348.

⁵⁸ *Sanofi II*, 470 F.3d 1368, 1374 (Fed. Cir. 2006).

⁵⁹ *Id.* at 1378.

⁶⁰ *Sanofi I*, 488 F. Supp. 2d at 323.

⁶¹ *Id.*

C. Procedural History

1. Abbreviated New Drug Application

Apotex applied for the ANDA of its generic version of clopidogrel bisulfate tablets in November 2001.⁶² In its ANDA, Apotex certified that the '265 patent is invalid.⁶³ Sanofi then filed a law suit against Apotex on March 21, 2002.⁶⁴ Consequently, the ANDA approval proceeding was stayed. But, the stay expired on May 17, 2005.⁶⁵ The FDA eventually approved the ANDA on January 20, 2006.⁶⁶

2. Patent Infringement Litigation

Under 35 U.S.C. § 271(e), if a generic drug company files the ANDA of a drug, the pioneer company of such drug can bring a patent infringement complaint in a federal district court.⁶⁷ Sanofi began its litigation on March 21, 2002.⁶⁸ On May 7, 2004, a court order was issued, saying that both parties agreed that Apotex's drug infringed claim 3 of the '265 patent.⁶⁹

Originally, the district court scheduled a trial in March 2006.⁷⁰ However, both parties had gone through a series of negotiations, and reached two temporary settlement agreements subject to the approvals of the FTC and state antitrust agencies.⁷¹ Thus, the trial did not occur. In one agreement, Apotex preserved a right to declare "regulatory denial" followed by a resume of the pending litigation.⁷²

On July 31, 2006, Apotex declared "regulatory denial."⁷³ After one week, Apotex launched its generic version of Plavix®.⁷⁴ Consequently, Sanofi filed a motion for preliminary injunction against Apotex on August 15, 2006, and it also requested a recall

⁶² *Id.* at 322.

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.* at 323.

⁶⁶ *Id.* at 323.

⁶⁷ *See id.* at 322–23.

⁶⁸ *Id.* at 322.

⁶⁹ *Id.* at 323.

⁷⁰ *Id.*

⁷¹ *Sanofi II*, 470 F.3d 1368, 1373 (Fed. Cir 2007).

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

of sold drugs.⁷⁵ “After a two-day evidentiary hearing, the district court granted the [preliminary injunction] on August 31, 2006, but denied the request for recall.”⁷⁶ The district court imposed a bond of 400 million USD on Sanofi, and scheduled a trial on January 22, 2007.⁷⁷

Apotex appealed to the Federal Circuit, and asked for a stay of the injunction.⁷⁸ The Federal Circuit denied the stay on September 21, 2006, and scheduled an oral argument on October 31, 2006.⁷⁹ Eventually, the Federal Circuit affirmed the district court’s injunction on December 8, 2006.⁸⁰ Thus, the case returned to the district court.⁸¹

From January 22 to February 15, 2007, the district court set a bench trial to adjudicate the facts surrounding the validity and unenforceability issues.⁸² The district court finally held that the ‘265 patent was valid and enforceable.⁸³ Apotex appealed again, and limited the issues to patentability.⁸⁴ The Federal Circuit affirmed the district court’s decision again on December 12, 2008.⁸⁵ There are no more pending cases regarding the patent disputes between Sanofi and Apotex.

3. Antitrust Charge

The patent dispute between Sanofi and Apotex was surrounded by a scheme of anti-competition.⁸⁶ The FDA stayed the ANDA approval proceeding until May 17, 2005.⁸⁷ After that, Apotex

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.* at 1374.

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Sanofi III*, 492 F. Supp. 2d 353, 358 (S.D.N.Y.)

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Sanofi IV*, 550 F.3d 1075, 1078 (Fed. Cir. 2008).

⁸⁴ *Id.*

⁸⁵ *Id.* at 1075, 1090.

⁸⁶ See Christopher Fasel, *Patent Term Limits, Anti-Trust Law, and the Hatch-Waxman Act: Why Defense of a Legally Granted Patent Monopoly Does Not Violate Anti-Trust Laws*, 17 KAN. J.L. & PUB. POL’Y 109, 123 (2007) (“The conflict between Apotex and BMS is a functional example of how overly enthusiastic regulatory interference from the FTC can inhibit the progress of the court system and actually create a more anti-competitive situation than would exist if the litigants were allowed to settle in their own natural manner.”).

⁸⁷ *In re Bristol Myers Squibb Co. Sec. Litig.*, 586 F. Supp. 2d 148, 152–53 (S.D.N.Y. 2008).

immediately started to produce its generic Plavix®, and prepared for selling the drug.⁸⁸ Thus, Bristol-Myers Squibb began to seek a settlement with Apotex.⁸⁹

The first settlement agreement was made in March 2006, and was subject to the review and approval of the FTC and the state attorneys general of all fifty states.⁹⁰ In May 2006, the states rejected to approve the first settlement agreement, so both parties began to negotiate again.⁹¹ The second settlement agreement was quickly reached, and was still subject to federal or state governments' approvals.⁹² The second settlement contained a written agreement and an oral agreement.⁹³

In the beginning, only the written agreement was submitted to governmental agencies.⁹⁴ However, on June 5, 2006, Apotex disclosed to the Department of Justice that the submitted written agreement was incomplete.⁹⁵ Consequently, the FTC asked both parties to certificate that there were no side agreements to the second settlement agreement and that both parties had not made any promises that were not explicitly written down in the second settlement agreement.⁹⁶

On June 12, 2006, Bristol-Myers Squibb filed the requested certification.⁹⁷ On July 26, 2006, one month later, the Federal Bureau of Investigation (“FBI”) began a criminal investigation about the settlements.⁹⁸ “[O]n May 10, 2007, Bristol-Myers Squibb agreed to plead guilty to two counts of making false statements to the government” regarding its settlement with Apotex.⁹⁹ “On June 11, 2007, . . . Bristol-Myers [Squibb] . . . plead guilty to two felony counts of fraud in violation of 18 U.S.C. § 1001.”¹⁰⁰

⁸⁸ *Id.* at 153.

