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University of California
Hastings College of the Law
200 McAllister Street
San Francisco, CA 94102

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In 2008, the Food and Drug Administration (FDA) implemented the Pre-Launch Activities Importation Request (PLAIR) program. The FDA exercises its enforcement discretion under the guise of the PLAIR program to permit drug manufacturers to import unapproved drugs into the United States so the manufacturers can expedite their commercial launches when they finally receive official FDA approval. But the ability to import unapproved finished drug products into the United States ahead of anticipated FDA approval conflicts with certain provisions of the Hatch-Waxman Act that permit brand-name companies to use permanent injunctions to prevent the importation of generic equivalents of their drugs before patent expiration. This article analyzes the conflict between the PLAIR program and the Hatch-Waxman Act and discusses solutions to the conflict.

AN INSIGHT INTO THE APPAREL INDUSTRY'S PATENT TROLL PROBLEM
by Ashli Weiss 121

Patent trolls have increasingly targeted the end users of patent-encumbered technology rather than suing the companies that created the allegedly infringing products themselves. Apparel companies provide a useful example of the predicament faced by a variety of similarly situated, nontechnology-oriented companies targeted by troll litigation. As high-profile end users of a variety of commercial technologies, apparel companies have proven to be popular targets for troll litigation. This article examines the apparel industry's patent troll problem through the lens of historical context, in order to describe how nontechnology companies expose themselves to liability by becoming dependent on third-party technology. It then uses lessons derived from the experiences of the apparel industry to make legislative recommendations.

NOTE

MENTAL HEALTH PARITY: THE PATIENT PROTECTION AND AFFORDABLE CARE ACT AND THE PARITY DEFINITION IMPLICATIONS
by Suann Kessler.....*145*

At least twenty-eight percent of American adults suffer from a mental or addictive disorder. However, even today, health insurance coverage for mental health services differs drastically from that of other medical services. Nonetheless, although it has yet to achieve parity with other medical services, health insurance coverage for mental health services has improved over time. Because the recent enactment of the Patient Protection and Affordable Care Act ("PPACA") appears to have filled the parity gaps left by the Mental Health Parity and Addiction Equity Act of 2008, many claim that mental health parity has finally been achieved. While the PPACA may superficially appear to have plugged all the gaps, the ultimate questions are whether it provides actual mental health parity, and whether it facilitates access to mental health services for those who truly need them. This note takes deeper look into these questions, and reveals that the PPACA may fall short of providing actual parity between mental health and other medical services.

The Conflict Between the FDA's Pre-Launch Activities Importation Request Program and the Hatch-Waxman Act

by ALEX CHENG AND MATTHEW AVERY*

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* Mr. Cheng is a J.D. candidate, University of California, Hastings College of the Law, 2014. Mr. Avery is an Associate at Baker Botts LLP in Palo Alto, California. The authors would like to thank Professor Robin Feldman for advising them on this note as part of the U.C. Hastings Law and Bioscience (LAB) Project. The views expressed in this note are the authors' alone, and do not necessarily reflect those of their affiliated institutions.

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Introduction

In 2008, the Food and Drug Administration (FDA) implemented the Pre-Launch Activities Importation Request (PLAIR) program.[1] The FDA exercises its enforcement discretion under the guise of the PLAIR program to permit the importation of unapproved finished drug products into the United States based on anticipated approval of a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA).[2] In other words, the FDA gives drug manufacturers permission to import unapproved drugs into the United States so the manufacturers can expedite their commercial launches when they finally receive official FDA approval.[3]

The FDA developed the PLAIR program with an eye toward the globalization of the pharmaceutical industry.[4] In particular, the intense competition and relatively small margins in the generic

1. Annual Guidance Agenda, 73 Fed. Reg. 153 (Jul. 30, 2008).

2. Food and Drug Administration, Draft Guidance for Industry on Pre-launch Activities Importation Requests (PLAIR), at 1 (2013) [hereinafter FDA, PLAIR Draft Guidance], *available at* http://www.fda.gov/downloads/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/UCM362177.pdf ("Historically, when applicants sought to import unapproved finished dosage form drug products in preparation for market launch, FDA considered such requests, informally referred to as Pre-Launch Activities Importation Requests (PLAIRs), on a case-by-case basis. FDA has decided to create a more formal program . . . .").

3. FDA, PLAIR DRAFT GUIDANCE, *supra* note 2, at 1; Kurt R. Karst, *PLAIRs–What are They and What are FDA's Current Policies?*, FDA LAW BLOG (Apr. 11, 2010), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2010/04/plairs-what-are-they-and-what-are-fdas-current-policies.html.

4. Karst, *supra* note 3.

industry mean that generic companies often must manufacture their drugs in foreign countries where production costs are lower.[5] While generic companies may be able to produce cheaper goods by manufacturing in foreign countries, they face additional burdens when they import their drugs into the United States, a process which is heavily regulated by the FDA.[6] One such burden is seeking PLAIR approval from the FDA to import a drug prior to FDA marketing approval.[7] But the ability to import unapproved finished drug products into the United States ahead of anticipated FDA approval conflicts with certain provisions of the Hatch-Waxman Act that permit brand-name companies to use permanent injunctions to prevent the importation of generic equivalents of their drugs before patent expiration.[8]

Sanofi-Synthelabo v. Apotex, Inc. is the first case under Hatch-Waxman in which a generic company, notwithstanding a permanent injunction, has requested to take advantage of the PLAIR program to import a generic drug into the United States before the expiration of the pioneer's patent.[9] Although arguments were made on both sides regarding whether Apotex should be allowed to take advantage of the PLAIR program despite the permanent injunction, *Sanofi v. Apotex* was dismissed for not being timely, and neither the District Court nor the Federal Circuit addressed the conflict between PLAIR and Hatch-Waxman.[10] However, it is likely that more generic manufacturers will attempt to take advantage of the PLAIR program

5. *Compare* World Health Organization, Pharmaceutical Industry, http://www.who.int/trade/glossary/story073/en/ (noting that some of the largest pharmaceutical companies have profit margins of about 30%) *with* THE HENRY FUND, GENERIC DRUG MANUFACTURERS (2013), http://tippie.uiowa.edu/henry/reports13/generics.pdf (showing that the profit margins for the five largest generic manufacturers range from 0.89% to 18.93%). *See also* Christelle Laot, *FedEx and Generic Drugs: Connecting Global Manufacturers to Consumer Markets*, FEDEX BLOG (Mar. 14, 2011), http://blog.fedex.designcdt.com/generic-drugs-markets.

6. *See* 21 U.S.C. § 355(a) (2012).

7. FDA, PLAIR DRAFT GUIDANCE, *supra* note 2, at 1.

8. 35 U.S.C. § 271(e)(4) (2012).

9. Sanofi-Synthelabo v. Apotex, Inc., (nonprecedential order) 1, 2 (Fed. Cir. 2012).

10. *See* Brief of Petitioner-Appellant at 5-6, *Sanofi-Synthelabo v. Apotex, Inc.*, No. 1:02-cv-02255-SHS (Fed. Cir. May 9, 2012); *see also* Brief of Respondent-Appellee at 3-6, 8-9 *Sanofi-Synthelabo v. Apotex, Inc.*, No. 1:02-cv-02255-SHS (Fed. Cir. May 9, 2012); *Sanofi-Synthelabo v. Apotex, Inc.*, (nonprecedential order) 1, 3 (Fed. Cir. 2012).

to overcome injunctions and import their drugs prior to FDA marketing approval.[11]

This Article analyzes the conflict between the PLAIR program and the Hatch-Waxman Act and discusses solutions to the conflict. Part 1 of this Article provides an overview of the Hatch-Waxman Act and the regulation of generic drugs. Part 2 provides an overview of the PLAIR program. Part 3 analyzes the validity of the PLAIR program. Part 4 analyzes the conflict between the PLAIR program and the Hatch-Waxman Act and provides a description of the *Sanofi v. Apotex* case. Part 5 discusses balancing the goals of the PLAIR program with the intent of the Hatch-Waxman Act. Part 6 discusses modifying the current regulatory regime to resolve the conflict between the PLAIR program and the Hatch-Waxman Act. Finally, Part 7 provides strategic considerations for practitioners in this area.

1. Overview of the Hatch-Waxman Act and the Regulation of Generic Drugs

1.1. The Regulation of Drugs Under the Food, Drug, and Cosmetic Act

In order to market a new drug, or to import it for marketing, a pharmaceutical company must first obtain FDA approval.[12] Section 355(a) of the Food, Drug, and Cosmetic Act (FDCA) provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug."[13] Because section 355(a) only prohibits importation of finished drug products (i.e., products that are ready for sale), the FDA has long allowed the importation of *unfinished* drug products into the United States, and has issued specific regulations to permit the importation of unfinished bulk products ahead of FDA approval.[14] Unfinished bulk products can undergo further manufacturing, processing, and repackaging in the United States prior to regulatory approval, so the finished drug product will be ready for an immediate market launch when the FDA

11. Kurt R. Karst, *FDA's PLAIR Program Collides with Hatch-Waxman*, FDA LAW BLOG (May 23, 2011), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2012/05/fdas-plair-program-collides-with-hatch-waxman.html.

12. *See* 21 U.S.C. § 355(a).

13. 21 U.S.C. § 355(a).

14. 21 C.F.R. § 314.410(a)(2) (2008) ("A drug substance intended for use in the manufacture, processing, or repacking of a new drug may be imported into the United States if it complies with the labeling exemption in § 201.122 pertaining to shipments of drug substances in domestic commerce.").

finally grants approval.[15] While FDA regulations allow the importation of unfinished bulk products, no such regulations exist for *finished* drug products. Consequently, finished drug products cannot be imported into the United States ahead of FDA approval, and therefore, will not be ready for market launch upon regulatory approval. This effectively places generic companies that manufacture in foreign countries at a competitive disadvantage to those who manufacture generics domestically.[16]

Despite the absence of such regulations, the FDA has historically exercised enforcement discretion to permit the importation of finished drug products into the United States ahead of anticipated FDA approval.[17] As the authority for this enforcement discretion, the FDA has cited section 336 of the FDCA,[18] which provides that the FDA is not required "to report for prosecution, or for the institution of . . . injunction proceedings, *minor violations* . . . whenever [it] believes that the public interest will be adequately served . . . ."[19] By allowing preapproval importation, the FDA seeks to promote competition and lower prices of drugs as quickly as possible.[20]

1.2. The Regulation of Generic Drugs Under the Hatch-Waxman Act

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, to amend section 355(j) of the FDCA and section 271(e) of the Patent Act to create the statutory scheme to regulate the modern generic pharmaceutical industry.[21] The intent of Hatch-Waxman was to "strike a balance between 'two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while

15. 21 C.F.R. § 201.122(c) (2012) ("A new drug application . . . has been submitted but not yet approved, disapproved, granted, or denied, the bulk drug is not exported, and the finished drug product is not further distributed after it is manufactured until after the new drug application . . . is approved . . . .").

16. Although it is beyond the scope of this article, it is worth noting that domestic manufacturers may also be at a disadvantage, since they likely cannot even begin to manufacture their generic products until the pioneer's patent expires.

17. Karst, *supra* note 3.

18. *Id*.

19. 21 U.S.C. § 336 (emphasis added); *see also* Karst, *supra* note 3.

20. E-mail from Peter Barton Hutt, Senior Counsel, Covington & Burling LLP, to Author (Feb. 18, 2014, 08:40 PST) (on file with author).

21. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355(j) (2012), 35 U.S.C. §§ 156, 271(e) (2012)).

simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.'"[22]

In order to enable competitors to bring generic copies of pioneer drugs to market, Hatch-Waxman provides for an Abbreviated New Drug Application (ANDA).[23] An ANDA applicant is only required to provide proof that its generic copy of the pioneer drug: (1) has the same active ingredient and the basic pharmacokinetics as the pioneer drug, (2) is bioequivalent to the pioneer drug and (3) the dosage form and strength of the pioneer and generic are the same.[24] However, unlike drug pioneers, an ANDA applicant is not required to provide independent proof of either the safety or the efficacy of the generic copy, and instead can rely on the clinical trial data of the pioneer drug.[25]

An ANDA applicant must make one of the following certifications with respect to *each* patent which claims the pioneer drug that it seeks to copy: (I) the drug is not patented or the patent information has not been filed; (II) the patent has expired; (III) the date when the patent expires and that the generic drug will not go on the market until that date passes; or (IV) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug.[26]

Patent challenges pursuant to Paragraph IV are a frequently deployed mechanism for the early introduction of generic competition.[27] When an applicant files an ANDA with Paragraph IV certification, two features of Hatch-Waxman apply: (1) thirty-month stay, and (2) 180-day marketing exclusivity. In addition, if the pioneer successfully sues the Paragraph IV challenger for patent infringement, then the Act allows the pioneer to get a permanent injunction against the generic challenger.

22. aaiPharma Inc. v. Thompson, 296 F.3d 227, 230 (4th Cir. 2002).

23. H.R. Rep. No. 98-857, pt. 1, at 16.

24. 21 U.S.C. § 355(j)(2)(A)(ii)–(iv).

25. 21 U.S.C. § 355(j)(2)(A).

26. 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV).

27. *See* FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (July 2002) (reporting challenges involving 130 drugs between 1984 and 2000); *Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act" Before the S. Comm. on the Judiciary*, 108th Cong. 117 (2003) (statement of Timothy Muris, Chairman, FTC) (noting challenges involving more than eighty drugs between January 2001 and June 2003).

1.2.1. Thirty-Month Stay

The Hatch-Waxman Act also provides that making a Paragraph IV certification is itself an act of patent infringement.[28] An applicant who files an ANDA with Paragraph IV certification must provide notice of the ANDA to the patent holder.[29] After receiving such notice, the NDA holder has forty-five days to bring an infringement action against the ANDA applicant.[30] If suit is not filed within that time, then the FDA can approve the ANDA immediately.[31] But if suit is brought during that time, then FDA is barred from approving the ANDA for thirty months.[32]

During the thirty-month stay, the FDA can only "tentatively approve" the ANDA, such that the ANDA can become effective immediately upon the expiration of the thirty-month stay.[33] The exceptions to the thirty-month stay are if either: (1) the patent expires, or (2) the district court finds that the patent is invalid or is not infringed during the thirty-month stay. In either case, the ANDA can be approved immediately.[34]

1.2.2. 180-Day Marketing Exclusivity

The statute provides that the first applicant to file a Paragraph IV ANDA with the FDA will be granted 180 days of market exclusivity upon entering the market with their generic equivalent.[35] The FDA is barred from approving later-filed ANDAs for the same drug until 180 days after the first filer begins marketing its generic copy of the pioneer drug.[36] The purpose of 180-day marketing exclusivity is to encourage Paragraph IV challenges by rewarding the first filer: "[i]n exchange for undertaking the costs and risks of patent litigation, the successful challenger is given [six] months of marketing without any other generic competition."[37] This marketing exclusivity

28. 35 U.S.C. § 271(e)(2)(A) ("It shall be an act of infringement to submit . . . an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . .").

29. 21 U.S.C. § 355(j)(2)(B).

30. 21 U.S.C. § 355(j)(5)(B)(iii).

31. *Id*.

32. *Id*.

33. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd).

34. 21 U.S.C. § 355(j)(5)(B)(iii)(I)–(IV).

35. 21 U.S.C. § 355(j)(5)(B)(iv).

36. *Id*.

37. Representative Henry Waxman, *Speech at the Generic Pharmaceutical Association's First Annual Policy Conference: Securing the Future of Affordable Medicine*

period is valuable to generic companies because they can sell their generic drugs at a price significantly higher than if multiple generic drugs were on the market.[38]

1.2.3. Permanent Injunction

Section 271(e)(4) of the Patent Act, which was added as part of the Hatch-Waxman amendments, allows courts to order the FDA to delay ANDA approval until a patent expires and to grant an injunction to prevent the manufacture, use, sale, or importation of a drug.[39] A patent holder is entitled to a permanent injunction pursuant to section 271(e)(4) if: (1) the patent holder brings an infringement action, and (2) the district court finds that the patent is both valid and infringed.[40] But Hatch-Waxman does not include any provisions that allow for a permanent injunction to be ignored for pre-launch importation purposes. And because the injunction provisions are part of the Patent Act, the FDA does not have discretion to interpret or enforce these injunctions.[41]

2. Overview of PLAIR Program

2.1. Pre-Launch Importation of Drugs Before the PLAIR Program

The FDA has long allowed drug manufacturers to import unfinished bulk products into the United States ahead of FDA approval.[42] Despite Section 355(a) of the FDCA, the FDA has issued regulations to permit the importation of unfinished bulk products into

(Sept. 20, 2005), *available at* http://www.house.gov/waxman/news_files/news_statements_generic_pharmaceutical%20_association_9.20.05.htm.

38. Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 178 n.56 (2008) ("For example, when generic Prozac (Fluoxetine) entered the market, the first generic challenger sold it at $1.91/capsule, or 12% below the cost of brand-name Prozac. Two months after the exclusivity period expired, multiple generics had entered the market and the price of generic Prozac had dropped to $0.32/capsule.").

39. 35 U.S.C. § 271(e)(4) ("For an act of infringement [caused by filing a Paragraph IV ANDA] (A) the court shall order the effective date of any approval of the drug . . . to be a date which is not earlier than the date of the expiration of the patent which has been infringed, (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States *or importation into the United States* of an approved drug, veterinary biological product, or biological product. . . .").

40. 21 U.S.C. § 355 (j)(5)(B)(iii)(II).

41. FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 161 (2000); *see also* discussion *infra* Part 3.3.

42. 21 U.S.C. § 355(a); 21 C.F.R. § 314.410(a)(2) (2008); 21 C.F.R. § 201.122(c) (2012).

the United States ahead of regulatory approval.[43] The only restriction on such importation is that the label of a drug in a bulk package must bear the statements "Caution: For manufacturing, processing, or repacking" and "Rx only."[44] These unfinished bulk products can then undergo further processing in the United States.