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.* at 155.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.* at 156.

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.* at 157.

¹⁰⁰ *Id.*

III. ABBREVIATED NEW DRUG APPLICATION

A. *Hatch-Waxman Act*

1. Purposes of the Hatch-Waxman Act

The Hatch-Waxman Act, also known as the Drug Price Competition and Patent Term Restoration Act of 1984, was enacted in 1984.¹⁰¹ The purposes of the Hatch-Waxman Act include increasing prescription drug availability and reducing patients' costs of drugs.¹⁰² To achieve the goals, the Hatch-Waxman Act allows a company seeking a generic drug approval to bypass the testing and proof of the safety and efficacy of such generic drug.¹⁰³ The price of the generic drug is expected to be lower than that of its brand-name drug, because the company does not have to invest a lot of money on the drug discovery and the clinic trials.¹⁰⁴ The procedure for generic drug applications is called "abbreviated new drug application."¹⁰⁵

2. Modification of the Act

In addition to simplifying the new drug approval procedure, the Hatch-Waxman Act provides another incentive which grants to a generic drug company who first challenges the patents protecting the brand-name drug a 180-day exclusive right by which the generic drug company can share the drug market with the pioneer drug company.¹⁰⁶ But, if the pioneer drug company disagrees with the challenge, it can bring a lawsuit, asserting

¹⁰¹ Fasel, *supra* note 86, at 112.

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ Liu, *supra* note 1, at 447.

¹⁰⁵ Melissa Ganz, *The Medicare Prescription Drug, Improvement, & Modernization Act of 2003: Are We Playing the Lottery with Healthcare Reform?*, 2004 DUKE L. & TECH. REV. 11, 10 (2004), available at <http://www.law.duke.edu/journals/dltr/articles/pdf/2004DLTR0011.pdf>.

¹⁰⁶ See Yana Pechersky, Note, *To Achieve Closure of the Hatch-Waxman Act's Loopholes, Legislative Action Is Unnecessary: Generic Manufacturers are Able to Hold Their Own*, 25 CARDOZO ARTS & ENT. L.J. 775, 776-77 (2007); see also Anne-Marie C. Yvon, Note, *Settlements Between Brand and Generic Pharmaceutical Companies: A Reasonable Antitrust Analysis of Reverse Payments*, 75 FORDHAM L. REV. 1883, 1895 & n.111 (2006) ("The exclusivity period allows the first-to-file applicant to compete solely with the brand company for 180 days and provides a strong incentive for generic companies to 'challenge weak or narrow drug patents.'").

patent infringement of the generic drug company.¹⁰⁷ The act will cause the marketing of the generic drug to stay for thirty months.¹⁰⁸

In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“Medicare Act of 2003”) to fix some problems, the most serious one of which was about manipulation by pioneer drug companies.¹⁰⁹ In the old system, pioneer drug companies manipulated the system by adding another patent claimed to cover the brand-name drug at dispute.¹¹⁰ So, generic drug companies had to challenge those additional patents again and again.¹¹¹ Then, the thirty-month stay could continue.¹¹² In the new system, the stay is only triggered by the original patents claimed to protect the brand-name drug at dispute.¹¹³

3. Basic Requirements of the Abbreviated New Drug Application

a. Existence of Prior New Drugs

To file an ANDA, there must be a prior approval of a brand-name drug (original new drug).¹¹⁴ The information of such brand-name drug is collected in Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, published by the FDA.¹¹⁵ Additionally, the Orange Book

¹⁰⁷ Pechersky, *supra* note 106, at 782.

¹⁰⁸ *Id.*

¹⁰⁹ *See id.* at 777 (“[T]his amendment eliminated the practice by brand name manufacturers of using a string of thirty-month stays to keep generic entrants off the market.”).

¹¹⁰ *Id.* at 782.

¹¹¹ *See id.* at 782–83 (“[E]ach new patent entry attached to a specific brand name drug required a separate notice of Paragraph IV certification, and each time such notice was issued . . . a new infringement lawsuit was initiated and a new thirty-month stay period was triggered.”).

¹¹² *Id.*

¹¹³ *See id.* (“[T]he Medicare Act of 2003 . . . requir[es] Paragraph IV certifications to cover only those patents that are listed in the Orange Book at the time of the initial ANDA filing, and . . . limit[s] the number of thirty-month stays that may be granted to just one.”).

¹¹⁴ *See Fasel, supra* note 86, at 112. (“An ANDA allows an applicant to incorporate safety and efficacy test results conducted by a prior NDA applicant into its application so long as the active ingredient in the generic drug is the same as, or the ‘bioequivalent’ of, the active ingredient in the NDA.”).

¹¹⁵ Pechersky, *supra* note 106, at 780; *see also* 21 U.S.C. § 355 (j)(7)(A) (2010) (listing the information made available to the public in the Orange Book).

lists the corresponding patents of such brand-name drug.¹¹⁶

b. Required Information

A generic drug company has to provide eight pieces of information. The first six pieces are required to show that a generic drug is the same as its corresponding brand-name drug: (1) the uses of the generic drug;¹¹⁷ (2) the active ingredients;¹¹⁸ (3) “the route of administration, the dosage form, and the strength of the [generic] drug”;¹¹⁹ (4) the bioequivalence;¹²⁰ (5) the labeling;¹²¹ and (6) the contents of the generic drug.¹²²

The last two pieces of the required information are about the patents related to the brand-name drug. First, a generic drug company has to file a certificate to show any of the following four situations: (1) no patent has been filed; (2) the patents have expired; (3) the patents will expire on specific dates; (4) the patents are invalid or not infringed.¹²³ Second, if the patents claim a method of use, the generic drug company must state that the claimed uses do not cover the uses of its generic drug.¹²⁴

B. Patent Invalidity Challenge from a Generic Drug Company

1. Paragraph IV Certification

A Paragraph IV certification is provided by 21 U.S.C. § 355 (j)(2)(A)(viii)(IV), where a generic drug company has to certify that the patents listed in the Orange Book and protecting the brand-name drug are “invalid or will not be infringed by the

¹¹⁶ Pechersky, *supra* note 106, at 780.

¹¹⁷ 21 U.S.C. § 355 (j)(2)(A)(i) (2010).

¹¹⁸ § 355 (j)(2)(A)(ii).

¹¹⁹ § 355 (j)(2)(A)(iii).

¹²⁰ § 355 (j)(2)(A)(i), (iv).

¹²¹ § 355 (j)(2)(A)(v), (C)(i)-(ii).

¹²² *See* § 355 (j)(2)(A)(vi), (b)(1)(B)-(F) (requiring that an ANDA include the components, composition, manufacturing methods, sampling, and labeling of, and for, the drug).

¹²³ § 355 (j)(2)(A)(vii), (b)(2)(A)(i)-(iv).

¹²⁴ *See* § 355 (b)(1) (“The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.”).

manufacture, use, or sale” of the generic drug.¹²⁵

After submitting a Paragraph IV certification, under 21 U.S.C. § 355 (j)(2)(B), the generic drug company has an obligation to notify the owners of the patents certificated.¹²⁶ First, the generic drug company has to make a statement in the certification that it will give notice.¹²⁷ Second, the timing of the notice is no later than twenty days after the date of the postmark of the FDA notice regarding the receipt of the ANDA application.¹²⁸ But, if the certification is made after the ANDA application, the generic drug company has to give notice at the time of the late submission of the certification.¹²⁹ Third, the notice should be given to the patent owners or the holders of the approval of the brand-name drug.¹³⁰ Lastly, the contents of the notice must include legal and factual grounds which support the assertions required by 21 U.S.C. § 355 (j)(2)(A)(vii)(IV).¹³¹

2. Responses from a Pioneer Drug Company

Under 35 U.S.C. § 271 (e)(2)(A) and (C)(ii);

[i]t shall be an act of infringement to submit—(A) an application under [21 U.S.C. § 355 (j)] for a drug claimed in a patent or the use of which is claimed in a patent, . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.¹³²

Therefore, the filing of a Paragraph IV certification creates a cause of action for the patent owner to sue a generic drug company for patent infringement.¹³³

If the patent owner does not bring an action for patent

¹²⁵ § 355 (j)(2)(A)(vii)(IV); *see also* Pechersky, *supra* note 106, at 780 (describing the certification requirement under the Hatch-Waxman Act).

¹²⁶ § 355 (j)(2)(B)(i), (iii).

¹²⁷ § 355 (j)(2)(B)(i).

¹²⁸ § 355 (j)(2)(B)(ii)(I).

¹²⁹ § 355 (j)(2)(B)(ii)(II).

¹³⁰ § 355 (j)(2)(B)(iii)(I)-(II).

¹³¹ § 355 (j)(2)(B)(iv)(II), (A)(vii)(IV).

¹³² 35 U.S.C. § 271 (e)(2)(A), (C)(ii) (2010); *Section Number Reference: Federal Food, Drug, and Cosmetic Act*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/ucm086299.htm> (last updated Apr. 30, 2009) (showing that FD&C Act Number 505 corresponds with 21 U.S.C. § 355).

¹³³ Fasel, *supra* note 86, at 112–13.

infringement within forty-five days after the filing date of the ANDA application, the ANDA application will be approved.¹³⁴ Then, the generic company will start to share the market of the brand-name drug. On the other hand, if the patent infringement litigation is brought on time, the FDA will stop the review of the ANDA application for thirty months starting from the date on which the generic drug company made a statement of a Paragraph IV certification to the FDA.¹³⁵

3. Declaratory Judgment against Other Relative Patents in the Orange Book

Once a generic drug company submits a Paragraph IV certification, it has standing to request a federal district court to declare either that the patents related to the brand-name drug are invalid or that its generic drug does not infringe the patents.¹³⁶ But, there are three limitations under 21 U.S.C. § 355 (j)(5)(C)(i)(I). First, the suit should be brought within forty-five days after the notice was given to the designated recipients.¹³⁷ Second, neither the patent owners nor the holders of the brand-name drug have brought a suit against the generic drug company regarding the ANDA application.¹³⁸ The third limitation is specifically related to an assertion of non-infringement.¹³⁹ The notice of the Paragraph IV certification should include an offer of confidential access, and such offer should indicate that the generic drug company is willing to disclose the information regarding the non-infringement issue.¹⁴⁰

Additionally, there are some exceptions to the second limitation. If there are more than one patents related to the brand-name drug but the suit regarding patent infringement is based only on one patent, the generic drug company still can ask for a declaratory judgment against the other patents listed in the

¹³⁴ § 355 (j)(5)(B)(iii).

¹³⁵ See § 355 (j)(5)(B)(iii).

¹³⁶ See Ankur N. Patel, Comment, *Delayed Access to Generic Medicine: A Comment on the Hatch-Waxman Act and the "Approval Bottleneck"*, 78 FORDHAM L. REV. 1075, 1091–92 (2009).