However, despite the absence of such regulations for the importation of finished drug products into the United States ahead of FDA approval, the Agency has historically exercised enforcement discretion to also permit such importation.[45] But this historical enforcement discretion was exercised informally and there is no record of how it was used by the FDA.[46]

2.2. The PLAIR Program

In 2008, the FDA launched the PLAIR program by issuing guidance documents describing its policy for exercising enforcement discretion with respect to the importation of unapproved drugs into the United States.[47] PLAIR formalizes the FDA's historical exercise of enforcement discretion to permit the importation of finished drug products into the United States ahead of anticipated FDA approval.[48]

Based on a PLAIR request, the FDA will decide on a case-by-case basis whether to permit importation of unapproved finished drug products.[49] An applicant should make a PLAIR request no more than two months prior to its expected launch date, but at least one month prior to the expected importation to allow the Agency time to process the request.[50] A PLAIR applicant is required to submit, among other things, information on: (1) the drug product name, and (2) the warehouse in United States where it will be stored pending FDA

43. 21 C.F.R. § 314.410(a)(2) (2008); 21 C.F.R. § 201.122(c) (2012).

44. 21 C.F.R. § 201.122 (2012).

45. Karst, *supra* note 2.

46. FDA, PLAIR DRAFT GUIDANCE, *supra* note 2, at 1 ("Historically, when applicants sought to import unapproved finished dosage form drug products in preparation for market launch, FDA considered such requests, informally referred to as Pre-Launch Activities Importation Requests (PLAIRs), on a case-by-case basis.")

47. Annual Guidance Agenda, 73 Fed. Reg. 153 (July 30, 2008); *see also* REGULATIONS.GOV (last visited Feb. 8, 2014) (The FDA published its annual guidance agenda, which included a notice that it was planning to publish a guidance document for the PLAIR program. No comments were submitted by the public in response to this agenda.), http://www.regulations.gov/#!documentDetail;D=FDA-2004-N-0056-0003.

48. FDA, PLAIR DRAFT GUIDANCE, *supra* note 2, at 1; *see also* Karst, *supra* note 3.

49. FDA, PLAIR DRAFT GUIDANCE, *supra* note 2, at 1.

50. *Id*. at 4-5.

approval.[51] In addition, a PLAIR applicant must also submit a letter signed by an authorized representative certifying that it will not sell the finished drug product before receiving regulatory approval.[52] Notably, the PLAIR applicant does not need to submit any information identifying injunctions that may prohibit the applicant from importing the finished drug product. The Agency has previously stated that it will respond to a PLAIR request within two weeks,[53] however the current draft guidance does not specify how long the Agency will take to respond. If the FDA approves the request, then the applicant may immediately begin importing the finished drug product, notwithstanding any injunctions.[54]

3. Validity of the PLAIR Program

Because there is no explicit statutory basis for the PLAIR program, it is unclear whether the FDA has the legal authority to allow the importation of unapproved finished drug products. The constitutional validity of the PLAIR program and the FDA's ability to exercise enforcement discretion under the FDCA are discussed in more detail below. In short, the FDA has the authority to regulate the importation of drugs into the United States and the right to exercise enforcement discretion to not prosecute a violation of section 355(a) of the FDCA. However, that authority is limited to the extent that the importation of finished drug products is not subject to restrictions by other regulatory schemes, including the Patent Act, outside the control of the FDA.

3.1. Constitutional Validity Under *Chevron v. NRDC*

The scope and extent of a federal agency's authority is limited by Congress.[55] Section 706 of the Administrative Procedure Act provides that a court must "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an

51. FDA, PLAIR DRAFT GUIDANCE, *supra* note 2, at 2-4.

52. *Id*. at 3-4.

53. FOOD AND DRUG ADMINISTRATION, PRE-LAUNCH ACTIVITIES IMPORTATION REQUEST (PLAIR) FREQUENTLY ASKED QUESTIONS (FAQS) 1, 2 (July 2013) [hereinafter FDA, PLAIR FAQ], *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/UCM297907.pdf.

54. FDA, PLAIR DRAFT GUIDANCE, *supra* note 2, at 5-6.

55. *See* Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984); Marbury v. Madison, 5 U.S. (1 Cranch) 137 (1803).

abuse of discretion, or otherwise not in accordance with law."[56] When an agency acts in a way that is allegedly arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, the reviewing court must evaluate the agency's actions using the two-step analysis described in *Chevron v. NRDC*. First, the court must review the agency's authorizing statute de novo to determine "[i]f the intent of Congress is clear."[57] If Congress clearly intended to allow the agency to act in the way challenged, then the challenge must be rejected and the action allowed.[58] However, if Congress did not clearly intend to allow the agency to so act, then the court should only defer to the agency when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law (e.g., if the agency has the power to engage in notice-and-comment rulemaking).[59]

Section 355(a) of the FDCA requires a pharmaceutical company to first obtain FDA approval in order to market, or to import to market, a new drug.[60] However, section 336 of the FDCA permits the FDA to exercise enforcement discretion with respect to "minor violations" of the FDCA if the "public interest will be adequately served."[61] As discussed in Part 1.1 above, the FDA has historically exercised enforcement discretion to permit the importation of finished drug products into the United States ahead of anticipated FDA approval, classifying these preapproval importations

56. 5 U.S.C. § 706 (2012) ("To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—(2) hold unlawful and set aside agency action, findings, and conclusions found to be—(A) arbitrary, capricious, an abuse of discretion, *or* otherwise not in accordance with law . . . In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.").

57. *Chevron*, 467 U.S. at 842.

58. *Id.* at 842-43.

59. United States v. Mead Corp., 533 U.S. 218, 226-27 (2001) ("[A]dministrative implementation of a particular statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law . . . Delegation of such authority may be shown . . . by an agency's power to engage in . . . notice-and-comment rulemaking.").

60. 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.").

61. 21 U.S.C. § 336 ("Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.").

as "minor violations."[62] However, Congress failed to define what constitutes "minor violations" or the "public interest," and therefore, it is not at all clear how far the Agency's enforcement discretion extends under Section 336 of the FDCA.

As required by the Administrative Procedure Act, the FDA has engaged in notice-and-comment rulemaking with respect to its regulations that permit the importation of unfinished bulk products into the United States ahead of FDA approval.[63] Under the second step described in *Chevron*, if a reviewing court determines that Congress delegated authority to the FDA generally to make rules carrying the force of law, and "if the statute is silent *or ambiguous* with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute."[64] As such, because the statute is ambiguous with respect to the scope of "minor violations," the FDA's regulations interpreting the FDCA to allow for preapproval importation of unfinished bulk product are valid and should be given deference by a reviewing court.

However, with respect to the importation of finished bulk product, the Agency has issued no regulations. And the FDCA is not silent with respect to the issue of the importation of new drugs—section 355(a) is quite explicit that marketing approval is needed before a sponsor may import new drugs into the country.[65]

Section 355 of the FDCA was intended to ensure the safety and efficacy of new drugs.[66] For example, section 355(b)(1) of the FDCA provides that an NDA or ANDA applicant is required to submit information, including "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use . . . ."[67] While the PLAIR program permits the importation of finished drug products into the United

62. Karst, *supra* note 3.

63. 1 C.F.R. § 314.410(a)(2) ; 21 C.F.R. § 201.122(c).

64. *Chevron*, 467 U.S. at 843.

65. 21 U.S.C. § 355(a).

66. Richard S. Fortunato, *FDA Disclosure of Safety and Efficacy Data: The Scope of Section 301(j)*, 50 FORDHAM L. REV. 1280 n.2-3 (1984) ("A new drug" is defined as a drug whose composition is not generally recognized "as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling," or a drug whose composition has been so recognized as a result of investigations, but which has not "been used to a material extent or for a material time." 21 U.S.C. § 321(p) (1982). . . . The Act provides that no person shall introduce into interstate commerce any new drug without premarket approval from the Secretary of Health and Human Services certifying that the drug is safe and effective for use. 21 U.S.C. § 355(a), (b) (1982)").

67. 21 U.S.C. § 355(b)(1).

States ahead of anticipated FDA approval, a pharmaceutical company is still prohibited from marketing its new drug ahead of actual FDA approval.[68] If the FDA does not grant approval, then a pharmaceutical company risks having to destroy or export its inventory.[69] The PLAIR program still prohibits pharmaceutical companies from marketing new drugs without actual FDA approval, so that even if a drug has been imported, the public is still protected from consuming potentially unsafe or ineffective drugs. Consequently, because the intent of the FDCA is to protect the public health by ensuring citizens are not exposed to adulterated or misbranded drugs,[70] and because the PLAIR program still prevents such exposure, it is not, at the very least, arbitrary, capricious, or an abuse of discretion under a *Chevron* analysis.

However, as previously noted, section 271(e)(4) of the Patent Act allows an NDA holder that has prevailed in a patent litigation to obtain a permanent injunction against a generic challenger to prevent it from importing its infringing drug product.[71] These injunctions seem absolute—there is no exception allowing the FDA or anyone else to disregard a permanent injunction for public interest reasons or otherwise. The Patent Act does not include a provision corresponding to section 336 of the FDCA granting enforcement discretion. Even if there were such a provision, it would likely apply to the agency having general authority over the Patent Act, the United States Patent and Trademark Office, not the FDA, which has no authority to interpret the Patent Act, and thus has no authority to issue regulations regarding permanent injunctions obtained under section 271(e)(4). Because the intent of Congress with respect to section 271(e)(4) seems clear, and because the FDA has no authority to say otherwise, courts performing a *Chevron* analysis should hold as unlawful and set aside any FDA action under the PLAIR program that would allow importation of an infringing drug product in violation of a permanent injunction. But if there are no permanent injunctions prohibiting importation, then per the second step of the *Chevron* analysis courts should defer to the FDA's decision to allow preapproval importation as a "minor violation" of section 355(a) of the FDCA.

68. FDA, PLAIR DRAFT GUIDANCE, *supra* note 2, at 2.

69. *Id*. at 6 ("the finished dosage form drug product should be exported or destroyed within 90 days of the refusal"); Laot, *supra* note 5.

70. 21 U.S.C. § 393(b).

71. 21 U.S.C. § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4).

3.2. Prosecutorial Discretion

Although PLAIR allows for the type of behavior that both section 355(a) of the FDCA and section 271(e)(4) of the Patent Act prohibit, it is important to distinguish between lawful and unlawful activity. PLAIR does not declare the importation of finished drug products into the United States ahead of anticipated FDA approval to be lawful. When the FDA grants a PLAIR request, the Agency is simply exercising its enforcement discretion to not prosecute a violation of section 355(a) of the FDCA. But it is also important to highlight that the FDA's determination to not prosecute an unlawful activity is well within its discretion.[72]

In the landmark case on prosecutorial discretion, *Heckler v. Chaney*, the Supreme Court affirmed the FDA's right to determine for itself how to enforce the FDCA.[73] For practical reasons, the FDA cannot act against each technical violation of the FDCA.[74] An agency decision not to enforce often involves a complicated balancing of a number of factors that are peculiarly within its expertise, including: (1) whether a violation has occurred, (2) whether the agency has sufficient resources to take action, (3) whether prosecuting the violation is an efficient use of agency resources, (4) whether the agency is likely to succeed if it acts, and (5) whether taking action aligns with the Agency's overall policies.[75] The *Heckler* court reasoned that the FDA is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities.[76]

The Supreme Court subsequently reiterated in *Buckman Co. v. Plaintiffs Legal Committee* that the FDA has "complete discretion" to decide how and when to enforce the FDCA, and must exercise its prosecutorial discretion to balance statutory objectives.[77] The *Buckman* decision suggests that the FDA essentially has unlimited

72. Heckler v. Chaney, 470 U.S. 821 (1985); Buckman Co. v. Plaintiffs Legal Committee, 531 U.S. 341, 348-49 (2001).

73. *Heckler*, 470 U.S. at 837-38 ("The general exception to reviewability provided by [the Administrative Procure Act] § 701(a)(2) for action "committed to agency discretion" remains a narrow one . . . but within that exception are included agency refusals to institute investigative or enforcement proceedings, unless Congress has indicated otherwise. In so holding, we essentially leave to Congress, and not to the courts, the decision as to whether an agency's refusal to institute proceedings should be judicially reviewable.").

74. *Id*. at 831.

75. *Id*.

76. *Id*. at 831-32.

77. *Buckman*, 531 U.S. at 348.

discretion to prosecute or excuse violations of the FDCA as it sees fit.[78] Notwithstanding *Heckler* and *Buckman*, a recent decision from the Court of Appeals for the District of Columbia shows that the FDA's enforcement discretion is not be entirely shielded from judicial review.[79] In *Cook v. Food and Drug Administration*, the D.C. Circuit held that where there are clear statutory guidelines for the FDA to follow in exercising its enforcement discretion, the FDA's compliance with such guidelines is subject to judicial review under the Administrative Procedure Act.[80] Consequently, *Cook* suggests that, because section 355(a) clearly prohibits importation of finished drug products "unless an approval of an application . . . is effective with respect to such drug," the FDA's decision not to prosecute violations of section 355(a)—as it does under PLAIR—may be subject to judicial review.[81] However, even if allowing preapproval importation under PLAIR is subject to judicial review, the Agency's allowance of such importations is not necessarily an abuse of discretion.

In light of *Heckler* and *Buckman*, the PLAIR program's allowance for "minor violations" of section 355(a) to permit the importation of finished drug products ahead of anticipated FDA approval is consistent with the scope of the Agency's enforcement discretion. Furthermore, even if the PLAIR program is subject to judicial review under *Cook*, allowing for preapproval importations is likely not an abuse of the FDA's prosecutorial discretion. Note, however, that this allowance is limited to the extent that the importation of finished drug products is not subject to restrictions by other regulatory schemes, including injunctions under the Patent Act, outside the control of the FDA.

3.3. Authority to Regulate

In a modern case on the scope of the FDA's regulatory power, *FDA v. Brown & Williamson Tobacco Corp.*, the Supreme Court held that where Congress enacts a regulatory scheme outside the control of the FDA, the Agency may not regulate that area.[82] The power of the FDA to regulate must always be grounded in a valid grant of

78. James M. Beck et al., *Don't Forget FDA Prosecutorial Discretion*, DRUG AND DEVICE LAW (Oct. 5, 2012), http://druganddevicelaw.blogspot.com/2012/10/dont-forget-fda-prosecutorial-discretion.html.

79. *See* Cook v. Food & Drug Admin., 733 F.3d 1, 10 (D.C. Cir. 2013).

80. *Id.*

81. 21 U.S.C. § 355(a); *see Cook*, 733 F.3d at 10.

82. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 161.

authority from Congress.[83] In other words, the FDA may only regulate in areas specified by its authorizing statute.

The FDCA grants the Agency the authority to regulate, among other things, drugs and devices.[84] In particular, pursuant to section 355(a), the FDA possesses the authority to regulate the importation of drugs into the United States.[85] However, such authority to regulate must be squared with the fact that the importation of drugs into the United States might also be subject to regulation by other regulatory schemes outside the control of the FDA, such as the Patent Act.

Under the Patent Act, the power to regulate patents is granted to the Secretary of Commerce.[86] The FDA is not granted any general authority with respect to the Patent Act. However, the Patent Act does grant the FDA authority to do one thing—the FDA has the power to determine the period of extension of patent terms for drugs, devices, and additives that are subject to regulation by the FDCA.[87]

There is no evidence that Congress intended to authorize the FDA to regulate patent-related issues beyond the specifically recited power to determine the period of extension of patent term for the limited class of items. Therefore, if a generic drug is subject to a permanent injunction pursuant to section 271(e)(4) of the Patent Act, it is not eligible for pre-launch importation. The FDA cannot ignore the statutory mandate of the Patent Act.

The foregoing discussion leads to the conclusion that, subject to the limitations discussed above, PLAIR is a valid regulatory program. The FDA has the authority to regulate the importation of drugs into the United States and the right to exercise enforcement discretion to not prosecute a violation of section 355(a) of the FDCA. However, that authority is limited to the extent that the importation of finished drug products is not subject to restrictions by other regulatory schemes, including the Patent Act, that are outside the control of the FDA.

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83. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 161.

84. 21 U.S.C. §§ 301, 321(g)-(h), 393.

85. 21 U.S.C. § 355(a).

86. 35 U.S.C. § 2(a).

87. 35 U.S.C. §§ 156(c)(d)(1)(C), 156(c)(4)(d)(2)(A)(ii)-(B)(ii) ("The term of a patent eligible for extension . . . shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued").

4. The Conflict Between the PLAIR Program and the Hatch-Waxman Act

4.1. The Conflict

When the FDA grants a PLAIR request, it does not declare the importation to be lawful—instead, the Agency simply exercises its enforcement discretion to not prosecute a violation of section 355(a) of the FDCA. However, importation under PLAIR may nevertheless violate a permanent injunction granted pursuant to section 271(e)(4) of the Patent Act, which was added as part of the Hatch-Waxman amendments.[88] Regardless of whether the FDA chooses not to prosecute a violation of section 355(a), it has no power to abrogate the Patent Act amendments added by Hatch-Waxman.[89]

If a generic company files an ANDA with a Paragraph IV certification, the brand-name company can respond by bringing an infringement action within forty-five days.[90] If the brand-name company does not file suit within that time, then the FDA can approve the ANDA immediately.[91] Here, there is no conflict between PLAIR and Hatch-Waxman since the brand-name company never asserted its patent rights, and thus the generic company can take advantage of an approved PLAIR request to import its generic drug ahead of anticipated ANDA approval.

However, if the brand-name company files suit within that time, then the FDA is barred from approving the ANDA until the expiration of a thirty-month stay.[92] The only exceptions to the thirty-

88. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355(j) (2012), 35 U.S.C. §§ 156, 271(e) (2012)).

89. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 120. Although it is beyond the scope of this Article, there is an alternative argument that the FDA has authority to abrogate injunctions issued under section 271(e)(4) by virtue of its authority to regulate all aspects of the Hatch-Waxman Act. Hatch-Waxman was created as a tool to allow the FDA to regulate generic drug marketing. Even though the permanent injunction provision of section 271(e)(4) was inserted into the Patent Act, by virtue of originating from Hatch-Waxman, the FDA may be able to abrogate permanent injunctions granted by 271(e)(4) by virtue of its arguable authority to regulate *all* aspects of the Hatch-Waxman Act (regardless of whether the amendments ended up in Title 21 or 35). Thus, generic manufacturers could use a PLAIR request to overcome an injunction under 271(e)(4) to import prior to final ANDA approval. However, if an injunction is issued under 271(a) (i.e., during a typical patent infringement action), then a PLAIR request could not be used to allow importation during the term of the injunction.