¹³⁷ § 355 (j)(5)(C)(i)(I)(aa); 35 U.S.C. § 271 (e)(5).

¹³⁸ § 355 (j)(5)(C)(i)(I)(bb).

¹³⁹ § 355 (j)(5)(C)(i)(I)(cc).

¹⁴⁰ § 355(j)(5)(C)(i)(I)(cc), (III) (“Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent . . . and may not disclose information of no relevance to any issue of patent infringement . . .”).

Orange Book.¹⁴¹ Even though the patentee unilaterally grants a covenant not to sue regarding the other patents, the generic drug company might still ask for a declaratory judgment.¹⁴² In those situations, no 21 U.S.C. § 355 (j)(5)(C)(i)(I) limitations apply.

C. Benefits and Risks of the Generic Drug Company

1. 180-Day Exclusivity Period of the Market Shared with the Pioneer Drug Company

If the patent owner does not sue the generic drug company or the generic drug company succeeds in arguing invalidity or non-infringement, the generic drug company can win a 180-day exclusivity period.¹⁴³ The period starts from the date of the first commercial marketing of the generic drug.¹⁴⁴ During the period, other ANDA applications cannot be effective.¹⁴⁵ Therefore, the 180-day exclusivity period can make the generic drug company promote the generic drug and retain a customer basis.¹⁴⁶ After gaining the loyalty of customers, the generic drug company can establish a barrier against the following generic drug manufacturers.¹⁴⁷

¹⁴¹ See, e.g., *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1334–35, 1340–41, 1343 (Fed. Cir. 2007) (holding that a generic drug company was entitled to declaratory judgment on “any or all” Orange Book patents where the declaratory judgment action and the infringement action by the brand-name drug company arose from the same controversy created by the generic drug company’s ANDA and paragraph IV certification).

¹⁴² See, e.g., *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1289–91, 1293, 1296–97 (Fed. Cir. 2008) (holding that even though a patentee drug company had granted a covenant not to sue, a controversy still existed entitling a generic drug company to file an action for a declaratory judgment when such an action is otherwise necessary to allow the FDA to approve the ANDA filed by the generic drug company).

¹⁴³ See *Fasel*, *supra* note 86, at 113–14 (describing a generic drug company’s incentives for filing an ANDA with a paragraph four certification).

¹⁴⁴ 21 U.S.C. § 355 (j)(5)(B)(iv)(I).

¹⁴⁵ See *id.* § 355 (j)(5)(B)(iv)(II)(aa) (“The term ‘180-day exclusivity period’ means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.”).

¹⁴⁶ *Pechersky*, *supra* note 106, at 780–81.

¹⁴⁷ See *id.* (explaining that 180 days as the “sole offeror of a lower-priced alternative to the brand name [drug]” allows the generic manufacturer to retain a greater market share even after the end of its exclusivity period).

2. Failure in the Patent Litigation

If the generic drug company loses the patent litigation, it will face three negative effects under 35 U.S.C. § 271 (e)(4). First, the court can decide the effective date of the ANDA application of the generic drug company, and the effective date should be later than the date of the expiration of the patent at dispute.¹⁴⁸ Second, the court can grant injunctive relief against the generic drug company, and “prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of [the generic drug].”¹⁴⁹ Third, the court can award damages or other monetary relief to the patent owner, “if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of [the generic drug].”¹⁵⁰

3. Settlement between the Pioneer Drug Company and Generic Drug Company

To avoid the consequences of losing the patent litigation, the generic drug company can settle the case with the patent owner. However, if such settlement results in violating the antitrust laws, the 180-day exclusivity period will be forfeited.¹⁵¹ The forfeiture is established if the violation is affirmed by the FTC or the court in an antitrust case brought by the FTC or the Attorney General of the United States.¹⁵²

IV. LESSONS FROM SANOFI-SYNTHELABO V. APOTEX, INC.

A. *Incentives of a Generic Drug Company to Challenge a Pioneer Drug Company*

The story of *Sanofi-Synthelabo v. Apotex, Inc.* is what Congress expected. Apotex was so ready to promote its generic Plavix®. After the expiration of the 30-month stay and the FDA approval, Apotex launched the marketing of the generic drug.¹⁵³ The

¹⁴⁸ § 271 (e)(4)(A) (2010).

¹⁴⁹ § 271 (e)(4)(B).

¹⁵⁰ § 271 (e)(4)(C).

¹⁵¹ § 355 (j)(5)(D)(i)(V) (2010).

¹⁵² § 355 (j)(5)(D)(i)(V).

¹⁵³ *Sanofi I*, 488 F. Supp. 2d at 323, 325 (S.D.N.Y. 2006); see also Saul, *supra* note 4 (stating that Apotex began selling generic Plavix® following FDA approval of its formulation and several years of patent litigation).

generic version was priced about 30 % lower than Plavix®.¹⁵⁴ The sale was very successful, because, “in the [first] three weeks since [the] launch,” Apotex’s drug had reached about 75% of the Plavix® market in the United States.¹⁵⁵ Although the generic Plavix® was eventually precluded from the market by preliminary injunction in 2006,¹⁵⁶ Bristol-Myers Squibb expected to lose its revenue of Plavix® after the patent expires.¹⁵⁷

At the same time, the patent owner fought for the validity of the patent and the infringement. But, in the beginning of the case, both parties had intended to settle. There might be some reasons. First, the substantial market players of Plavix® are only Bristol-Myers Squibb and Apotex.¹⁵⁸ Obviously, the settlement might optimize both parties’ advantages. Bristol-Myers Squibb might maintain the profitability of the Plavix® sale, while Apotex could avoid the cost of the patent litigation or the competition of Bristol-Myers Squibb’s authorized generic drugs.¹⁵⁹ Second, the antitrust limitation on the 180-day exclusivity period seems to provide an incentive for the settlement in this case. 21 U.S.C. § 355(j)(5)(D)(i)(V) does not completely ban a settlement between the generic drug company and pioneer drug company.¹⁶⁰ Rather, the forfeiture depends on whether the FTC could take an action and win.¹⁶¹ Understandably, Apotex could wait to see whether Bristol-Myers Squibb could provide an appropriate offer that the federal anti-trust agencies could agree with.