90. 21 U.S.C. § 355(j)(5)(B)(iii).

91. 21 U.S.C. § 355(j)(5)(B)(iii).

92. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd).

month stay are if the patent expires, or if the district court finds that the patent is either invalid or not infringed, at which point the FDA can approve the ANDA immediately.[93] If one of these exceptions occurs, there is again no conflict between PLAIR and Hatch-Waxman since the brand-name company has no valid patent rights to assert against the ANDA filer. In this case, the generic company can take advantage of an approved PLAIR request to import its generic drug ahead of anticipated ANDA approval.

The conflict between PLAIR and Hatch-Waxman arises only when a district court finds that the patent is both valid and infringed.[94] In this case, the FDA cannot approve the ANDA until the patent expires.[95] Furthermore, the brand-name company is entitled to seek a permanent injunction against the generic pursuant to section 271(e)(4) of the Patent Act, which can be used to stop the generic company from importing its infringing drug product before the date that the patent expires.[96] Therefore, under Hatch-Waxman, the generic company should not be able to take advantage of PLAIR to import its generic drug into the United States ahead of anticipated ANDA approval.[97]

The problem with the PLAIR program is that it does not consider the Hatch-Waxman Act, notwithstanding the fact that Hatch-Waxman essentially serves as the statutory basis for regulating the entire generic pharmaceutical industry.[98] Under the PLAIR program, a generic company could theoretically import its generic drug ahead of anticipated ANDA approval, regardless of whether there is a permanent injunction barring such importation.[99] This is precisely what occurred in *Sanofi v. Apotex*, discussed below, where

93. 21 U.S.C. § 355(j)(5)(B)(iii)(I)–(IV).

94. Note that the conflict also likely only arises when the generic challenger is the first Paragraph IV ANDA filer. Later filers typically cannot launch their products until after the first filer's 180-day exclusivity period has expired. Depending on when the first filer begins marketing its generic drug, later filers have at a minimum 180 days after the patent expires to import their generic drugs. Since the patent has expired, later filers who take advantage of PLAIR to import during the 180-day exclusivity period to be ready to launch when the 180-day exclusivity period expires will not conflict with section 271(e)(4) of the Patent Act.

95. 21 U.S.C. § 355(j)(5)(B)(iii)(II).

96. *Id*.

97. 35 U.S.C. § 271(e)(4)(B).

98. *See* FDA, PLAIR DRAFT GUIDANCE, *supra* note 2.

99. *Id.*

the FDA did not consider a prior permanent injunction and approved the PLAIR request.[100]

4.2. Sanofi v. Apotex

Sanofi v. Apotex is the first Hatch-Waxman case in which the conflict with the PLAIR program has been raised as an issue. Sanofi-Synthelabo (Sanofi) is the owner of U.S. Patent No. 4,847,265 (the '265 patent), which expired on November 17, 2011, with a period of pediatric exclusivity that expired on May 17, 2012.[101] The '265 patent covers Plavix (clopidogrel bisulfate), a blockbuster drug used to treat heart attacks and strokes.[102]

On November 16, 2001, Apotex filed an ANDA for Plavix that included a Paragraph IV certification against '265 patent.[103] Since Apotex was the first applicant to file a Paragraph IV ANDA, it was entitled to 180 days of marketing exclusivity against later-filing applicants.[104]

In response to the ANDA filing, Sanofi brought an infringement action against Apotex in the District Court for the Southern District of New York in March 2002.[105] More than five years later, the Court held that the '265 patent was both valid and infringed, and that Sanofi was entitled to a permanent injunction against Apotex per section 271(e)(4) of the Patent Act.[106] In December 2008, the Court of Appeals for the Federal Circuit affirmed.[107]

In January 2006, while the infringement action was still pending in the District Court, the FDA approved the ANDA.[108] Before the District Court could render its decision on the validity of the '265 patent, Apotex initiated an at-risk launch on August 8, 2006, (which also triggered the start of its 180-day exclusivity period).[109]

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100. *See* Brief of Petitioner-Appellant at 2-3, Sanofi-Synthelabo v. Apotex, Inc., No. 1:02-cv-02255-SHS (Fed. Cir. May 9, 2012).

101. Sanofi-Synthelabo v. Apotex, Inc., 492 F. Supp. 2d 353, 356 (S.D.N.Y. 2007).

102. *Id*.

103. *Id*. at 357.

104. *Id*.

105. *Id*.

106. *Id*. at 397.

107. Sanofi-Synthelabo v. Apotex, Inc., 550 F. 3d 1075, 1090 (Fed. Cir. 2008).

108. *Apotex clopidogrel at-risk launch costs US$442 million*, GABI ONLINE – GENERIC AND BIOSIMILARS INITIATIVE (Feb. 3, 2012), http://www.gabionline.net/Generics/News/Apotex-clopidogrel-at-risk-launch-costs-US-442-million; *Sanofi-Synthelabo*, 492 F. Supp. 2d at 357.

109. Sanofi-Synthelabo v. Apotex Inc., 488 F. Supp. 2d 317, 344 (S.D.N.Y. 2006) *aff'd sub nom.* Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368 (Fed. Cir. 2006). On August 8,

However, just three weeks later, the District Court issued a preliminary injunction ordering Apotex to stop its sales of generic Plavix (and subsequently issued a permanent injunction, as mentioned above).[110]

Then in April 2012, notwithstanding the permanent injunction, Apotex filed a PLAIR request with the FDA to import its generic product ahead of anticipated ANDA approval on May 17, 2012, which was the date of the expiration of the '265 patent.[111] On May 7, 2012, the FDA approved the PLAIR request.[112]

Just a few days before the PLAIR request was approved by the FDA, Apotex filed a motion pursuant to Fed. R. Civ. P 60(b)(6) to amend the 2007 permanent injunction to include the underlined text:

> [Apotex is] hereby permanently enjoined from engaging in the commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States of drug products as claimed in [the '265 patent], until the expiration of [the '265 patent] and any period of pediatric exclusivity that may be granted, *except for importation by Apotex to its own warehouse facilities prior to the expiration of the pediatric exclusivity period to the extent such importation is permitted by [the FDA] pursuant to a [PLAIR request] made by Apotex and granted by the FDA*.[113]

Apotex argued that because it initiated an at-risk launch and forfeited its 180-day marketing exclusivity, it must be permitted to take advantage of PLAIR so as not to be placed at a competitive disadvantage.[114] Other manufacturers of generic Plavix would be able to use the PLAIR program to import their products ahead of

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2006, Apotex initiated an at-risk launch of its generic product, in advance of a determination on the merits of its invalidity defense against the '265. *Id.* Sanofi moved for a preliminary injunction prohibiting Apotex from distributing its generic product. *Id.* On August 31, 2006, the District Court for the Southern District of New York granted a preliminary injunction, but denied a recall on the approximately six-month supply of generic product that had already been shipped to distributors in the United States. *Id.*

110. GABI ONLINE – GENERIC AND BIOSIMILARS INITIATIVE, *supra* note 108. Note that by launching at-risk, Apotex triggered the start of its 180-day exclusivity period, but then lost the benefit of the exclusivity period when it was enjoined shortly thereafter. *Sanofi-Synthelabo*, 488 F. Supp. 2d at 344-45. However, this was a small loss, since when Apotex lost in litigation it was forced to amend its Paragraph IV certification to a Paragraph III certification, which would have caused an immediate forfeiture under 35 U.S.C. § 355(j)(5)(D)(III).

111. Sanofi-Synthelabo v. Apotex, Inc., No. 2012-1383 (Fed. Cir. May 15, 2012) (order denying motion).

112. *Id*.

113. Brief of Petitioner-Appellant at 2-3, *Sanofi-Synthelabo v. Apotex, Inc.*, No. 1:02-cv-02255-SHS (Fed. Cir. May 9, 2012) (emphasis in original).

114. *Id.*

anticipated ANDA approval, and therefore Apotex's competitors would be ready to launch the minute after Sanofi's exclusivity expired on May 17, 2012.[115] In contrast, the permanent injunction would bar Apotex from even importing its generic product until May 17, 2012.[116] Because the first-mover advantage is critical in generic drug sales, even the slight marketing delay caused by the permanent injunction would unfairly present Apotex with "extreme and undue hardship."

On May 10, 2012, the District Court denied Apotex's motion to amend the 2007 permanent injunction, holding that the five-year delay in bringing the motion was not reasonable.[117] Unfortunately, the District Court did not address whether the proposed amendment to allow importation under PLAIR would have been granted if it had been brought in a timely manner. A few days later, the Court of Appeals for the Federal Circuit affirmed, also without addressing the substance of the proposed amendment.[118] Then on May 18, 2012, the day Sanofi's exclusivity expired, the FDA approved the ANDAs of Apotex and six other generic companies.[119] Apotex's competitors were able to immediately launch their generic products.[120] Although Apotex also launched its own generic version of Plavix, as evidenced by the fact that it is currently marketing the product in the United States, the company has not publicized the specific date on which it launched its version following the FDA's en masse approval.[121]

The *Sanofi* case shows how conflict between the Hatch-Waxman Act and the PLAIR program stems from the fact that the FDA and the courts are enforcing two different sets of rules. The policies of the PLAIR program only require the FDA to review a limited set of information, which does not include possible injunctions

115. Brief of Petitioner-Appellant at 2-3, *Sanofi-Synthelabo v. Apotex, Inc.*, No. 1:02-cv-02255-SHS (Fed. Cir. May 9, 2012).

116. *Id*. at 5-6.

117. *Sanofi-Synthelabo*, No. 2012-1383 (order denying motion).

118. *Id*.

119. *Drug In Focus April 2012: Clopidogrel*, GENERICSWEB (Apr. 2012), http://www.genericsweb.com/download/DIF%20Clopidogrel.pdf. The six other generic companies were Dr. Reddy's Laboratories Ltd., Mutual Pharmaceuticals Co., Mylan Inc., Roxane Laboratories, Inc., Sun Pharma USA, and Torrent Pharmaceuticals Ltd.

120. *Dr Reddy's Laboratories, Mylan Launch Clopidogrel Tablets in US Market*, ECONOMIC TIMES (May 18, 2012), http://articles.economictimes.indiatimes.com/2012-05-18/news/31765607_1_paragraph-iv-tablets-generic-version.

121. *Clopidogrel Tablets USP, 75MG, 30 TABLET (BOTTLE) - Apotex Products: United States*, APOTEX CORP., http://www.apotex.com/us/en/products/detail.asp?m=45969 (last visited Apr. 11, 2014).

against the requester.[122] In *Sanofi v. Apotex*, Apotex did not submit information on the permanent injunction against it, and the FDA presumably was not aware of it when approving the PLAIR request.[123] The courts, in contrast, refused to allow Apotex to insert PLAIR-related language into the permanent injunction. As shown in *Sanofi*, the courts reviewed the entire record before it, which included the 2007 permanent injunction.[124]

Because the courts did not address the substance of Apotex's motion, we do not know whether a court would allow a permanent injunction issued under section 271(e)(4) of the Patent Act to be abrogated by a PLAIR request. However, as discussed in Part 3, *supra*, while the FDA has the authority to regulate the importation of drugs into the United States and the right to allow preapproval importation via the PLAIR program, the Agency does not have any authority to regulate with respect to the Patent Act. As such, the courts should not allow PLAIR-based importations during the pendency of a permanent injunction.

5. The PLAIR Program and the Intent of the Hatch-Waxman Act

The goal of the PLAIR program is to allow pharmaceutical companies to import unapproved finished drug products in preparation for market launch.[125] Here we discuss how this goal does not conflict with the intent of the Hatch-Waxman Act, which is to strike a balance between conflicting policy objectives—enabling generic companies to bring low-cost drugs to the market while maintaining incentives for pioneers to develop and launch innovative new drugs.[126] These objectives are reflected in the two parts of the Hatch-Waxman Act: Title I, the Drug Price Competition Act, which amended section 355 of the FDCA, and Title II, the Patent Term Restoration Act, which amended section 271 of the Patent Act.[127] The intent of each part is separate and distinct, and therefore, the

122. FDA, PLAIR DRAFT GUIDANCE, *supra* note 2, at 1.

123. *See* Brief of Petitioner-Appellant at 2-3, *Sanofi-Synthelabo v. Apotex, Inc.*, No. 1:02-cv-02255-SHS (Fed. Cir. May 9, 2012). Interestingly, even if the FDA were aware of the permanent injunction, it is not clear that this would have had any effect on its decision to approve Apotex's PLAIR request.

124. *Sanofi-Synthelabo*, No. 2012-1383 (order denying motion).

125. FDA, PLAIR DRAFT GUIDANCE, *supra* note 2, at 2-3.

126. *aaiPharma Inc.*, 296 F.3d at 230; Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990); *see also* H.R. REP. NO. 98-857, pt. I, at 14-15 (1984).

127. H.R. Rep. No. 98-857, pt. 1, at 20; pt. 1, at 37.

PLAIR program and its effects will be discussed in the context of Title I and Title II in Parts 5.1 and 5.2, respectively.[128]

5.1. Title I and Making Generic Drugs Available to the Public

The intent of the Drug Price Competition Act is to make more generic drugs available to the public.[129] It is in the public interest that generic drug manufacturers bring their products to market as soon as possible because the price of generic drugs is significantly discounted from the price of brand-name drugs.[130] In addition, it is in the public interest that there be as many generic competitors in the marketplace as possible, since the more generic competitors there are in the marketplace, the cheaper the generic drugs become.[131] The PLAIR program aligns with the intent of Title I by helping generic manufacturers expedite the commercial launch of their products.[132] As such, from this policy standpoint, Apotex arguably should have been permitted to take advantage of its approved PLAIR request.

As discussed in Part 1.2, *supra*, the Hatch-Waxman Act primarily helps bring generics to market via the ANDA process, which most notably allows generic competitors to use Paragraph IV certifications to seek market entry prior to the expiration of the patents covering the brand-name drug.[133] Additionally, in order to encourage Paragraph IV challenges, Hatch-Waxman provides that the first applicant to file an ANDA with a Paragraph IV certification will be granted 180 days of market exclusivity upon market launch, in

128. H.R. Rep. No. 98-857, pt. 1, at 14; pt. 2, at 11.

129. H.R. Rep. No. 98-857, pt. 1, at 14 ("The purpose of Title I of the Bill is to make available more low cost generic drugs by establishing a generic drug procedure for pioneer drugs first approved after 1962.").

130. FOOD AND DRUG ADMINISTRATION, GENERIC DRUGS: QUESTIONS AND ANSWERS, http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm (last visited Mar. 11, 2013) (According to the FDA, "[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price.").

131. Avery, *supra* note 38, at 179 n.56 ("For example, when generic Prozac (Fluoxetine) entered the market, the first generic challenger sold it at $1.91/capsule, or 12% below the cost of brand-name Prozac. Two months after the exclusivity period expired, multiple generics had entered the market and the price of generic Prozac had dropped to $0.32/capsule.").

132. FDA, PLAIR DRAFT GUIDANCE, *supra* note 2, at 1; Kurt R. Karst, *PLAIRs–What are They and What are FDA's Current Policies?*, FDA LAW BLOG (Apr. 11, 2010), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2010/04/plairs-what-are-they-and-what-are-fdas-current-policies.html.

133. H.R. Rep. No. 98-857, pt. 1, at 16; *see also* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

exchange for assuming the costs and the risks associated with litigation.[134]

In *Sanofi v. Apotex*, Apotex was the first applicant to file an ANDA with Paragraph IV certification, and therefore secured the 180-day exclusivity period.[135] However, Apotex lost in litigation, lost the exclusivity period, and was enjoined from importing generic Plavix until the expiration of Sanofi's patent.[136] In contrast, Apotex's competitors were able to import and stockpile their products prior to patent expiry via the PLAIR program.[137] Consequently, these other generic manufacturers were ready and able to ship generic Plavix to their customers the minute Sanofi's patent expired.[138] Apotex argued that it would not be able to compete in the marketplace against its competitors because by being delayed in market launch by even a single day, it risked losing profits forever because it would not be able to match the delivery schedules of its competitors.[139]

While this result for Apotex was legally correct, it was also contrary to the intent of the Hatch-Waxman Act to encourage generic manufactures to bring more of their products to the market. By challenging Sanofi's patents, Apotex assumed the costs and risks associated with litigation. However, just because Apotex lost in litigation does not mean that it should be placed at a competitive disadvantage compared to later filing applicants who did not face the costs and the risks associated with litigation. But this is precisely what occurred in *Sanofi v. Apotex*.[140] After Sanofi successfully sued Apotex for patent infringement, Apotex converted its Paragraph IV certification to a Paragraph III certification, in which it certified it would not launch its generic product until after Sanofi's patent expired.[141] Apotex was able to manufacture its generic product in a

134. 21 U.S.C. § 355(j)(5)(B)(iv); Representative Henry Waxman, *Speech at the Generic Pharmaceutical Association's First Annual Policy Conference: Securing the Future of Affordable Medicine* (Sept. 20, 2005), *available at* http://www.house.gov/waxman/news_files/news_statements_generic_pharmaceutical%20_association_9.20.05.htm.

135. *Sanofi-Synthelabo*, 492 F. Supp. 2d at 357.

136. 35 U.S.C. § 271(e)(4); *Sanofi-Synthelabo*, 492 F. Supp. 2d at 397; *Sanofi-Synthelabo*, 550 F.3d at 1090.

137. Brief of Petitioner-Appellant at 3, 5 *Sanofi-Synthelabo v. Apotex, Inc.*, No. 1:02-cv-02255-SHS (Fed. Cir. May 9, 2012).

138. *Id*.

139. *Id*. at 5-6.

140. *Id*. at 3, 5.

141. Letter from Keith Webber, Deputy Director, Office of Pharmaceutical Science, Center for Drug Evaluation and Research, to Kiran Krishnan, Director, North American

foreign country prior to the expiry of Sanofi's patent, but it was not able to import this product into the United Sates.[142] Apotex's competitors were not similarly restrained. Consequently, even though there was effectively no difference between Apotex and its competitors—no one was going to launch a generic prior to the expiration of Sanofi's exclusivity period—Apotex was placed at a competitive disadvantage merely for taking the risk of filing the first Paragraph IV challenge. This should not be the result. Instead, keeping with the intent of Hatch-Waxman, Apotex should have been permitted to take advantage of its approved PLAIR request to expedite its product launch.

5.2. Title II and Incentivizing Research and Development by Brand-Name Manufacturers

The intent of the second part of Hatch-Waxman, the Patent Term Restoration Act, is to induce brand-name companies to make the investments necessary to research and to develop new drugs by restoring some of the patent term lost during the FDA approval process.[143] Title II permits the extension of the term of a patent for a definite period of time provided that certain requirements are met, where this period of time is primarily based on marketing delays created while the product is awaiting FDA approval.[144] Congress was explicit that the extension of the patent term should be a definite period of time with no other direct or indirect method of extending patent term, and thereafter, *immediate* competition should be encouraged.[145] For that reason, Title I, the Drug Price Competition Act, permits the filing and tentative approval of ANDAs before

Regulatory Affairs, Apotex Corp. (May 12, 2012) (on file with the Food and Drug Administration).

142. 35 U.S.C. 271(e)(4)(b) (emphasis added) ("For an act of infringement . . . injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale *within the United States* or importation into the United States of an approved drug, veterinary biological product, or biological product. . . .").

143. H.R. Rep. No. 98-857, pt. 2, at 11 ("Title II of the Bill encourages drug manufacturers to assume the increased costs of research and development of certain products which are subject to premarketing clearance by restoring some of the time lost on patent life while the product is awaiting FDA approval.").

144. H.R. Rep. No. 98-857, pt. 1, at 46.

145. *Id*. ("Article 1, Section 8, Clause 8 of the Constitution empowers Congress to grant exclusive rights to an inventor for a limited time. That limited time should be a definite time, and thereafter, immediate competition should be encouraged. For that reason, Title I of the Bill permits the filing of Abbreviated New Drug Applications before a patent expires and contemplates that the effective approval date will be the expiration date of the valid patent covering the original product.").

patent expiration, and contemplates that the *effective* approval date will be the expiration date of the valid patent.[146] In practice, there should be no lag between patent expiration and competition, and the generic drug should be able to enter the market the minute after the brand-name manufacturer's patent expires. But if the first applicant to file an ANDA with Paragraph IV certification loses in litigation, pursuant to section 271(e)(4) of the Patent Act, it can be enjoined from importing its generic product into the United States before patent expiration, causing such a lag.[147] This is precisely what happened in *Sanofi v. Apotex*. Sanofi's marketing exclusivity expired on May 16, 2012 and Apotex's competitors were able to start shipping their generic products to customers at 12:01 a.m. on May 17.[148]

However, this result is contrary to the intent of the Hatch-Waxman Act. By delaying importation of generic drugs until after patent expiration, section 271(e)(4) of the Patent Act effectively grants a *de facto* patent term extension, which is in direct conflict with Congress' explicit intent to allow generic competition immediately after patent expiration. PLAIR allows generic companies to warehouse their drugs in the United States prior to FDA approval so that they can expedite their market launches once they receive final approval from the Agency. The PLAIR program aligns with the intent of Title II by ensuring that there is immediate competition after patent expiration. Thus, from a policy standpoint, Apotex arguably should have been permitted to take advantage of its approved PLAIR request.

6. Solutions to the Conflict Between the PLAIR Program and Hatch-Waxman and Guidance for Practitioners

Although PLAIR does not conflict with the goals of the Hatch-Waxman Act, and regardless of whether the FDA chooses to exercise enforcement discretion to not prosecute a violation of the FDCA, the Agency has no power to abrogate the statutory mandates of Hatch-Waxman. Under the current laws, pharmaceutical patent holders should be able to use permanent injunctions to prevent any importation prior to patent expiration, including preapproval importations via PLAIR requests. Ultimately, whether to allow

146. H.R. Rep. No. 98-857, pt. 1, at 46 (emphasis added). Note that this aligns with the Patent and Copyright Clause of the Constitution, which empowers Congress to grant exclusive rights to inventors "for limited times." U.S. CONST. art. I, § 8, clause 8.

147. 35 U.S.C. § 271(e)(4).

148. Brief of Petitioner-Appellant at 3, 5 *Sanofi-Synthelabo v. Apotex, Inc.*, No. 1:02-cv-02255-SHS.

generic companies to take advantage of PLAIR despite the conflict with Hatch-Waxman comes down to a policy choice that is up to Congress to make—it must choose whether to protect the patent rights of innovators or to speed generic drug competition.

6.1. Protecting Patent Rights

As discussed in Part 3, the FDA's enforcement discretion does not give the Agency the power to override injunctions under section 271(e)(4) of the Patent Act that prohibit importation of a generic drug. To ensure that the FDA does not approve PLAIR requests during the term of a patent injunction, the FDA should amend the PLAIR process so that an applicant is required to submit information identifying any injunctions that may prohibit importation of its product. For example, the FDA could amend the PLAIR Draft Guidance[149] to require the following be included with all PLAIR requests:

> (j) A letter signed by an authorized representative of the applicant certifying under 18 U.S.C. § 1001 that the applicant is not a party to a court order subject to an injunction prohibiting importation of the drug product.

This requirement will save both the FDA and the courts resources. Such a requirement would allow the FDA to reject PLAIR requests that seek to illegally import products during the term of an injunction (or to summarily deny such requests if they fail to submit this required information). In turn, this would prevent courts from having to weigh in on whether importation under the PLAIR request is proper.

Requiring PLAIR applicants to notify the FDA of injunctions prohibiting importation of their product would avoid the issue raised in *Sanofi v. Apotex*, where the FDA has approved Apotex's PLAIR request without considering the permanent injunction against Apotex that prohibited importation before the expiration of Sanofi's patent. The conflict between PLAIR and Hatch-Waxman is a waste of resources for both the FDA and the courts, and revision of the PLAIR process is necessary.

6.2. Accomplishing the Intent of Hatch-Waxman

Given that PLAIR accomplishes the intent of Hatch-Waxman, one solution to resolving the conflict between them is to incorporate language into the Hatch-Waxman Act permitting PLAIR-based

149. FDA, PLAIR DRAFT GUIDANCE, *supra* note 2 at 2-4.

importation. Congress could revise section 271(e)(4) of the Patent Act with an amendment of subsection (B), adding similar language to the underlined text below:

> For an act of infringement [caused by filing an ANDA with a Paragraph IV certification]
>
> (A) the court shall order the effective date of any approval of the drug . . . to be a date which is not earlier than the date of the expiration of the patent which has been infringed,
>
> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, *except importation into the United States shall be allowable to the extent that such importation is permitted by the Food and Drug Administration pursuant to a Pre-launch Activities Importation Request.*[150]

Such an amendment to subsection (B) would allow generic companies to import their products during the term of an injunction, while still prohibiting them from actually marketing their products until the brand-name manufacturer's patent expires, thereby protecting the pioneer's patent rights. Furthermore, section 271(e)(4) could be further amended to only allow importation if the PLAIR applicant submits a letter signed by an authorized representative certifying under 18 U.S.C. § 1001 that it will not sell, offer to sell, or distribute its product prior to receiving final marketing approval from the FDA.[151] Requiring such a letter would ensure that PLAIR still prohibits pharmaceutical companies from marketing new drugs without actual FDA approval, so that even if a drug has been imported, the public is still protected from consuming potentially unsafe or ineffective drugs.

7. Strategic Considerations for Practitioners

Until Congress or the FDA acts, practitioners are left with flawed statutory and regulatory schemes. If a district court issues a permanent injunction pursuant to section 271(e)(4) of the Patent Act to prohibit the generic company from importing its infringing drug product before the date that the patent expires, then the generic should not be able to take advantage of PLAIR to import its generic drug into the United States ahead of anticipated ANDA approval. The following sections discuss strategic considerations and

150. 35 U.S.C. § 271(e)(4) (emphasis added).

151. This would codify one of the current requirements for submitting PLAIR requests. *See* FDA, PLAIR DRAFT GUIDANCE, *supra* note 2 at 3-4.

precautions for lawyers representing both generic manufacturers filing PLAIR requests and brand-name manufacturers seeking to stop preapproval importation of generics.

7.1. Guidance for Generic Companies

In order for a generic company to take advantage of the PLAIR program, it may wish to avoid the possibility of being enjoined under section 271 (e)(4) by filing its ANDA with a Paragraph III certification rather than a Paragraph IV certification. Since filing a Paragraph III certification is not an act of patent infringement, the pioneer will not be able to sue the ANDA applicant to seek an injunction.[152] Of course, the disadvantage of filing a Paragraph III certification is the generic applicant must wait until the pioneer's patent expires to enter the market, but this may be a moot point in certain cases.

For example, the first generic company to file an ANDA will likely include a Paragraph IV certification in order to secure the 180-day exclusivity period.[153] However, if during litigation it appears that the pioneer may prevail in proving both validity and infringement of its patent, the first filer may want to amend its Paragraph IV certification to a Paragraph III certification before the court can rule and issue an injunction. While this will cause the first filer to forfeit its 180-day exclusivity period,[154] it will also prevent the first filer from being enjoined from importing infringing product during the patent term.[155] In this case, the generic challenger will not be able to enter the market until the pioneer's patent expires, but this is no different from if the generic lost in litigation and was enjoined. But by switching over to a Paragraph III certification before a court can issue an injunction, the generic manufacturer will preserve its ability to use the PLAIR program to import finished drug product prior to patent expiry, allowing it to launch immediately thereafter.[156]

This strategy may also be useful for later ANDA filers. The first ANDA filer will typically enter into a reverse-payment settlement with the pioneer, where it agrees to delay marketing its generic product (typically until several months before the patent

152. 21 U.S.C. § 355(j)(2)(A)(vii)(III).

153. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

154. 21 U.S.C. § 355(j)(5)(D)(III); *see also* Avery, *supra* note 38, at 186.

155. 21 U.S.C. § 355 (j)(5)(B)(iii)(II).

156. Brief of Petitioner-Appellant at 2-3, 5, *Sanofi-Synthelabo v. Apotex, Inc.*, No. 1:02-cv-02255-SHS.

expires).[157] This means that any later filers will be prevented from entering the market until the first filer's 180-day exclusivity period runs, which may be no sooner than the expiration of the pioneer's patent.[158] If the later ANDA filer includes a Paragraph IV certification, it will pointlessly risk an infringement suit and a possible injunction with little chance of entering the market before the first filer's exclusivity period is over. Since an injunction would prevent the later filer from utilizing the benefits of the PLAIR program, it may be advantageous for the later filer to simply file a Paragraph III certification from the start.

7.2. Guidance for Brand-Name Companies

In order for a brand-name company to prevent a generic manufacturer from using the PLAIR program to import finished drug product prior to the expiration of its patents, the pioneer must prevail in showing both validity and infringement of its patents, and then successfully secure an injunction barring the generic manufacturer from importing its product during the term of the patent. Furthermore, the pioneer should ensure that the injunction bars all importation into the United States, with no exceptions for PLAIR-based importations.

If the pioneer becomes aware of a PLAIR request filed by a generic challenger that has been previously enjoined under section 271(e)(4), the pioneer may consider filing a citizen petition with the FDA requesting that it deny the PLAIR request.[159] In such a petition, the pioneer should inform the FDA of the injunction and argue that the FDA should deny the PLAIR request because the Agency does not have the authority to contravene the injunction by authorizing importation of the generic product prior to patent expiry. Alternatively, the pioneer may wish to be more aggressive and sue the FDA directly, seeking to enjoin the Agency from approving the PLAIR request. While the authors are not aware of any such petitions or lawsuits, these strategies may allow a pharmaceutical patent holder to stop the FDA from approving a PLAIR request and prevent any importation prior to the expiration of its patents.

157. Matthew Avery & Mary Nguyen, *The Roadblock to Generic Drugs: Declaratory Judgment Jurisdiction for Later Generic Challengers*, 15 N.C. J.L. & TECH. 1, 8-9 (2013).

158. *Id.* at 10-11.

159. *See* Matthew Avery et al., *The Antitrust Implications of Filing "Sham" Citizen Petitions with the FDA*, 65 HASTINGS L.J. 113, 122-23 (2013).

Conclusion

A conflict arises between the PLAIR program and the Hatch-Waxman Act when the FDA allows preapproval importation notwithstanding an injunction against a generic manufacturer prohibiting such importation. While the FDA has the authority to regulate the importation of drugs into the United States and the right to allow preapproval importation via the PLAIR program, it does not have the authority to abrogate patent injunctions issued under section 271(e)(4) of the Patent Act (which was added as part of the Hatch-Waxman amendments).

Nevertheless, the PLAIR program does not conflict with the objectives of the Hatch-Waxman Act of facilitating generic market entry while preserving incentives for pioneer's to develop innovative new products. Under the current laws, pharmaceutical patent holders should be able to use permanent injunctions to prevent any importation prior to patent expiration, including preapproval importations via PLAIR requests. However, if Congress decides that speeding generic competition is more important than protecting the patent rights of pioneers, then it could resolve this conflict by amending section 271(e)(4) to include language permitting PLAIR-based importations. In the meantime, the FDA should amend the requirements of PLAIR requests so that applicants are required to notify the FDA of any injunctions prohibiting importation of their products. Doing so would help the Agency to avoid violating the patent rights of pioneers and approving illegal importations.

An Insight into the Apparel Industry's Patent Troll Problem

by ASHLI WEISS*

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* J.D. candidate, University of California, Hastings College of the Law, 2014. Ms. Weiss is the Senior Technology Editor of the *Hastings Law Journal* and the President and Founder of the Hastings Fashion, Art & Design Law Society.

Introduction

> The folks that you're talking about [patent trolls] are a classic example [of the problems facing the U.S. patent system]; they don't actually produce anything themselves. They're just trying to essentially leverage and hijack somebody else's idea and see if they can extort some money out of them… [O]ur efforts at patent reform only went about halfway to where we need to go and what we need to do is pull together additional stakeholders and see if we can build some additional consensus on smarter patent laws.
>
> —Barack Obama, President of the United States[1]

Patent trolls, also known as non-practicing entities or patent assertion entities, have had a terribly destructive effect on the American economy. Alleged infringers paid patent trolls $29 billion in 2011, and troll activity between 2007 and 2011 is estimated to have resulted in $300 billion of lost wealth.[2] In an attempt to mitigate the damaging effects of patent trolls, the U.S. House of Representatives passed the Innovation Act on December 5, 2013. The bill was designed to counteract troll activity by increasing patent ownership transparency, heightening pleading requirements, and introducing defendant-friendly fee-shifting and joinder provisions.[3] The bill followed the introduction of seven other pieces of legislation, demands by the Obama administration, and a national anti-troll advertising campaign highlighting the problems associated with patent trolls.[4]

Of the many examples of patent troll litigation, troll suits targeting apparel companies provide a useful illustration of how

1. Patent Assertion and U.S. Innovation, Executive Office of the President (June 2013), *available at* http://www.whitehouse.gov/sites/default/files/docs/patent_report.pdf (hereinafter *Patent Assertion and U.S. Innovation Executive Memo*) (President Obama held a Google Hangout where he took questions from the public for an hour. Toward the end, an entrepreneur spoke and noted that patent trolls frequently sue her peers. This quote was taken from President Obama's response.).

2. *Id*. at 9-10.

3. H.R. 3309, 113th Cong. (2013).

4. *See* Electronic Frontier Foundation, *Current Legislative Proposals for Patent Reform* https://www.eff.org/issues/current-legislative-proposals-patent-reform (Briefing all legislative, executive and state actions addressing the patent troll problem) (last updated Dec. 9, 2013); Patent Assertion and U.S. Innovation Executive Memo, *supra* note 1; Laura Sydel, *Taking the Battles Against Patent Trolls to the Public*, All Tech Considered (Aug. 30, 2013, 5:21 PM), http://www.npr.org/blogs/alltechconsidered/2013/08/30/217272814/taking-the-battle-against-patent-trolls-to-the-public (discussing the Nation Retail Federation's campaign against patent trolls).

patent trolling affects end users. Because the apparel industry has long clung to a legacy business model, only in recent years adopting new and innovative modern technologies, it might not seem like natural target of patent trolls.[5]

Furthermore, rather than developing technologies such as online shopping carts or the attachment of PDF receipts to emails in-house, apparel companies tend to utilize such technologies as end users by purchasing them from other vendors.[6] A casual observer might conclude that apparel companies' reliance on outside companies' technology would not make them particularly appealing targets for patent litigation. After all, apparel is primarily a creative industry that focuses on the aesthetics of fashion and not on technological innovation.

However, patent trolls have increasingly targeted the end users of patent-encumbered technology, and in turn have frequently targeted companies in the apparel industry.[7] The unfortunate reality is that the apparel industry provides an appealing and vulnerable target for troll litigation. Apparel is a multibillion dollar industry, and the fact that companies in the apparel industry primarily utilize other companies' cutting-edge technology contributes to the decision to settle litigation rather than challenge asserted patents in court—generally, it is much cheaper to settle and pay a license than to go to court.[8] Given apparel companies' deep pockets and tendency toward settlement, then, it is unsurprising that patent trolls find them tempting targets. As this article will illustrate in detail, patent trolls have filed many suits against apparel companies. The problems patent troll suits pose to apparel companies provide a useful example of the predicament faced by a variety of similarly situated, nontechnology-oriented companies targeted by troll litigation.

The threat of continued troll litigation has led retail industries like apparel to turn to Congress in search of a solution to the patent

5. *See generally* Mathew Carroll, *Three Future Waves of Innovation in E-Commerce for Fashion & Apparel*, FORBES (Nov. 1, 2011), http://www.forbes.com/sites/matthewcarroll/2011/11/01/3-future-waves-of-innovation-in-e-commerce-for-fashion-apparel-quora/.