Therefore, *Sanofi-Synthelabo v. Apotex, Inc.* tells us that the

¹⁵⁴ Saul, *supra* note 4.

¹⁵⁵ Pechersky, *supra* note 106, at 800–01 (alteration in original).

¹⁵⁶ *See id.* at 796, 799–800.

¹⁵⁷ *See* Bloomberg News, *New Chairman at Drug Maker*, N.Y. TIMES, Feb. 13, 2008, <http://www.nytimes.com/2008/02/13/business/13bristol.html> (stating that Bristol-Myers Squibb “prepar[ed] for the loss of more than \$3 billion in annual revenue in 2012” due to competition from generic Plavix).

¹⁵⁸ *See* Andrew Pollack, *Novartis Buys Rights to a Drug to Thin Blood*, N.Y. TIMES, Feb. 12, 2009, <http://www.nytimes.com/2009/02/12/health/12portola.html>. There might be a provider of alternatives in the future. *See id.*; *see also* Duff Wilson, *Challenge Arises over an F.D.A. Panel’s Approval of a Lilly Drug*, N.Y. TIMES, Mar. 3, 2009, <http://www.nytimes.com/2009/03/03/health/policy/03lilly.html> (stating that “prasugrel, a blood thinner intended to replace Plavix®,” was approved by the FDA in 2009).

¹⁵⁹ *See* Pechersky, *supra* note 106, at 783, 797 (explaining how a pioneer drug company could defeat the marketing of a generic drug company by authorizing another generic drug company to sell a lower-price drug).

¹⁶⁰ 21 U.S.C. § 355 (j)(5)(D)(i)(V) (2010).

¹⁶¹ *Id.*

Hatch-Waxman Act might create an incentive for a pioneer company and a generic drug company to consider an option of not competing against each other. On one hand, Congress wants to lower drug prices. On the other hand, a generic drug company wants to share the market that exclusively belongs to the pioneer company.

B. Feasibility of Challenging the Patentability of a Brand-name Drug

The Hatch-Waxman Act designed a system to trigger generic drug companies to attack pharmaceutical patents owned by or licensed to pioneer drug companies. In the mind of Congress, drug patents seem to be easily challengeable. That view might be based on a traditional critique that the USPTO is not an effective gatekeeper to bar silly or unnecessary patents.¹⁶² However, the feasibility of challenging the patentability of a brand-name drug could be questionable. The intent to create an incentive to destroy drug patents might be too optimistic.

In order to get a patent, a brand-name drug has to be novel¹⁶³ and non-obvious.¹⁶⁴ The patent application of the brand-name drug has to fulfill written requirements.¹⁶⁵ The story behind *Sanofi-Synthelabo v. Apotex, Inc.* reflects a scenario where a drug developer discovers several derivatives from the original chemical compound.¹⁶⁶ Because the patents for those derivatives are filed at different occasions, one derivative might render another derivative not novel or obvious.¹⁶⁷

The most serious challenge could be obviousness as here in *Sanofi-Synthelabo v. Apotex, Inc.*¹⁶⁸ Obviousness is a question of

¹⁶² *E.g.*, Mark A. Lemley & Bhaven Sampat, *Is the Patent Office a Rubber Stamp?*, 58 EMORY L.J. 181, 181-82 (2008).

¹⁶³ 35 U.S.C. § 102 (2010).

¹⁶⁴ *Id.* § 103.

¹⁶⁵ *Id.* § 112.

¹⁶⁶ *See Sanofi II*, 470 F.3d 1368, 1372–73, 1375 (Fed. Cir. 2006).

¹⁶⁷ *See Sanofi III*, 492 F. Supp. 2d 353, 356–62, 379–81, 383–84, 386–90, 392 (S.D.N.Y. 2007) (“According to Apotex, clopidogrel bisulfate was rendered obvious by the ‘596 patent because . . . a person of ordinary skill in the art would have viewed as obvious the active enantiomer of PCR 4099 in the form of each of the three salts used for ester compounds in the examples of the ‘596 patent—namely, the hydrochloride, bisulfate and hydrobromide.”).

¹⁶⁸ *See id.* at 357, 393 (stating that Apotex brought challenges pursuant to both the statutory requirement of nonobviousness and the judicial doctrine of obviousness-type double-patenting); *see also* Andrew V. Trask, Note, “*Obvious to Try*”: A Proper Patentability Standard in the Pharmaceutical Arts?, 76

law based on underlying fact-findings.¹⁶⁹ The fact-findings “include (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of non-obviousness.”¹⁷⁰ “[I]n cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound.”¹⁷¹ A chemist does not need to really modify a known compound, but, rather, it is about whether the chemist would obviously have tried to modify the known compound.¹⁷² Additionally, “the structure of the compound and its properties are inseparable considerations in the obviousness determination.”¹⁷³

Particularly, in *Sanofi-Synthelabo v. Apotex, Inc.*, the Federal Circuit stated that “a close structural similarity between a new chemical compound and prior art compounds is generally deemed to create a prima facie case of obviousness, shifting to the patentee the burden of coming forward with evidence of nonobviousness.”¹⁷⁴ Then, the adjudication became a battle of expert witnesses.¹⁷⁵

Sheila Kadura pointed out that many pharmaceutical patents are vulnerable under the invalidity challenge.¹⁷⁶ But, this view might underestimate some important factors of non-obviousness, collectively known as “secondary considerations,” including “commercial success, long felt but unsolved needs, failure of

FORDHAM L. REV. 2625, 2625–28 (2008) (noting that pharmaceutical compounds can be rejected for obviousness based on structural similarity even though structurally similar compounds can produce drastically different therapeutic effects).