6. *See* Laura Sydell, *Taking the Battle Against Patent Trolls to the Public*, NATIONAL RETAIL FEDERATION (Aug. 30, 2013), http://www.npr.org/blogs/alltechconsidered/2013/08/30/217272814/taking-the-battle-against-patent-trolls-to-the-public.

7. *See* Press Release, The White House, Office of the Press Secretary, FACT SHEET: White House Task Force on High-Tech Patent Issues (Jun. 4, 2013), *available at* http://www.whitehouse.gov/the-press-office/2013/06/04/fact-sheet-white-house-task-force-high-tech-patent-issues.

8. *See* Sydell, *supra* note 6.

troll problem.[9] A bill that addresses the patent troll issue facing apparel requires insightful solutions, which this article aims to provide by detailing key elements to be included in proposed legislation. It begins by discussing the history of technology and apparel, and where this relationship stands today. The article then explains the reasoning behind patent trolls' targeting of apparel, and provides several recent cases as examples. Lastly, the final section analyzes the Innovation Act H.R. 3309, which appears to be the bill that Congress is most likely to choose as its answer to the patent troll problem. This final section recommends amendments to the Innovation Act that address the specific problems troll suits create for the apparel industry.

Part I: The Perfect Target

A choice target for patent trolls is a company with a combination of certain desirable economic and structural characteristics. These characteristics include the widespread adoption of new technologies and the use of these technologies as an end user.[10] As apparel companies have grown and changed over the past century they have developed many of these characteristics.

A. The Rise of Technology in Apparel

The integration of technology into the apparel business model has been gradual, a process greatly influenced by the history of the industry itself.[11] America's apparel industry first emerged in the 19th Century.[12] At the time, tailors had personal relationships with their customers and would craft garments to fit each of them individually.[13] Over time, tailors recognized that the shaping, fitting and assembly of garments involved steps that did not vary from one customer to the next, and developed a mathematical sizing system to accommodate most people with very few patterns.[14] Beginning in the 20th Century, tailors began to develop these patterns into comprehensive paper "information systems" which enabled the exact reproductions needed

9. *See* Stephen Schatz, *Retailers Urge Action To Combat Patent Troll Demand Letters*, NATIONAL RETAIL FEDERATION (Nov. 7, 2013), http://www.nrf.com/modules.php?name=News&op=viewlive&sp_id=1690.

10. *See infra* Section I.D.

11. *See* Carroll, *supra* note 5.

12. *See Short History of Ready-Made Clothing*, National Institute of Standards & Technology (Oct. 8, 2004), http://museum.nist.gov/exhibits/apparel/history.htm.

13. *Id*.

14. *Short History of Ready-Made Clothing*, National Institute of Standards & Technology (Oct. 8, 2004), http://museum.nist.gov/exhibits/apparel/history.htm.

for the cutting and stitching of clothing in mass production systems.[15] It was thus with the rise of the mass production of clothing that the apparel industry began to integrate more advanced technological tools into their traditional, old-fashioned business model.[16]

The apparel industry experienced a technological boom in the mid-1990s as companies began to modernize their operations.[17] The business side of apparel eagerly integrated new technologies into its brick-and-mortar locations, enabling the printing of receipts at cash registers, the sale of gift cards, and the use of networked devices like computers and printers.[18] However, the apparel industry was slow to develop a significant Internet presence, and it was not until 2005 that companies began to experience large scale growth online.[19] Nonetheless, today nearly every apparel company has an Internet presence. Modern technology, especially the internet, has upended the apparel industry's business model and led to extensive structural changes.[20]

B. The Apparel Industry and Technology Today

In the apparel industry today, companies that wish to survive and compete have found it necessary to aggressively adopt modern technologies.[21] Customers familiar with the benefits of modern technology expect a higher level of service and convenience. As market leaders have adapted and changed, free market pressures have pushed other apparel companies to follow suit.

It was only a few years ago that apparel companies advertised exclusively through traditional mediums like print and television. [22]

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15. *Short History of Ready-Made Clothing*, National Institute of Standards & Technology (Oct. 8, 2004), http://museum.nist.gov/exhibits/apparel/history.htm.

16. *Id*.

17. *See generally* JAMES E. DION, THE EFFECTS OF POS IMPLEMENTATION AND RETAIL TECHNOLOGY ON SALES AND PROFITABILITY FOR SMALL TO MED SIZED RETAILERS, TRICITY RETAIL 1-2 (2003), *available at* http://www.tricityretail.com/brochures/wp_posimplementation.pdf.

18. *Id*.

19. *See* James B. Stewart, *Internet Big Four: Worth a Look as Growth Stocks*, WALL ST J. (May 4, 2005), http://online.wsj.com/news/articles/SB111516197645623835.

20. *See generally* UCHE OKONKWO, LUXURY ONLINE: STYLE, SYSTEMS, STRATEGIES (2010).

21. *See* Plunkeet Research, Ltd., *Introduction to the Retail Industry*, http://www.plunkettresearch.com/retailing-stores-market-research/industry-and-business-data (last visited Apr. 10, 2014).

22. John S. Major & Valerie Steele, *Fashion Industry: Media and Marketing*, ENCYCLOPAEDIA BRITANNICA, http://www.britannica.com/EBchecked/topic/1706624/fashion-industry/296479/Media-and-marketing (last visited Apr. 10, 2014).

Today, the world of apparel advertising has grown beyond traditional media and expanded into the online realm, a natural transition given the highly visual worlds of both fashion and the internet.[23] A competitive apparel company today must engage with consumers online, over social networks, and through customers' mobile phones. These technological outlets are more targeted and efficient, and allow companies to gather and utilize various types of information about their customers in order to guide the design of their product lines.

As a result, technology has transformed the role of the designer in shaping trends. Rather than relying upon a designer's intuition of people's desires, retailers can now collect customer data and analyze it to anticipate the styles and items that people will want to buy. Indeed, this kind of data processing has become such a powerful tool that retailers can correctly predict a customer's purchasing needs before they even know that they want a particular item. In a recent example of the predictive power of retail data processing, Target sent customized advertisements to a customer for pregnancy-related products before she even knew she was pregnant, a prescience enabled by superior data processing.[24] The apparel industry has begun processing customer data in similar ways.[25] Data processing has proven itself to be a useful tool, changing the way brands interact with customers, the way retailers identify and capitalize on emerging trends, and even the way retailers manage their supply chains.[26]

Although some of this data is obtained through brick-and-mortar stores, apparel companies collect much of it through e-commerce, which has become a vital sales platform for the industry. E-commerce offers companies the advantages of lower operational costs, twenty-four-hour and seven-days-a-week sales windows, and greater customer reach made possible by virtual storefronts accessible

23. Major, et al., *supra* note 22.

24. *See* Kashmir Hill, *How Target Figured Out a Teen Girl Was Pregnant Before her Father Did*, FORBES (Feb. 16, 2012), http://www.forbes.com/sites/kashmirhill/2012/02/16/how-target-figured-out-a-teen-girl-was-pregnant-before-her-father-did/ (explaining how every time a consumer goes shopping, intimate details about their consumption patterns are being recorded and used by the retailer).

25. *See* Jeffrey Edward Axline & Brian Joseph Lebl, Leveraging Downstream Data in the Footwear/Apparel Industry at 11 (May 11, 2007) (unpublished M. Eng. thesis, Massachusetts Institute of Technology).

26. *See* Jessica Binns, *Top Apparel Companies Transform Their Processes With Business Intelligence*, APPAREL, Oct. 2013, *available at* http://apparel.edgl.com/case-studies/Top-Apparel-Companies-Transform-Their-Processes-with-Business-Intelligence88796.

from anywhere.[27] In 2012, e-commerce apparel sales grew almost four times faster than brick-and-mortar retail sales.[28] This growth is predicted to continue. In a recent article, eight CEOs from top retail companies listed "investing big in online shopping" as one of their top three goals.[29] Experts forecast that U.S. online retail sales will grow from $231 billion in 2012 to $370 billion in 2017, representing 10% of total U.S. retail sales in 2017.[30] In addition, apparel companies increasingly have begun to emphasize mobile commerce, or transactions made on smartphones and tablets.[31] Although sales on mobile devices are a relatively newer development, experts predict that mobile sales are set to increase dramatically in the coming years.[32] In 2012 mobile commerce accounted for 11% of U.S. e-commerce retail sales, but by 2016 is expected to account for a full quarter of U.S. e-commerce retail sales.[33] Technology has already fundamentally reshaped the way apparel companies do business, and the evidence thus far suggests that the deep integration of modern technology and modes of business into the apparel industry is far more than a passing trend.

C. The Patent Troll Business Model

The patent troll business model focuses solely on the acquisition and assertion of patents. Trolls scour the legal landscape for vaguely worded, broadly defined patents, often buying them from bankrupt companies or small inventors.[34] They commonly act through shell

27. LOIS F. HERZECA & HOWARD S. HOGAN, FASHION LAW AND BUSINESS: BRANDS AND RETAILERS 505 (2013).

28. *Id.* (citing Carmela Aquino, *2013 U.S. Digital Future in* Focus Series, COMSCORE, INC. (Aug. 22, 2013), http://www.comscore.com/insights/blog/2013_digital_future_in_focus_series).

29. Barbara Thau, *Eight Retail CEOs (Including Wal-Mart's) Reveal Top Goals for 2013*, FORBES (Jan. 17, 2013, 8:30 AM), http://www.forbes.com/sites/barbarathau/2013/01/17/eight-retail-ceos-including-wal-marts-reveal-top-goals-for-2013/.

30. *See* Herzeca & Hogan, *supra* note 25 (citing *U.S. Online Retail Forecast, 2012 to 2017*, INTERNET RETAILER (Apr. 2013), http://www.internetretailer.com/trends/sales/).

31. *See* Thau, *supra* note 29.

32. *See* Herzeca & Hogan, *supra* note 25 (citing Claire Can Miller, *Do People Actually Shop on Phones? The Answer is Decidedly Yes*, N.Y. TIMES BITS BLOG (Jan. 9, 2013), http://www.bits.blogs.nytimes.com/2013/01/09/do-people-acctually-shop-on-phones-the-anwser-is-decidedly-yes/).

33. *See* Herzeca & Hogan, *supra* note 27.

34. Dan D'Ambrosio, *Patent Trolls Demand Infringement Fees*, USA TODAY (Nov. 12, 2013), http://www.usatoday.com/story/money/business/2013/11/12/patent-trolls-demand-infringement-fees/3511307/.

companies whose only asset is a single patent.[35] All litigation is filed through these shell entities, so when they assert their rights in the patent in question, they leave no assets vulnerable to countersuit.[36] Furthermore, the consequences of patent trolling are significant: a recent study estimated that the direct accrued cost of patent troll lawsuits on targeted firms was $29 billion in 2011.[37] The profitability of the patent troll business model derives in large part from two key factors: (1) the ease of asserting patents against a large number of potential infringers, at very little cost to the troll; and (2) the large potential liability to the accused infringers, who are inclined to pay a relatively small licensing fee rather than to take on the expense of a patent trial and the risk of a large judgment if they are ultimately found to have infringed the asserted patents.

Data shows that the patent troll business model works, and is very profitable. In 2007, patent trolls filed 22% of all patent infringement lawsuits.[38] Four years later, in 2011, the suits filed by patent trolls increased to 40% of such lawsuits.[39] Observers have argued that the jump in filing was due in large part to recent changes in the law brought about by the America Invents Act ("AIA"), as litigants rushed to file patent infringement claims before certain provisions of the new law went into effect.[40] In 2012, however, filings by trolls increased yet again—according to a study by Colleen Chien, trolls initiated 62% of all patent litigation in that year.[41]

35. D'Ambrosio, *supra* note 34.

36. *Id*.

37. James E. Bessen & Michael J. Meuer, *The Direct Costs From NPE Disputes*, 99 CORNELL L. REV. 387, 389 (2014).

38. *See* Sara Jeruss, Robin Feldman & Joshua H. Walker, *The America Invents Act 500: Effects of Patent Monetization Entities on US Litigation*, 11 DUKE LAW & TECH. REV. 357 (2012) (an article providing statistical information that supports the proposition that patent monetization entities play a role in a substantial portion of the lawsuits filed today).

39. *Id.*

40. *See, e.g.*, General Patent Corporation, *America Invents Act Turns Out to Be a Law of Unintended Consequences*, http://www.generalpatent.com/america-invents-act-turns-out-be-law-unintended-consequences (Dec. 2012).

41. Colleen Chien, *Patent Trolls by the Number*, PatentlyO (Mar. 14, 2013) (referring to a statistic provided by RPX Corporation, a company that provides solutions to troll threats for its member companies and has great data principally maintained by Seth Besse), *available at* http://www.patentlyo.com/patent/2013/03/chien-patent-trolls.html.

Patent troll suits often end in settlement.[42] Defendants simply prefer to pay licensing fees rather than face the huge cost of litigating a patent and the danger of being found to have infringed a patent and having to pay a large judgment.[43] The average patent troll litigation costs a defendant $2 million and takes an average of eighteen months to reach a final judgment.[44] Even though studies have shown that trolls actually lose more than 90% of the time when their patents are actually challenged in court, most defendants, when confronted by the sobering possibility of such costs, choose to settle for an amount that is far lower than the cost of litigation.[45] These high costs also discourage the countersuits against trolls, which mean that it is unlikely that a given troll's patent will be invalidated. Without countersuits, trolls remain free to continue filing suits on the basis of weak or invalid patents, further perpetuating the cycle and subjecting more accused infringers to the same tactics.

Furthermore, trolls primarily assert software and software-related business patents, which together account for 89% of troll litigation.[46] Software patents are nearly five times as likely, and business method patents are nearly fourteen times as likely, to be wielded in a lawsuit as compared to chemical patents.[47] A report released by the nonpartisan Government Accountability Office explains that this disparity is caused at least in part by the "prevalence of low-quality patents," which can be asserted against a broad range of defendants because such patents frequently contain overly broad claims and do not clearly and properly delineate the property right being granted.[48] Although there is some uncertainty inherent to all patent claims, this problem is particularly pronounced for software patents.

Trolls use the overbreadth of software patents to their advantage. Trolls will often assert bad patents against defendants

42. *See* The Internet Association, *Patent Trolls Harm American Industry and Innovation* at 1 (2013), http://internetassociation.org/wp-content/uploads/2013/12/IA_PatentTrolls_v8.pdf.

43. *See* John R. Allison, Joshua H. Walker & Mark A. Lemley, *Patent Quality and Settlement Among Repeat Patent Litigants*, 99 Georgetown L.J. 677, 709 (2011).

44. Drew Curtis, Founder, Fark.com, TED Talk: How I beat a patent troll (Feb. 2012), *available at* http://www.ted.com/talks/drew_curtis_how_i_beat_a_patent_troll.html.

45. *See* Chien, *supra* note 41.

46. *See* United States Government Accountability Office, *Assessing Factors That Affect Patent Infringement Litigation Could Help Improve Patent Quality*, 14 (Aug. 2013) (hereinafter *GAO Report*), *available at* http://www.gao.gov/assets/660/657103.pdf.

47. *Id.*

48. *Id.* at 28.

whose activities only fall within the purview of the patents in question due to the patents' overly broad claim language.[49] In fact, trolls assert more litigation against non-tech companies than tech companies.[50] Trolls also target non-tech companies more frequently because, as the end users of allegedly patent-encumbered technologies created by other companies, they provide a pool of large numbers of unrelated defendants.[51] Thus, there are many more entities from which to demand royalties and threaten litigation, allowing a troll to shake down many companies over numerous uses of a single product.[52]

D. Apparel is the Perfect Target for a Patent Troll

It has taken time for apparel to become a multi-billion dollar industry.[53] During this journey the apparel industry has adopted various technologies, and in the process has caught the attention of patent trolls—themselves a part of another billion-dollar industry.

The apparel industry relies on cutting-edge technology to stay connected to its customers. To maintain their competitive edge, apparel companies incorporate the newest and most innovative technologies within their organizations.[54] As apparel companies adopt new technologies, they offer new targets to patent trolls so that even after a prior dispute is resolved, trolls invariably have another technology and another patent on which they can bring suit.

As explained above, apparel companies are generally end users of patented technology.[55] As end users, apparel companies use third-party technology to solve a problem or fulfill a need. In other words, they do not develop or sell any patented technology themselves, but instead merely use the products of other companies—products that

49. *GAO Report*, *supra* note 46, at 28.

50. *See* Chien, *supra* note 41.

51. *See* Heesun Wee, *Patent Trolls Target US Businesses, Consumers Ultimately Foot The Bill*, CNBC (Mar. 31, 2014), http://www.cnbc.com/id/101514899.

52. *See* National Retail Federation and Shop.org, Statement submitted to the United States House of Representatives Committee on Small Business for its hearing on "Patent Reform Implementation and New Challenges for Small Business" held on May 15, 2013 (hereinafter *NRF and Shop.org Letter*), *available at* http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCwQFjAA&url=http%3A%2F%2Fwww.nrf.com%2Fmodules.php%3Fname%3DDocuments%26op%3Dshowlivedoc%26sp_id%3D7600&ei=JvCtUpD_JcTuoAS324CYAQ&usg=AFQjCNE9536kOQDwK0NqaAnVxpl14Zd8kQ&sig2=IewLqzoX4-M2vviX4ZMPUQ&bvm=bv.57967247,d.cGU.

53. *See* Lauren Effron, *Why do Female Models Make More than Male Models?*, ABC NEWS (Oct. 10, 2013), *available at* http://abcnews.go.com/Business/female-models-make-male-models/story?id=20534067.

54. *See supra* Section I.B.

55. *Id.*

are potentially patent-encumbered. Being an end user makes for a larger pool of potential infringers for patent trolls to target as compared to the developer or seller of the patented technology, since for every creating entity there may be numerous customers that have deployed a patent-encumbered product.

The continued use of such technologies seems to be an inevitable part of the future of apparel companies. This is partly because the pace with which modern technologies are being integrated into the apparel business model has never been greater and is projected to increase significantly in years to come.[56] The benefits of technology have allowed apparel companies to operate more efficiently and extend their reach into the online world, and the products and services that have allowed this are now thoroughly integrated into their business model. From advertisements, sales, communications and distribution, technology is ingrained every step of the way. Further, consumers now expect a certain level of convenience and service provided by modern technology. Should an apparel company forego technology in one area that its competitor has not, the former may lose its customer base to the latter.

Once apparel companies are exposed to patent litigation, they are especially likely to settle. The majority of apparel companies operate on thin profit margins and lack the legal resources, such as in-house counsel, to fight complex patent infringement claims.[57] Furthermore, the structure and focus of the typical apparel company is such that it cannot dedicate a great deal of operational bandwidth to proactive defensive practices when it comes to anticipating patent litigation. Designers are focused on creation of garments and the business side is focused on sales, and if a company has in-house counsel it is likely they only have the resources to focus on issues closer to the company's main operations like trademark and copyright. Consequently, an apparel company is often blindsided and ill-prepared for litigation when served with a lawsuit by a patent troll. Rather than pay an amount that could bankrupt the company by going to trial, the apparel company will usually settle with the patent troll by paying a licensing fee.

There are also a few coincidences that potentially explain why apparel companies have become such a frequent target for patent trolls. First is apparel's timing in increasing its integration of technology into its business model. The apparel industry began

56. *See supra* Section I.B.

57. *See* NRF and Shop.org Letter, *supra* at note 52.

heavily investing and using technology around 2005.[58] This is around the same year that patent trolls began to develop and expand their particular brand of abusive litigation practices.[59] Since 2005, both apparel's use of technology and patent trolls' filing of lawsuits have increased considerably.[60] Second is the type of patented technologies that apparel companies typically use. Apparel companies use products that potentially implicate many software-related business method patents.[61] Such patents are exactly the type that trolls most often leverage in abusive litigation.[62] The timely increase in technology used by apparel companies and their heavy use of software-related business method patents combine to make apparel companies an even more attractive target for patent trolls.

Part II: Troll Litigation Aimed at Apparel

A. Limited Data Hurdle

There is no published breakdown on the effect of patent troll litigation and apparel companies. There are several reasons for this.

First, the lack of a commonly agreed-upon definition for the term "patent troll" inhibits the starting point for many inquiries into the effects of patent trolls as well as reform efforts.[63] There is currently no commonly agreed-upon definition of who is and is not a patent troll, and the terms nonpracticing entity, patent assertion entity, and patent troll are often used interchangeably.[64] Defining these terms for use in legislation, or settling on a widely acceptable definition in a manner that clearly identifies an entity that engages in abusive litigation, has proven to be challenging.[65] Consequently, outcomes can vary between different studies in part because their criteria depend upon the study's individual definition for a patent troll.[66]

58. NRF and Shop.org Letter, *supra* at note 52.

59. George H. Pike, *Blackberry: Lawsuit and Patent Reform,* INFORMATION TODAY, INC. (last visited Mar. 25, 2014), *available at* http://www.infotoday.com/it/may06/Pike.shtml.

60. *See* Sections 1.B, 1.C.

61. *See* NRF and Shop.org Letter, *supra* note 52.

62. *See supra* Section 1.B.

63. Jeruss et al., *supra* note 38 at 366.

64. *Id.*

65. *See id.* at 367.

66. *Id*. at 367-69.

The study and identification of activity by patent trolls is also hindered by the entities' structure and arrangements.[67] Patent troll activities are shrouded in complex layers of subsidiaries or revenue-sharing agreements, and their structures have thousands of shell companies.[68] This makes it near impossible to know who is pulling the strings.

Furthermore, as previously mentioned, much of the litigation initiated by patent trolls ends in settlement. This is partly due to the high cost of litigation, resulting in 90 percent of such matters ending with the defendant paying a licensing fee or entering into a settlement.[69] The information provided in settlement agreements are notorious for being accessible only by the parties involved.[70] Thus, data regarding the activity of patent trolls is incomplete, and when there is data regarding settlements, it is often misleading.

B. Analysis of Apparel as a Troll Target

In recent years, over 200 retailers have contacted the National Retail Federation ("NRF") to report that they were the target of patent trolls' abusive litigation practices.[71] The NRF is the world's largest retail trade association and is the voice of retail worldwide, representing retailers of all types and sizes from the United States and more than 45 countries abroad.[72] The association has actively pursued the interests of retail in the battle against patent trolls.

The NRF defines a retail company as one focused primarily on selling consumer goods directly to the end consumer.[73] This definition, and the NRF's statistics, includes chain restaurants.[74] According to the NRF, retailers have seen an increasing number of

67. *See* Sara Jeruss, Robin Feldman & Tom Ewing, *Patent Monetization Entities Filed 58% of Lawsuits in 2012*, IP WATCHDOG (Apr. 14, 2013), http://www.ipwatchdog.com/2013/04/15/patent-monetization-entities-filed-58-of-lawsuits-in-2012/id=39079/.

68. *Id*.

69. *See* Allison et al., *supra* note 43.

70. James Bessen, *Patent Trolling Was Up 11 Percent Last Year*, THE WASHINGTON POST: THE SWITCH (Jan. 31, 2014), http://www.washingtonpost.com/blogs/the-switch/wp/2014/01/31/patent-trolling-was-up-11-percent-last-year/.

71. *See* NRF and Shop.org Letter, *supra* at note 52.

72. National Retail Federation, *Mission Statement and About the National Retail Federation*, http://www.nrf.com/modules.php?name=Pages&sp_id=146&pmenu_id=1&mn_type=1 (last visited Dec. 15, 2013).

73. *Id.*

74. *Id.*

patent lawsuits in recent years, and about 40 percent come from patent trolls.[75]

In taking a closer look at patent troll litigation filed against only apparel companies, I found no statistical analysis exists specific to this category. To fill the void, and to better understand litigation filed by patent trolls against apparel companies, I analyzed complaints filed against top apparel companies. I was able to identify which trolls most frequently file suit against apparel companies and the patents that were used by these trolls in filing mass amounts of complaints against individual apparel companies.

The focus group I used to initiate the study was comprised of apparel companies derived from four reputable brand-ranking resources. Those resources included Brand Finance, Interbrand, Millward Brown and the World Luxury Association. I compared each resource's listed brands and the most frequently cited brands. The final list included Louis Vuitton, Chanel, Gucci, Prada, Tiffany & Co., Hermès, J.Crew, Gap, Coach, Guess?, H&M, Nike, Victoria's Secret and Zara.

Matters involving patent infringement are federal cases, so I was able to limit my research of complaints through the administrative database of the United States federal courts, PACER.[76] I began my research by searching for each brand in the PACER database, limiting the results to suits filed between 2010 and 2013. The results revealed four entities strategically targeting apparel: GeoTag, Webvention, Parallel Networks and ArrivalStar. These four entities filed more than half of the 98 complaints filed against the focus group.

Having found the names of these repeat offenders, I went back to PACER to perform individualized searches. I broadened my initial focus group of fourteen apparel companies to include all apparel companies. Then, I examined each complaint filed by the respective troll against an apparel company. By analyzing the complaints I was able to pinpoint which patent each respective troll was asserting against hundreds of retailers.

C. The Most Notorious Trolls and Their Actions Against Apparel Companies

A company called GeoTag has asserted U.S. Patent Number 5,930,474 ('474) against hundreds of apparel companies. Titled

75. National Retail Federation, *NRF Welcomes White House Announcement on Patent Litigation Abuse* (June 4, 2013), *available at* http://www.nrf.com/modules.php?name=News&op=viewlive&sp_id=1589.

76. *See generally* PACER, http://www.pacer.gov/ (last visited Dec. 15, 2013).

"Internet Organizer for Accessing Geographically and Topically Based Information," the '474 patent claims "system[s and methods] which associate . . . on-line information with geographical areas."[77] In other words, and as GeoTag has interpreted it, the '474 patent claims a website that has a map showing locations on it.

GeoTag has been so litigious with the '474 patent that it picked up the nick-name "Google Maps Patent Troll."[78] Its persistence in asserting this patent is readily apparent upon review of its complaints. In one, GeoTag filed suit against over 50 companies, nearly all of which were apparel companies.[79] Over the past several years GeoTag has brought a number of such suits asserting the '474 patent against different apparel companies.[80]

Next, Webvention is a company that claims to own rollover online pictures with embedded hyperlinks. Webvention owns U.S. Patent Number 5,251,294, entitled "Accessing, assembling, and using bodies of information."[81] Webvention has asserted this patent against Giorgio Armani, Adidas, Abercrombie and Fitch, Armani Exchange, Neiman Marcus and several other apparel companies.[82]

A typical cease and desist letter sent by Webvention regarding the '294 patent reveals the manner in which such trolls attempt to set the terms for their extortive activities: "For the next 45 days, Webvention is willing to license the '294 patent for a one-time, fully paid-up licensing fee of $80,000.00 for a non-exclusive, company wide right to use Webvention technology."[83] Pundits joked sarcastically

77. U.S. Patent No. 5,930,474 (filed Jan. 31, 1996) (issued July 27, 1999).

78. *See* Lance Cleveland, *Beware: GeoTag Patent Trolls Lurking*, CHARLESTON SOFTWARE ASSOCIATES (July 17, 2013), http://www.charlestonsw.com/beware-geotag-patent-trolls-lurking/.

79. Plaintiff's First Amended Complaint, GeoTag, Inc. v. Circle K Stores, Inc., 11-CV-405 (E.D. Tex. Sept. 13, 2011).

80. *See generally* Complaint for Patent Infringement, GeoTag, Inc. v. Gucci America Inc. et al., 10-CV-00571 (E.D. Tex. Dec. 17, 2010); Complaint, GeoTag Inc. v. Eye Care Centers of America, Inc., 11-CV-404 (E.D. Tex. Nov. 03, 2011).

81. U.S. Patent No. 5,251,294 (filed Feb. 7, 1990) (issued Oct. 5, 1993).

82. *See* Complaint, Webvention LLC v. Adidas America Inc., 11-cv-03623 (E.D. Tex. Oct. 5, 2010); Complaint, Webvention LLC v. A/X Armani Exchange LLC , 12-cv-00017 (Dist. Md. Jan. 10, 2012); Complaint, Webvention LLC v. Giorgio Armani Corporation, 11-CV-00486 (E.D. Tex. Nov. 17, 2011); Complaint, Tommy Hilfiger Group B.V. v. Webvention Holdings LLC et al, 11-CV-00266 (Dist. Del. Mar. 30, 2011); Complaint for Declaratory Judgment, American Apparel Inc. v. Webvention Holdings LLC, 10-CV-00936 (Dist. Del. Nov. 1, 2010); Complaint, Webvention LLC v. Abercrombie & Fitch Co., 10-CV-00253 (E.D. Tex. July 20, 2010).

83. *See* Matthew Lasar, *Rollover Image on Your Website? That Will be $80,000 (Please)*, ARS TECHNICA (Oct. 14, 2010), http://arstechnica.com/tech-policy/2010/10/patent-troll-takes-over-the-web-can-it-be-stopped/.

about the gracious tone of Webvention's letter in only requiring a mere $80,000 when the requested fee could bankrupt a company.[84]

Another troll that has targeted apparel companies is Parallel Networks, which sued about 120 different companies in a single patent infringement lawsuit alleging infringement of its U.S. Patent Number 6,446,111.[85] The patent covers the use of individualized applets on handheld devices to speed up data transfer rates and has been asserted against almost everyone involved in e-commerce.[86] The victims of this patent suit included Tiffany & Co., Victoria's Secret, The Gap, and many other apparel companies.[87]

ArrivalStar is one of the most active patent trolls I came across, having filed hundreds of lawsuits in recent years for several of its patents that cover technology that tells a customer when its packages will arrive. Tracking the shipping of a purchase from the vendor's warehouse to a customer's front porch is a common and useful feature offered by many online retailers. Among those hundreds of apparel companies whose use of this kind of tracking was targeted by ArrivalStar were Chanel, Spanx, Toms Shoes and Lacoste.[88]

It is notable that the ArrivalStar patent troll has never taken its patents anywhere near a trial, and hardly any of its lawsuits even have gone beyond early stages of litigation.[89] A major implication of this tactic is that the patent's validity is never seriously threatened. One attorney for a defendant, whose case ended up settling, expressed concern about having no opportunity to challenge ArrivalStar's patents. The attorney explained that he can't force ArrivalStar into court if the company agrees not to sue, because "there's no longer a case or controversy to satisfy standing requirements . . . I'd love to do

84. *See* Matthew Lasar, *Rollover Image on Your Website? That Will be $80,000 (Please)*, ARS TECHNICA (Oct. 14, 2010), http://arstechnica.com/tech-policy/2010/10/patent-troll-takes-over-the-web-can-it-be-stopped/.

85. Dennis Crouch, *And the Internet Won: Parallel Networks Versus Website Operators*, PATENTLYO (Jan. 21, 2013), http://www.patentlyo.com/patent/2013/01/parallel-networks-v-abercombie-fitch-et-al-fed-cir-2013-back-in-2010-parallel-networks-sued-about-120-different-compa.html.

86. U.S. Patent No. 6,446,111 (filed June 18, 1999) (issued Sept. 3, 2002).

87. *See generally* Original Complaint for Patent Infringement, Parallel Networks, LLC v. Abercrombie & Fitch Co., 10-CV-00111 (E.D. Tex. Mar. 29, 2010).

88. *See generally* Complaint, ArrivalStar S.A. v. Chanel, Inc., 13-CV-22528 (S.D. Fl. July 15, 2013); Complaint, ArrivalStar S.A. v. Spanx, 13-CV-22489 (S.D. Fl. July 12, 2013); Complaint, ArrivalStar S.A. v. Toms Shoes, Inc., 13-CV-22490 (S.D. Fl. July 12, 2013); Complaint, ArrivalStar S.A. v. Lacoste USA, Inc., 13-CV-20647 (S.D. Fl. Feb. 22, 2013).

89. Joe Mullin, *Patent Troll Backs Down, Agrees to Stop Suing Public Transit Agencies*, ARS TECHNICA (Aug. 21, 2013), http://arstechnica.com/tech-policy/2013/08/patent-troll-backs-down-agrees-to-stop-suing-public-transit-agencies/.

work that others can free-ride upon, but I can't pursue a case in court without a client that's being injured."[90]

D. Synopsis of Findings

Trolls are well known for asserting one patent against hundreds of defendants patentable a time. In their suits against apparel companies, Geotag, Webvention, Parallel Networks and ArrivalStar were all involved in "campaigning" of this kind.[91] These are just examples of a larger trend, and many other trolls have sued apparel companies on patents claiming such features as the rendering of JPEGs, the concept of embedding a URL in a text message, scanning a paper document into a computer and then attaching it to an e-mail, online shopping cart technology, and smartphone apps that include a link to privacy policies posted on the companies' web sites.[92]

Prior to the enactment of the AIA, this kind of campaigning—suing large numbers of defendants in a single litigation—was a characteristic for which trolls were notorious. The complaints filed by Geotag in 2010 are a prime example of this abusive type of litigation. This type of litigation was, however, thwarted with the implementation of the AIA. In typical pre-AIA litigation filed by patent trolls, a troll would file a patent infringement suit against numerous defendants that had nothing in common, other than the fact that each had been accused of infringing the same patent. The AIA restricts the ability of plaintiffs to file one lawsuit against numerous defendants in situations such as these. Now, joinder of defendants is permitted only where the claims against the defendants arise out of "the same transaction, occurrence, or series of

90. Joe Mullin, *Patent Troll Backs Down, Agrees to Stop Suing Public Transit Agencies*, ARS TECHNICA (Aug. 21, 2013), http://arstechnica.com/tech-policy/2013/08/patent-troll-backs-down-agrees-to-stop-suing-public-transit-agencies/.

91. *See supra* Section II.B.1.

92. *See* Richard Mescher, *Update on Patent Trolls*, TECHNOLOGY LAW SOURCE (May 15, 2013) (providing an overview on several patent trolls and the patents they troll with), http://www.technologylawsource.com/2013/05/articles/intellectual-property-1/patents/update-on-patent-trolls/; National Retail Federation, *NRF Welcomes White House Announcement on Patent Litigation Abuse* (Jun. 4, 2013) (providing several examples of patents that patent trolls have asserted against retail), http://www.nrf.com/modules.php?name=News&op=viewlive&sp_id=1589; Erica Wilson, *Setback for Patent Troll Under "Patent Exhaustion" Doctrine Liberates Mobile Technology*, PAYMENT LAW ADVISOR (Aug. 22, 2013) (discussing the patent that covered links embedded in text messages), http://www.paymentlawadvisor.com/2013/08/22/setback-for-patent-troll-under-patent-exhaustion-doctrine-liberates-mobile-technology/; Patent Assertion and U.S. Innovation Executive Memo, *supra* note 1 (providing examples of patents that patent trolls have asserted against companies in general).

transactions, or occurrences relating to the making, using, importing into the United States, offering for sale, or selling the same accused product or process" and requires that questions of fact common to all defendants or counterclaim defendants arise in the same action.[93]

My research indicates that patent trolls appear to have responded to this change by drafting very vague complaints, which can be reused against many different defendants. With one complaint that is vague enough, a patent troll is able to use it against every defendant against whom the troll asserts its patent. This was readily observable in the complaints filed by Geotag, Webvention, Parallel Networks and ArrivalStar.[94] Each of these patent trolls used the same words, and only substituted the name of the defendant in their complaints.[95]

Using the same complaint against several hundred different companies shifts the burden to the defendant.[96] The complaints are vaguely worded and do not pinpoint the exact nature of the alleged infringement.[97] Often, the complaints are so vague that defendants do not even know what is being asserted against them.[98] With low pleading standards the complaint passes muster, and defendants are forced to either draft response pleadings asking for a more definite statement as to the cause of action or perform their own discovery on what is exactly the issue.[99]

A final observation concerns the type of patents that trolls are asserting against apparel. Geotag, Webvention and ArrivalStar all asserted software-related business method patents in their complaints against the apparel companies. These patents typically claim methods

93. Wes Klimczak, *IP: How the AIA has affected patent litigation*, INSIDE COUNSEL (June 18, 2013), http://www.insidecounsel.com/2013/06/18/ip-how-the-aia-has-affected-patent-litigation.

94. *See generally supra* Section II.B.1.