¹⁶⁹ *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359 (Fed. Cir. 2007).

¹⁷⁰ *Pfizer, Inc.*, 480 F.3d at 1360 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)).

¹⁷¹ *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007).

¹⁷² See Trask, *supra* note 168, at 2627–28, 2656–57 (“[T]he Takeda court considered whether a skilled artisan [in the field] would have had a reasonable expectation of success that chemically modifying compound b would have resulted in beneficial changes in toxicity or efficacy.”).

¹⁷³ *Sanofi IV*, 550 F.3d 1075, 1086 (Fed. Cir. 2008).

¹⁷⁴ *Id.*

¹⁷⁵ See *id.* at 1087–89 (noting that the district court considered expert testimony from both sides in making its decision based on nonobviousness).

¹⁷⁶ Sheila Kadura, Note, *Is an Absolute Ban on Reverse Payments the Appropriate Way to Prevent Anticompetitive Agreements Between Branded-and Generic-Pharmaceutical Companies?*, 86 TEX. L. REV. 647, 654 (2008).

others,”¹⁷⁷ the extent of licensing, copying by others, the invention’s unexpected results, and simultaneous invention.¹⁷⁸ A brand-name drug invention at least fulfills commercial success.

To establish commercial success, a brand name-drug invention has to pass a two-prong test.¹⁷⁹ First, there must be evidence showing commercial success,¹⁸⁰ such as the number of units sold, market share, growth in market share, replacement of earlier units sold by others, and dollar amounts of the sale.¹⁸¹ Second, “that success must be shown to have in some way been due to the nature of the claimed invention, as opposed to other economic and commercial factors unrelated to the technical quality of the patented subject matter.”¹⁸² Here, in *Sanofi-Synthelabo v. Apotex, Inc.*, Plavix® is the market dominator and the biggest revenue-contributor of Bristol-Myers Squibb, so the first prong is easy to pass. Regarding the second prong, the success of Plavix® results primarily from the therapeutic effect of Plavix®. If Plavix® cannot cure the targeted diseases, no doctors will recommend Plavix®, and no patients will use Plavix®. The commercial advertisement has a small effect, because ill people will not buy a drug simply for their sensational purposes. So, the second prong is also easy to pass.

As a result, the expectation that the patent of a market-dominating drug could be easily challenged and invalidated seems to be unrealistic in a situation of monopolistic drugs. If the patent of a monopolistic drug is novel under 35 U.S.C. § 102, the patent can still pass the test of non-obviousness, because of the inherent characteristics of the monopolistic drug.

C. Competition Outweighing Patent Protection

Competition is not always right. There has been a case where

¹⁷⁷ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

¹⁷⁸ Jay Jongjitirat, Note, *Leapfrog Enterprises v. Fisher-Price: Secondary Considerations in Nonobviousness Determinations*, 42 U.C. DAVIS L. REV. 599, 611–12 (2008).

¹⁷⁹ See Dorothy Whelan, Note, *A Critique of the Use of Secondary Considerations in Applying the Section 103 Nonobviousness Test for Patentability*, 28 B.C. L. REV. 357, 368–69 (1987) (stating that in order to use “commercial success as evidence of nonobviousness” a patentee must prove two things).

¹⁸⁰ *Id.* at 369.

¹⁸¹ *Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1149–51 (Fed. Cir. 1983).

¹⁸² *Cable Elec. Prods., Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1027 (Fed. Cir. 1985).

different pioneer drug companies joined together to provide H.I.V. drugs.¹⁸³ What if both companies create their generic drug divisions to intrude the market of the other's brand-name drug and to take the corresponding patents? That will not be good for the society. Thus, the non-competition in the pharmaceutical industry is allowable, and it is a matter of degree.

The Hatch-Waxman Act encourages the competition because of the desire for low-price drugs.¹⁸⁴ However, can we see the light of positive non-competition? In the story of *Sanofi-Synthelabo v. Apotex, Inc.*, Bristol-Myers Squibb once offered to Apotex two settlement agreements which could prevent Apotex's launch of generic Plavix® until the '265 patent expires.¹⁸⁵ In one agreement, Bristol-Myers Squibb agreed that "[it] would seek only 70% of Apotex's profits in damages from net sales of [Apotex's] generic if [it] had not launched its own generic; it would seek 60% if it had launched its own."¹⁸⁶ That clause indicated that Bristol-Myers Squibb would have had its own generic Plavix®. Then, the question is why Bristol-Myers Squibb did not choose to license its patent to Apotex. The possible answer could be as follows. Apotex had an ability to manufacture generic Plavix®, but it did not first come to Bristol-Myers Squibb for patent licensing. Instead, Apotex established its own brand and its own distribution network. As time went by, more and more surrounding contractual relationships had been established in the drug market. Consequently, there was no room for licensing negotiation. In addition, the ANDA system encouraged Apotex to destroy the '265 patent for public interests. The settlement between Bristol-Myers Squibb and Apotex depended on the antitrust agencies. The agencies refused to approve the proposed settlement agreement. So, Apotex had to challenge the '265 patent by ignoring the commercial success of Plavix®.

Can we have a system which prevents an unnecessary fight between a pioneer drug company and generic drug company? Imagine the following hypothetical scenario. Apotex has an ability to manufacture Plavix®, but Bristol-Myers Squibb refuses

¹⁸³ Natasha Singer, *Glaxo and Pfizer Join Forces to Develop and Market H.I.V. Drugs*, N.Y. TIMES, Apr. 17, 2009, <http://www.nytimes.com/2009/04/17/business/17drug.html>.

¹⁸⁴ See Fasel, *supra* note 86, at 112–14.

¹⁸⁵ *In re Bristol Myers Squibb Co. Sec. Litig.*, 586 F. Supp. 2d 148, 152–53, 155 (S.D.N.Y. 2008).

¹⁸⁶ *Id.* at 153.

to grant a license to Apotex after some negotiations. At that moment, Apotex is not sure whether it could strike the '265 patent, but it wants to try that. Then, it files an ANDA application with a Paragraph IV certification. So, the battle begins. As the battle goes on, Bristol-Myers Squibb later believes that the best interest of the company is to settle the case. Now, two options are in its mind while it reaches the settlement. First, it wants to keep Apotex from the market by paying money to Apotex. Alternatively, it wants to limit Apotex's business of generic Plavix®, if it has to license the '265 patent. Can we see both options work in the ANDA practice? If they work, the unnecessary patent challenge could be avoided. Bristol-Myers Squibb could focus on drug development rather than patent litigation, while Apotex will not recoup its litigation cost by raising the price of generic Plavix®. The next section will propose a modification of the Hatch-Waxman Act.

D. Proposed Modification of the Hatch-Waxman Act

1. Balance of Drug Development and Drug Pricing

Developing a brand-name drug usually costs billions in U.S. dollars.¹⁸⁷ Securing a monopolistic or less-competitive market is a way by which a brand-drug company could recoup the expensive investment on drug development.¹⁸⁸ The market monopoly is not only from the patents that protects a brand-name drug, but also from the FDA's regulations.¹⁸⁹ To compensate a pioneer drug company for its endeavors, the Hatch-Waxman Act should consider the weight of keeping the innovation of new drug development, so that we could have more pioneers to invent new drugs for saving lives.¹⁹⁰

¹⁸⁷ Eric E. Williams, *Patent Reform: The Pharmaceutical Industry Prescription for Post-Grant Opposition and Remedies*, 90 J. PAT. & TRADEMARK OFF. SOC'Y 354, 363 (2008).

¹⁸⁸ *Id.* at 363–64.

¹⁸⁹ See *id.* at 373–74; Aidan Hollis, *Closing the FDA's Orange Book*, REG., Winter 2001, at 14, 14, available at <http://www.cato.org/pubs/regulation/regv24n4/v24n4-2.pdf> (explaining how the FDA aids "originator firms" in extending their monopolies on certain drugs "by allowing the firms to list new patents . . . for previously introduced drugs, and by extending automatic protection to the original drug").

¹⁹⁰ Under the attack and endless threat of Apotex, Bristol-Myers Squibb still moves on to develop new drugs. See Natasha Singer and Duff Wilson, *Drug Firms Dreaming of Deals*, N.Y. TIMES, Feb. 25, 2009, <http://query.nytimes.com/gst/fullpage.html?res=9C01E2D8133BF936A15751C0>

The Hatch-Waxman Act implies that the patent for a drug is easily challenged. But, the above analysis indicates that such implication is not realistic. If a generic drug company fails to invalidate the drug patent, it is expected that a pioneer drug company will recoup the litigation cost from the patients. The result is the increase of the drug price. That is not an achievement Congress expected. Therefore, when facing a situation like the story of *Sanofi-Synthelabo v. Apotex, Inc.*, some win-win solutions should be provided to eliminate unnecessary fights but still to trigger the challenge of a generic drug company. Otherwise, such competition might cause unemployment.¹⁹¹

2. Alternative: Voluntary Licensing

The proposed alternative is to allow a generic drug company to acquire a voluntary license at some point during the patent dispute with a pioneer drug company. Such licensing can also help the pioneer drug company to save its patent. The concept is rooted from “compulsory license” that was developed in the 1883 Paris Convention.¹⁹² Compulsory licensing allows a government to take over a patentee to decide whether to license his patent.¹⁹³ However, compulsory licensing is considered as a threat to pioneer drug companies, because the expectation of recouping the cost of drug development is reduced by limiting the exclusive right of a pioneer drug company.¹⁹⁴ Thus, to implement a form of

A96F9C8B63 (“[T]he company has therapies in development to fight cancer, viruses and immune-system diseases -- biologic drugs that are less subject to generic competition or price pressures because they are derived from living cells instead of easy-to-copy chemical formulas.”); Jim Edwards, *BMS Is Losing Suits in Plavix-Apotex Fiasco; Another \$125M Down the Toilet*, BNET (July 28, 2009), <http://www.bnet.com/blog/drug-business/bms-is-losing-suits-in-plavix-apotex-fiasco-another-125m-down-the-toilet/2276> (listing the ongoing shareholder’s suits against Bristol-Myers Squibb).

¹⁹¹ See Associated Press, *Profits Up, Drug Makers Pledge to Cut More Jobs*, N.Y. TIMES, July 25, 2008, <http://www.nytimes.com/2008/07/25/business/25drug.html> (“The same drug generated discussion among analysts who cover Bristol-Myers, who say that approval of prasugrel could cut into sales of Bristol’s top seller, the blood thinner Plavix. Bristol-Myers executives, however, told the analysts that prasugrel was more of a niche drug, aimed at about 15 percent of the patients now treated by Plavix.”).