95. *Id.*

96. *See generally* Mike Masnick, *Patent Troll Lawyers Smacked Down, Made To Pay Sanctions, For Mass Lawsuits Followed By Quick Settlement Offers*, TECHDIRT (Aug. 8, 2011), http://www.techdirt.com/articles/20110805/17230815417/patent-troll-lawyers-smacked-down-made-to-pay-sanctions-mass-lawsuits-followed-quick-settlement-offers.shtml.

97. D'Ambrosio, *supra* note 34.

98. *See* Andrea Huspeni, *The Rising Threat of Patent Trolls and What You Can Do To Protect Your Startup*, ENTREPRENEUR (Apr. 15, 2013), http://www.entrepreneur.com/article/226367.

99. *See* Jeff Becker, *The Latest in Patent Reform: The Innovation Act (H.R. 3309)*, BAKER BOTTS INTELLECTUAL PROPERTY REPORT (Dec. 2013), http://www.bakerbotts.com/file_upload/IPReport201312-TheLatestInPatentReformTheInnovationActHR3309.htm.

that purport to cover the printing of receipts at cash registers, the sale of gift cards, and the connection of any product such as a computer or printer to an Ethernet network.[100]

Part III: Congressional Solution

The activity of patent trolls is coming under increasing scrutiny from Congress, and their response comes at a critical time. Our country is at a crossroads and legislative measures are needed to address the patent troll problem. The Innovation Act, which at this point appears the likeliest reform to pass in Congress, makes several changes that could help protect apparel companies from abusive patent troll litigation, but the bill contains several weaknesses that should be addressed before it becomes law.

A. The Innovation Act

Introduced by House Judiciary Committee Chairman Bob Goodlatte, the Innovation Act, passed in the House on December 5, 2013.[101] The bill makes many changes to various provisions of the Patent Act, three of which may help solve the kinds of issues facing apparel companies.

First, The Innovation Act attempts to deter vaguely worded complaints. The Act heightens the pleading standard in patent cases, requiring a claimant to identify the patents and claims that are allegedly infringed, and to specify how they are being infringed.[102] This provision would help clarify for defendants what exactly a plaintiff alleges they have done to infringe the plaintiff's patent.

This heightened pleading standard would likely increase the cost of campaigning for patent trolls. Trolls use vague pleadings so they can simply substitute different defendants' names when filing new suits, keeping down the costs of filing multiple infringement actions.[103] Raising pleadings standards will require patent trolls to expend more time and money in asserting their patents, which will make campaigning more expensive and may could potentially lead to less patent troll litigation.

Second, the Innovation Act requires courts to make decisions about whether a patent is valid or invalid early in the litigation process and requires the Judicial Conference to make rules to reduce

100. *See* NRF and Shop.org Letter, *supra* note 52.

101. H.R. 3309, 113th Cong. (2013).

102. H.R. 3309 § 281A.

103. *See supra* Section II.C.

the costs of discovery in patent litigation.[104] These provisions seek to prevent patent trolls from dragging patent cases on for years based on invalid claims and to lower the costs of discovery. With these provisions, apparel companies will, hopefully, be encouraged to assert their rights against patent trolls rather than settle.

Third, the Innovation Act incorporates a provision that would protect end users from patent trolls. The bill creates a voluntary process allowing small businesses to postpone expensive patent lawsuits while larger sellers complete related patent lawsuits against the same plaintiffs.[105] In other words, it is meant to protect customers who bought the product off-the-shelf. If the voluntary process works, it would deter the harmful effects of the common patent troll tactic of going after the end user. For example, a patent troll that goes after an apparel company that provides free Internet for its clientele via a wireless router can postpone the litigation until the suit between the patent troll and the maker of that router is finalized.

B. Weaknesses of the Innovation Act

The Innovation Act will solve many immediate problems that have damaged the nation's patent system and economy. Its provisions go to the heart of current abusive patent litigation practices. There are weaknesses, however, that must be addressed to adequately protect the apparel industry from vexatious troll litigation.

1. Customer-Suit Provision

First, there are issues with the Innovation Act's customer-suit provision. With the current bill, the customer-suit provision creates a voluntary process for a customer to postpone the lawsuit while a larger seller completes a similar patent lawsuit against the same plaintiff.[106] This provision is problematic because it assumes that the patent troll will always go after the larger seller of the patent and it relies upon a final judgment resulting from the suit between the patent troll and larger seller. Greater protection for end users must be provided. If the Innovation Act is passed with the customer-suit provision as it stands now, apparel companies will continue to be targeted by patent trolls.

To protect apparel companies, the Innovation Act should strengthen its customer-suit provision by completely immunizing end

104. H.R. 3309 § 299A.

105. H.R. 3309 § 296.

106. H.R. 3309 § 296.

users from patent troll litigation. By preventing suits against end users, the patent troll would be forced to bring the suit against the proper defendant—the manufacturer, distributor or retailer who is selling the allegedly infringing technology. This proposed alteration would also change the civil procedure process. Suits brought against the end user would result in the implementation of a mandatory stay upon intervention on the part of the manufacturer. Upon the commencement of the stay, the patent troll would be forced to pursue the more appropriate target.

The modified customer-suit provision would have a good political support base. There are many businesses and consumers who have been subjected to licensing demands or outright lawsuits based on their use of ordinary staples of commerce as end users. This provision would effectively eliminate an abusive patent troll practice while still allowing effective enforcement of legitimate patent holder's rights.[107]

2. Heightened Pleading Standard Provision

Second, there is a possibility that the heightened pleading standard proposed in the Innovation Act might not deter patent trolls from filing suit. The current provision requires a claimant to identify the patents and claims that are allegedly infringed, and to specify how they are being infringed.[108] Virtually every court in the U.S. already mandates similar disclosures. These disclosures are called "infringement contentions" and are required at some point during the course of a patent litigation. While the Goodlatte bill would accelerate these contentions and convert them into a prerequisite before filing a complaint, patent trolls generally prepare detailed drafts of these charts prior to launching suit.[109]

There are also arguments as to whether a heightened pleading standard is even appropriate. The Innovation Act's heightened pleading could reduce the frequency of frivolous lawsuits while narrowing the scope and lowering the costs of discovery.[110] On the

107. *See* Levenfeld Pearlstein, LLC, *The Obama Administration Hops on the Anti-Troll Bandwagon* (June 6, 2013), http://www.lplegal.com/content/obama-administration-hops-anti-troll-bandwagon.

108. H.R. 3309 § 281A.

109. *See* Michael Rossen, *A Closer Look at Patent Troll Legislation (pt 1): Pleading Requirements*, TECHPOLICYDAILY (Nov. 18, 2013), *available at* http://www.techpolicydaily.com/technology/patent-troll-legislation-closer-look/.

110. *See* Law & Economics Center, *Measuring the Effects of Heightened Pleading Standards Under Twombly and Iqbal* (last visited Dec. 15, 2013), *available at* http://www.masonlec.org/programs/46.

other hand, the heightened pleading standard might reduce or eliminate access to the legal system for both low quality and meritorious cases alike.[111]

The NRF has also voiced concerns over the heightened pleading standards provision, and hopes to see more clarification in how plaintiffs must clearly state their initial demands regarding a patent.[112]

3. Failure to Address Software-Related Business Method Patents

Third, the current version of the Innovation Act fails to address software-related business method patents. These types of patents are arguably the root cause of the patent mess.[113]

In an earlier version of the Innovation Act, the bill contained a continuation and expansion of the "Transitional Program for Covered Business Method Patents."[114] This provision provides a fast-track process at the U.S. Patent and Trademark Office for knocking out low-quality patents by letting companies challenge suspicious "business method" patents, many of which cover basic software practices. The provision was, however, eliminated by the force of powerful lobbies (notably for Microsoft and IBM).[115]

As the Innovation Act stands today, there is no efficient way to challenge the huge number of bad software-related business method patents. Without a rule providing a mechanism to challenge these patents at the Patent Office, companies' only other option often lies in persuading a jury that the patent is obvious or that the invention it describes is not new.

The NRF has also voiced concerns over the absence of a provision addressing software-related business method patents. It hopes to see clarification over how patent lawsuits can cover these types of patents; for example, business methods that pertain to how businesses conduct transactions over the Internet or post content to web sites regarding their products and services.[116]

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111. Law & Economics Center, *Measuring the Effects of Heightened Pleading Standards Under Twombly and Iqbal* (last visited Dec. 15, 2013), *available at* http://www.masonlec.org/programs/46.

112. *See* Paul Demery, *'Patent Troll' Legislation Moves Ahead in Congress*, INTERNET RETAILER (Dec. 11, 2013), *available at* https://www.internetretailer.com/2013/12/11/patent-troll-legislation-moves-ahead-congress.

113. *See* Jeff John Roberts, *House Passes Innovation Act by Vote 325-91: A Small Solution to a Big Patent Problem,* GIGAOM (Dec. 5, 2013), http://gigaom.com/2013/12/05/house-passes-innovation-act-325-91-a-small-solution-to-a-big-patent-problem/.

114. *Id.*

115. *Id.*

116. *See* Demery, *supra* note 112.

Conclusion

Apparel companies are ideal targets for patent trolls. They have technology inextricably intertwined into their business model and purchase it as end users. Furthermore, they have an ever-increasing rate of technological consumption and are ill-equipped to litigate patent disputes. These attractive characteristics have not gone unnoticed by trolls.

Over a few short years, there have been thousands of complaints filed against apparel companies by patent trolls. These complaints seek to enforce patent rights that are vague and obscure. Although Congress is working to combat the abusive litigation strategies used by patent trolls, its current proposed legislation is not strong enough. An adequate bill would take into account the unique history and characteristics of the apparel industry, and use this information as its guide in implementing effective legislation.

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Mental Health Parity: The Patient Protection and Affordable Care Act and the Parity Definition Implications

by SUANN KESSLER*

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Introduction

At least twenty-eight percent of American adults suffer from a mental or addictive disorder.[1] Thus, it may seem surprising that attempts to establish federal guidelines for mental health services under health insurance plans did not take place until the 1970s.[2] Yet the fact that health insurance coverage for mental health services differs drastically from that of other medical services is not as startling when taking into account mental health's history, and its complete

* J.D. Candidate, University of California, Hastings College of the Law, 2014. The author thanks Professor Robert Schwartz for all of his guidance and support.

1. Aviv Shamash, *A Piecemeal, Step-by-Step Approach Toward Mental Health Parity*, 7 J. HEALTH & BIOMED. L. 273, 276 (2011).

2. *Id.*

isolation from the medical field.[3] Although it has yet to achieve parity with other medical services, health insurance coverage for mental health services has improved over time. Because of the unfair and unequal treatment that has evolved between insurance coverage of mental health services and other medical services, parity refers to, among other things, the equalization of the reimbursement rates for these services.[4] Because the recent enactment of the Patient Protection and Affordable Care Act ("PPACA") appears to have filled the parity gaps left by the Mental Health Parity and Addiction Equity Act of 2008, many claim that mental health parity has finally been achieved.

While the PPACA may superficially appear to have plugged all the gaps, the ultimate questions are whether it provides actual mental health parity, and whether it facilitates access to mental health services for those who truly need them. A deeper look reveals it may fall short of providing actual parity between mental health and other medical services. Responses to the new PPACA provisions also cast doubt on whether parity has been achieved. For example, insurance companies have begun implementing nonreimbursement policies for mental health services that do not trigger the parity requirements of the PPACA. In light of the ever-changing and advancing health care market, evaluation of parity in mental health services requires a more sophisticated analysis. The question of parity in mental health services requires answering two essential questions. First, how should parity be defined in the current health care market? Second, besides financial and treatment limitations, should other factors now be included in evaluating parity?

Part I of this note will track the history of mental illness as well as describe how America initially attempted to treat these illnesses. Part I will also touch upon the suggestion that beliefs about the causes of mental illnesses contributed not only to the disparate kinds of treatment received by the mentally ill, but also to the delay of federal legislation mandating mental health parity. Part II will identify the major factors that have limited Americans' access to mental health services, and which ultimately motivated the enactment of legislation mandating mental health parity. Part III will discuss parity

3. John Mauldin, *All Smoke and No Fire? Analyzing the Potential Effects of the Mental Health Parity and Addiction Equity Act of 2008*, 35 LAW & PSYCHOL. REV. 193, 196-97 (2011).

4. Amanda Clark, *The Patient Protection and Affordable Care Act and Efforts of the Mentally Ill to Achieve Equal and Adequate Health Care Coverage*, 88 U. DET. MERCY L. REV. 357, 358 (2010).

advancements and failures associated with each of the following three acts: the Mental Health Parity Act of 1996, the Mental Health Parity and Addiction Equity Act of 2008, and the Patient Protection and Affordable Care Act. Part IV will address the problems that arise from the narrow definition of parity in today's health insurance plans. Part V will propose a solution to this parity definition issue, and Part VI concludes.

I. Brief History of Mental Illness

The discovery of skulls with burr-like holes from as early as 5,000 B.C. suggests that the treatment of mental illnesses has occupied human beings for millennia.[5] It is likely that humans have endured mental health problems for as long as they themselves have existed.[6] In ancient times, the symptoms of mental illness were thought of not as illness, but rather as signs of either demonic possession, or divine punishment for devious behavior or the sins of one's parents.[7] Even today, mental illness is still believed by some to be punishment for immoral or sinful behavior.[8] Beliefs regarding the underlying causes of mental disorders have contributed not only to the heavy stigma attached to people who suffer from mental illness, but also to various forms of so-called "treatment," or lack thereof, that these individuals have been forced to endure.[9]

Treatment of mental illness has progressed significantly from early treatments like boring holes in patients' skulls to more modern approaches like outpatient and preventative care. Mental illness has historically been treated in many ways, including drilling holes through one's skull, performing exorcisms, purging or bleeding harmful substances out of the body, and sedating the individual.[10] Starting in the 1600s, the mentally ill were locked up in asylums

5. ROY PORTER, MADNESS: A BRIEF HISTORY 10 (2003).

6. *See* Shamash, *supra* note 1, at 273 ("[M]ental illness has been present in society since ancient times").

7. *See* Stacey A. Tovino, *Neuroscience and Health Law: An Integrative Approach?*, 42 AKRON L. REV. 469, 475 (2009); *see also* PORTER, *supra* note 5, at 12 ("[C]ertain disorders were caused by spirit invasion, sorcery, demonic malice, the evil eye, or the breaking of taboos").

8. Tovino, *supra* note 7.

9. *See* Allison Foerschner, *The History of Mental Illness: From "Skull Drills" to "Happy Pills"*, STUDENT PULSE (Mar. 31, 2013); see also PORTER, supra note 5, at 15 ("The disorder was in turn countered by prayers, incantations, and sacrifices offered at temples dedicated to Asklepios, the god of healing.").

10. Foerschner, *supra* note 9.

because society deemed them too dangerous to the public.[11] In the United States, incarceration of the mentally ill began in the 1840s.[12] Worse still, the great majority of asylums, institutions, and prisons severely abused the mentally ill by subjecting them to such inhumane treatment as chaining them to walls like animals.[13] Electroshock therapy, lobotomies, therapeutic asylums, and psychiatric drugs were also incorporated as methods to cure mental disease.[14] By the 1940s, taxed by the rising number of committed patients, in conjunction with systematic understaffing and underfunding, institutions and asylums for the treatment of the mentally ill were dilapidated and further deteriorating.[15] For several reasons, the 1950s saw a radical shift in public perception of mental illness and how it should be treated.[16] Part of this change was a response to the overcrowding of state mental institutions, but World War II, the expansion of federal welfare programs, and other social events all contributed to a nationwide movement called deinstitutionalization, under which the mentally ill were released back into society.[17] Outpatient care became the preferred treatment for individuals with a mental disorder, along with an emphasis on preventive care.[18]

Private health insurance had emerged earlier, the early 1930s, with employer-sponsored health insurance developing not long after.[19] However, because outpatient mental health services were not an option until the 1960s, private health insurance companies rarely covered these services.[20] Provision of mental health services has historically been regarded as the province of the states, and even after

11. *See* EDWARD SHORTER, A HISTORY OF PSYCHIATRY: FROM THE ERA OF THE ASYLUM TO THE AGE OF PROZAC 154 (1998).

12. *Timeline: Treatments for Mental Illness*, PBS, http://www.pbs.org/wgbh/amex/nash/timeline/index.html (last visited Mar. 31, 2013).

13. *Id.*

14. Jonathan Fish, *Overcrowding on the Ship of Fools: Health Care Reform, Psychiatry, and the Uncertain Future of Normality*, 11 HOUS. J. HEALTH L. & POL'Y 181, 198 (2012); Shamash, *supra* note 1, at 273.

15. Fish, *supra* note 14, at 197; *see also Timeline: Treatments for Mental Illness, supra* note 12, ("In the United States, the number peaks at 560,000 in 1955.").

16. Mauldin, *supra* note 3, at 194.

17. *See* Shijie Feng, *Madness and Mayhem: Reforming the Mental Health Care System in Arizona*, 54 ARIZ. L. REV. 541, 545-46 (2012); *see also Timeline: Treatments for Mental Illness*, *supra* note 12, ("The number of institutionalized mentally ill people in the United States will drop from a peak of 560,000 to just over 130,000 in 1980.").

18. Mauldin, *supra* note 3, at 194.

19. David Blumenthal, *Employer-Sponsored Health Insurance in the United States – Origins and Implications*, 355 NEW ENG. J. MED. 82, 83 (2006).