¹⁹² Jamie Feldman, Note, *Compulsory Licenses: The Dangers Behind the Current Practice*, 8 J. INT’L BUS. & L. 137, 137 (2009).

¹⁹³ *Id.* at 140.

¹⁹⁴ *Id.* at 141–42; see also Andrew A. Phillips, Comment, *Strengthen Pharmaceutical Patent Rights: Lowering the Cost of Prescription Drugs by Stopping the Reckless Patent Litigation Abuse of Generic Companies*, 13 CONN. INS. L.J. 397, 412–14 (2007) (explaining how compulsory licenses discourage

compulsory licensing in the Hatch-Waxman Act, some modification should be made to eliminate the potential threat to the drug innovation of pioneer drug companies.

Voluntary licensing, as one alternative of the present ANDA system, is explained as follows. If a pioneer drug company is willing to settle the case by granting a license voluntarily, the next question could be what a legal settlement agreement should include as a reward to the pioneer drug company for its voluntary licensing. One way might be to pay the generic drug company which, then, agrees to delay the launch of the generic drug. But, such way has a serious antitrust concern.¹⁹⁵ In the story of *Sanofi-Synthelabo v. Apotex, Inc.*, the former vice president of Bristol-Myers Squibb was indicted because of the antitrust violation.¹⁹⁶ So, a solution is given to prevent the negative impact of the antitrust law.

The modified concept of compulsory licensing allows a pioneer drug company to choose to settle the case by accepting a voluntary license or to continue to fight. If voluntary licensing is selected, the law will force the generic drug company to withdraw its Paragraph IV certification. The law will still grant an exclusivity period so that a generic drug company has an incentive to enter into a voluntary license agreement, instead of vigorously attacking a drug patent.

The procedure of voluntary licensing is as follows. Before a pioneer drug company decides to sue a generic drug company, there should be a pre-litigation period during which both parties could think of a voluntary license. The power to initiate voluntary licensing is vested in the pioneer drug company that could have an option to settle the case without bringing the invalidity issue of its patent in the court. The pioneer drug company can evaluate its resources to see whether to defend for

investment in research and development “because of the low probability that [the drug company] will ever recoup its . . . costs”).

¹⁹⁵ Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 38-40 (2009); see also Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 584-85 (2007) (arguing that patent settlement agreements “are deserving of close antitrust scrutiny” when they create unusually high “barriers to third-party generic entry”).

¹⁹⁶ See Press Release, U.S. Dep’t of Justice, Former Bristol-Myers Squibb Senior Vice President Indicted for Lying to the Federal Government About Popular Blood-Thinning Drug (Apr. 23, 2008), available at http://www.justice.gov/atr/public/press_releases/2008/232525.pdf.

its patent or to share the market with the generic drug company. At that time, because the generic drug company has submitted a Paragraph IV certification, the pioneer drug company should have necessary information to estimate the outcome and cost of the case. On the other hand, the generic drug company could have a legitimate reason to think of licensing again. If a voluntary license is accepted, the generic drug company will not lose an exclusivity period, meaning that an option of voluntary licensing will never harm its commercial interests. Last, the court could be a decision-maker of licensing fees or other clauses if both parties are willing to be subject to the court.

Under the proposed modification of the Act, the pioneer drug company and generic drug company could have a win-win solution after a Paragraph IV certification was filed. The patent for the brand-name drug does not need to be destroyed. Perhaps both parties could enjoy the monopoly secured by the patent.

V. CONCLUSION

Congress enacted the Hatch-Waxman Act to induce generic drug companies to challenge pioneer drug companies. The goal was to lower the prices of prescribed drugs. The theory is that because generic drug companies do not need an expensive investment in drug development, they must prove lower prices. While the Act awards a 180-day exclusivity period to the first generic drug company which challenges the patent for a brand-name drug, the Act ignores the complexity of patent litigation. The story of *Sanofi-Synthelabo v. Apotex, Inc.* just reflects one extreme case, where the patent at dispute is uncontestable.

In *Sanofi-Synthelabo v. Apotex, Inc.*, both parties once intended to end the war. Maybe because the market of Plavix® is less competitive, both parties tried to avoid the expensive trial. Apotex was not worried about losing the exclusivity period, while Bristol-Myers Squibb thought of maintaining the monopoly. The antitrust law intervened to stop the scenario, which resulted in the indictment of the former vice president of Bristol-Myers Squibb. Though Apotex went on to fight against the patent as what the Act expected, Apotex finally lost. The drug market remained the same, and there have been no upcoming generic drug companies which want to challenge the patent at dispute. Definitely, the Act seems to underestimate the strength of brand-name drug patents and other negative impacts unnecessary patent litigation might give.

To encourage the settlement of unnecessary challenge of brand-name drug patents without undermining the goal of the Act, this essay provides one modification of the Act. Compulsory licensing might be a clue. But, the original concept of compulsory licensing should be modified as voluntary licensing to eliminate the threat to the innovation of pioneer drug companies. First, the power to trigger voluntary licensing is vested in pioneer drug companies. Second, the initiation of the procedure begins before the patent owner sues the generic drug company. Third, the generic drug company could decide whether to accept the offer and settle the case. If the voluntary licensing succeeds, the generic drug company can still preserve a 180-day exclusivity period.

The war is not the answer. Brand-name drug patents are not threatening. The Hatch-Waxman Act does not have to encourage an unnecessary patent fight. Based on the current ANDA framework, the procedure of modified compulsory licensing might be added as an option for brand-name drug and generic drug companies to reconsider how to provide affordable drugs.