20. *See* Fish, *supra* note 14, at 210.

the advent of private health insurance states continued to provide the majority of funding for mental health services.[21] It was not until the mid-20th century that the federal government began to expand its role in taking care of the mentally ill.[22] For instance, in 1946, President Truman signed into law the National Mental Health Act (NMHA), which created the National Institute of Mental Health.[23] The NMHA encouraged the training of mental health professionals and mental health research by providing federal financial assistance.[24] Furthermore, in 1965, the federal government created Medicaid and Medicare, both of which offered public health insurance coverage for mental health services.[25]

The twentieth century also witnessed the emergence of modern psychiatry.[26] Psychiatry was long regarded as a pseudo-science like alchemy.[27] Initial skepticism toward psychiatry most likely was due to the fact that the origin and biological processes of mental disorders were largely unknown.[28] Eventually, with the publishing of the third revision of the Diagnostic and Statistical Manual of Mental Disorders (DSM-III) in 1980, the medical field legitimized the practices of psychiatry and psychology.[29] Acceptance of psychiatry and psychology as legitimate branches of medicine has led to increased acceptance and awareness of mental illnesses as well.[30]

Nevertheless, stigmatization of the mentally ill continues to persist in America.[31] Because the majority of mental disorders do not have readily observable symptoms, some see these disorders as "lesser" illnesses.[32] Such beliefs perpetuate the stigma against the mentally ill, and lead many to question whether claims for insured mental health treatments are meritorious.[33] This stigmatization

21. Fish, *supra* note 14, at 200.

22. *Id.*

23. *Id.*

24. *Id.*

25. Olukunle Fadipe, *Affordable Mental Health Care in the Post Healthcare Reform Era*, 57 WAYNE L. REV. 575, 578 (2011).

26. PORTER, *supra* note 5, at 9.

27. *Id*. at 1.

28. Fish, *supra* note 14, at 183.

29. *See id.* at 186-210 (discussing the history of psychiatry).

30. *Id.* at 245.

31. *See* Clark, *supra* note 4, at 357.

32. DAVID CUTLER, YOUR MONEY OR YOUR LIFE: STRONG MEDICINE FOR AMERICA'S HEALTH CARE SYSTEM 33 (2005).

33. Mauldin, *supra* note 3, at 193.

manifests through discrimination against the mentally ill on many fronts, including in social interactions, access to housing, access to health care, and employment.[34] Many authorities have identified the stigma against mental illness as one of the principal reasons for limited funding for mental health research, lack of parity in public and private health insurance coverage, and lack of available and reimbursable treatments for mental illnesses.[35] In light of the history of mental health treatment in the United States, it is not surprising that federal legislation mandating parity with regards to insurance coverage of mental health services was not passed until 1996.

II. Before Mental Health Parity Legislation

Several major flaws in public health insurance coverage of mental health services have historically limited access to mental health care in the United States. First, at a basic level, it has been extremely difficult to gain access to public insurance programs because of their strict eligibility requirements.[36] For example, to be eligible for Medicare, one must be over sixty-five years of age or disabled and receiving Social Security Disability Insurance benefits.[37] To be eligible for Medicaid, one must be considered to be part of the "deserving poor."[38] That is, one must have a good justification for being poor.[39] Being part of the "deserving poor" means fitting into one of the following categories: "the elderly, disabled, blind, children, parents, and pregnant women."[40]

The division of Medicaid funding between the federal governments and the states has also contributed to difficulties in getting access to mental health services.[41] Because each state has defined mental illness in its own terms, mental health coverage under

34. Shamash, *supra* note 1, at 273-74; *see also* Clark, *supra* note 4, at 357 ("Those suffering from mental illnesses have been stigmatized in all aspects of their lives by peers, businesses, media, and insurance companies.").

35. *See* Tovino, *supra* note 7.

36. *See* BARRY R. FURROW, THOMAS L. GREANEY, SANDRA H. JOHNSON, TIMOTHY S. JOST & ROBERT L. SCHWARTZ, HEALTH LAW: CASES, MATERIALS, AND PROBLEMS 597 (6th ed. 2008).

37. Fadipe, *supra* note 25.

38. BARRY R. FURROW, THOMAS L. GREANEY, SANDRA H. JOHNSON, TIMOTHY S. JOST & ROBERT L. SCHWARTZ, HEALTH CARE REFORM: SUPPLEMENTARY MATERIALS 229 (2012 ed. 2012).

39. *Id.*

40. *Id.*

41. *Id.*

Medicaid is neither uniform nor consistent across the country.[42] Under Medicaid, definition of mental illness is critical in determining which mental disorders were and were not covered.[43] As a result, each state's Medicaid program covered different mental disorders and to varying degrees.[44]

Employer-sponsored private insurance is the next largest source of insurance coverage after public health insurance programs.[45] Like the public programs, employer-sponsored plans have had restrictions that limit access to mental health services. First, like the states under Medicaid, employer-sponsored insurers decide how mental illness will be defined.[46] As a result, individuals with employer-sponsored insurance have faced the same problems as Medicaid-eligible individuals stemming from inconsistent coverage of mental health services.[47] Second, private insurers could choose not to offer mental health coverage,[48] although most employer-sponsored insurance plans have in fact offered some form of coverage for mental health services.[49] However, insurers have treated coverage of mental health services separately from coverage for other illnesses, by having independent requirements.[50] Consequently, what mental health coverage has been offered has carried with it higher premiums, fewer services, and shorter coverage periods than for other medical services.[51]

Another problem has been inflated health care spending in the United States, with the country spending "more dollars and the highest percentage of gross domestic product (GDP) of any nation on

42. *See* Sara Nadim, *The 2008 Mental Health Parity and Addiction Equity Act: An Overview of the New Legislation and Why an Amendment Should be Passed to Specifically Define Mental Illness and Substance Use Disorders*, 16 CONN. INS. L.J. 297, 312 (2009).

43. *See id.* at 312-13.

44. *See id.*

45. Fadipe, *supra* note 25, at 579.

46. *Id.* at 578.

47. *See id.*

48. *Id.* at 579.

49. *Id.*

50. Mauldin, *supra* note 3.

51. Fadipe, *supra* note 25, at 579; *see also* Nadim, *supra* note 42, at 300 ("In the 1990's, the majority of employer-sponsored health plans that did include mental health services placed far greater restrictions on mental health services than for other medical services. In 1998, sixty-two percent of health plans imposed limits on inpatient treatment for mental health services and fifty-seven percent imposed limits on outpatient treatment. These limits were imposed purely on mental health services and typically not placed on other medical services.").

health care."[52] In addition, mental health care costs have risen over time as well, with inpatient psychiatric care costs significantly increasing from $3 billion in 1969 to $21 billion in 1986.[53] Unfortunately, the astounding climb in overall health care costs has not resulted in an equivalent rise in the quality of care. Despite vastly increased spending, in 2000 the United States ranked only thirty-seventh worldwide in overall health system performance.[54] Recently, the idea of managed care has spread in the health care market as a structure for insurers to utilize to reduce costs and increase quality of care.[55] The introduction of managed care saw mental health services offered on a level that approached parity with other health care services.[56] Yet health costs continued to rise,[57] and in response, insurance companies began cutting comprehensive mental health plans.[58] The access-limiting adjustments that insurers imposed included "increased deductibles, reduced maximum inpatient days and outpatient visits covered annually, and decreased lifetime and annual limits."[59] Thus, despite brief hopes that managed care would result in parity for mental health services, coverage remained far below that for other medical services.

III. Mental Health Parity Legislation

Before mental health parity legislation was introduced, some turned to the courts in efforts to receive mental health benefits on par with other medical benefits.[60] Similarly to how the states had adopted divergent definitions of mental illness, courts reached drastically different results in resolving these claims.[61] Interestingly, plaintiffs were more likely to succeed when the courts focused on the disorder's symptoms instead of the disorder's biological origins.[62] Similarly, courts found in favor of plaintiffs when they classified the condition

52. Glen Cheng, *The National Residency Exchange: A Proposal to Restore Primary Care in an Age of Microspecialization*, 38 AM. J. L. AND MED. 158, 160 (2012).

53. Shamash, *supra* note 1, at 277.

54. Cheng, *supra* note 52.

55. Shamash, *supra* note 1, at 277.

56. *Id.*

57. *Id.*

58. *Id.*; Tovino, *supra* note 7, at 489.

59. Shamash, s*upra* note 1, at 277.

60. *Id.* at 279.

61. *Id.*

62. *Id.*

as a physical impairment, as opposed to a mental impairment.[63] Unfortunately, the stigma attached to mental illness was prevalent in court proceedings as well. In order to try to solve this judicial inconsistency, fifteen states each passed some sort of law addressing mental health parity before 1996.[64]

However, the ubiquity of mental health disorders—affecting one in four adults in 2010, totaling approximately 57.7 million Americans—and the costs associated with this prevalence, meant that if significant and wide-reaching changes in coverage of mental health services were to be realized, mental health parity at the federal level would be required.[65] In 1992, Senators Pete Domenici and John Danforth drafted the first national bill focused on mental health parity, which advocated change through the "indirect mechanism of insurance regulation."[66] Although the bill was unfortunately scuttled early on, the fact that it was introduced provided evidence that views were shifting and federal legislation would be forthcoming.[67]

A. Mental Health Parity Act of 1996

In response to the growing urgency for mental health parity, Senators Domenici and Paul Wellstone proposed a mental health parity amendment to the Kassebaum-Kennedy bill for health care portability, also known as the Health Insurance and Portability and Accountability Act of 1996 ("HIPAA").[68] After passing the Senate, the proposed amendment to HIPAA was met with criticism in the House concerning whether it would result in health insurance premium increases.[69] In order to pass HIPAA promptly, Senators Nancy Kassebaum and Ted Kennedy chose to delete the proposed amendment from the bill.[70] Determined to secure passage of the mental health parity amendment, Senators Domenici and Wellstone then decided to attach the amendment to the Employee Retirement

63. *See* Shamash, s*upra* note 1, at 279.

64. *See* Fadipe, *supra* note 25, at 580.

65. *Mental Illness: Facts and Number,* NAT'L ALLIANCE ON MENTAL ILLNESS, http://www.nami.org/Template.cfm?Section=About_Mental_Illness&Template=/ContentManagement/ContentDisplay.cfm&ContentID=53155 (last visited Mar. 31, 2013); Fadipe, *supra* note 25, at 592 ("One study estimates the cost of serious mental illness to the nation at $193.2 billion a year.").

66. Mauldin, *supra* note 3.

67. *Id.*

68. Nadim, *supra* note 42, at 300.

69. *Id.*

70. *Id.*

Income Security Act of 1974 and the Public Health Services Act.[71] The amendment was yet again met with much opposition in the House over potential costs.[72] As a consequence, the final version of the amendment, known as the Mental Health Parity Act of 1996 ("MHPA"), bore little resemblance to the original amendment and ultimately did little to advance mental health parity.[73]

The greatest impact on mental health parity wrought by the MHPA came as a result of its restriction on insurance companies' ability to set unequal annual and lifetime aggregate spending limits on mental health services as compared to other medical services.[74] However, this prohibition, or parity mandate, was severely confined by several qualifications built into the MHPA.[75] First, and most importantly, the prohibition against disparate annual and lifetimes caps only applied to insurers that included mental health services in their benefits package.[76] Because the MHPA contained no requirement that health insurance plans must include mental health benefits,[77] insurers had the legally available option of completely dropping coverage of mental health services if they did not want to comply with the MHPA's limited parity mandate.[78] Second, the MHPA afforded these health plans an "opt-out of parity" provision if the cost of providing parity raised overall plan costs more than one percent.[79] Third, the parity mandate "did not extend to substance abuse treatments."[80] Finally, the MHPA granted small employers, defined as having fifty or fewer employees, an exception to the parity mandate.[81] Consequently, the mental health parity mandate created by the MHPA was extremely limited and far from comprehensive.[82]

The MHPA's mental health parity mandate was also deficient because it permitted insurers to discriminate against the mentally ill

71. Nadim, *supra* note 42, at 300.

72. *Id.*

73. Shamash, *supra* note 1, at 280.

74. *Id.* at 281.

75. *See* Shamash, *supra* note 1, at 281.

76. Fadipe, *supra* note 25, at 580.

77. Shamash, *supra* note 1, at 282.

78. *See id.* at 282-83 ("The modest cost increases that resulted from compliance with the MHPA provided an explanation as to why less than one percent of insurers dropped mental health benefits in reaction to the legislations.").

79. Clark, *supra* note 4, at 363.

80. Tovino, *supra* note 7, at 490.

81. Fish, *supra* note 14, at 211.

82. *Id.* at 212.

through other means.[83] For instance, large-group health plans were allowed to block patient access to out-of-network mental health providers, and these plans could impose disparate restraints on deductibles, co-payments, premiums, and number of visits covered for mental health services.[84] Furthermore, since the MHPA did not provide a standard definition of mental health, insurers could pick and choose which mental illnesses they wanted to cover based on their definition of mental health.[85] Finally, the MHPA also contained a sunset provision which completely eliminated the parity requirements by 2006.[86] As might be expected of a statute fraught with loopholes, insurance companies exploited the technicalities in the MHPA in order to comply with the parity mandate instead of increasing mental health coverage.[87] The American Psychological Association stated in a 2002 report that eighty-seven percent of employers who complied with the parity mandate decided to reduce the mental health benefits not controlled by the MHPA, which effectively rendered "the effects of the law moot."[88] In sum, the MHPA accomplished very little in changing scope of coverage for mental health services at the national level.[89]

After the failure of the MHPA, Congress considered several similar versions of the Mental Health Equitable Treatment Act ("MHETA"), which sought to eliminate the weaknesses of the MHPA.[90] However, each of these acts, the MHETA of 1999, the MHETA of 2001, the MHETA of 2002 and the MHETA of 2003, would ultimately be unsuccessful in becoming law.[91]

B. Mental Health Parity and Addiction Equity Act of 2008

Senators Domenici and Wellstone persisted in their efforts to pass a full and comprehensive mental health parity mandate.[92] Along

83. *See* Fish, *supra* note 14, at 211.

84. Clark, *supra* note 4, at 363; Fadipe, *supra* note 25, at 580.

85. Shamash, *supra* note 1, at 282.

86. Tovino, *supra* note 7, at 490-91.

87. Desiree Busching & Simon Kapochunas, *Timothy's Law: Introducing New York to Mental Health Parity*, 25 HOFSTRA LAB. & EMP. L.J. 601, 617 (2008).

88. *Id.*

89. Mauldin, *supra* note 3, at 199.

90. Busching & Kapochunas, *supra* note 87 ("intended 'to provide for full parity with respect to health insurance coverage for certain severe biologically based mental illnesses and to prohibit limits on the number of mental-illness-related hospital days and outpatient visits that are covered for all mental illnesses.'").

91. *Id.* at 617-18.

92. Nadim, *supra* note 42, at 304.

with these senators' unwavering determination, five significant advances factored into the increased support for, and successful passage of, the Mental Health Parity and Addiction Equity Act in 2008.[93] First, scientific research finally affirmed that there were biological bases and effective treatments for many mental illnesses.[94] Second, as a result of troops returning from the Middle East with serious mental illnesses, the stigma towards mental illness began to wane.[95] Third, employers started noticing that employees who received mental health services missed fewer days at work, whereas a lack of mental health services was associated with reduced employee productivity.[96] Fourth, and of significant importance, mental health groups were able to assuage cost concerns associated with providing mental health parity.[97] Finally, "the experimentation with parity at both the state level and in the health insurance program for federal employees, including members of Congress, ha[d] prove[n] workable."[98] These changes in public perception of mental illnesses ultimately resulted in Congress enacting an amendment to the MHPA as part of the Emergency Economic Stabilization Act of 2008.[99] This amendment, known as the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 ("MHPAEA"), was projected to enhance coverage of mental health services for 113 million people.[100]

The MHPAEA augmented the MHPA's parity mandate by decreeing that group health plans could no longer contain more restrictive financial and treatment limits for mental health services than for all other medical services.[101] The MHPAEA prohibited financial limitations like separate cost sharing requirements for only mental health benefits, as well as specifically stating that parity must exist in "deductibles, copayments, coinsurance, and out-of-pocket

93. *See* Nadim, *supra* note 42, at 304-05.

94. *Id.*

95. *Id.* at 305-06.

96. *Id.*

97. *Id*. at 304-05 ("A 2006 study in the New England Journal of Medicine found that insurers' costs rose less than half a percentage point when full parity was required for federal workers starting in 2001. The Congressional Budget Office Cost Estimate also stated that if the more generous House bill were enacted, the costs for premiums would increase for group health insurance by an average of only about 0.4 percent.").

98. *Id.* at 306.

99. Fadipe, *supra* note 25, at 581.

100. Nadim, *supra* note 42, at 306.

101. Shamash, *supra* note 1, at 284.

expenses" for medical services and mental health services.[102] To prevent treatment limitations, the MHPAEA forbade insurers from setting disparate treatment stipulations on mental health services, including "limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the cope or duration of treatment."[103] Parity was also prescribed for access to out-of-network mental health providers.[104] In addition, the MHPAEA explicitly included substance use disorder benefits in its expanded parity mandate.[105] And because the MHPA's sunset clause had generated numerous fears and doubts regarding the lifetime of its limited parity mandate, the MHPAEA's drafters purposefully omitted a sunset provision.[106]

Regrettably, the MHPAEA suffered from the same essential defect as the MHPA: the parity mandate did not require insurers to cover mental health services at all.[107] In other words, the MHPAEA's mental health parity provisions only pertained to insurers who provided coverage of mental health services, which they were not required to do under the law.[108] Moreover, the MHPAEA's parity mandate did not apply to small employers with 50 or fewer employers.[109] Again like the MHPA, the MHPAEA provided insurers with a cost exemption, which stated that insurers did not have to comply with the parity mandate "if the overall implementation of the bill would result in an increased cost of two percent or more during the first year after the legislation goes into effect and one percent in the following years."[110] Because the MHPAEA lacked specific definitions of mental and substance use disorders, it again allowed insurers to determine which mental illnesses to cover and which to not.[111] The MHPAEA also continued

102. 42 U.S.C.A. § 300gg-5(a)(3) (West Supp. 2009); Nadim, *supra* note 42, at 306.

103. 42 U.S.C.A. § 300gg-5(a)(3)(B)(iii); Nadim, *supra* note 42, at 306-07.

104. Shamash, *supra* note 1, at 285.

105. *Id.*

106. *See* Mauldin, *supra* note 3, at 200.

107. Shamash, *supra* note 1, at 286.

108. Fadipe, *supra* note 25, at 581.

109. Fish, *supra* note 14, at 213; *see also* Shamash, *supra* note 1, at 306 ("the Equity Act's small employer exemption will significantly limit the Act's effectiveness. As of 2009, approximately 170 million individuals obtained insurance through an employment based insurance plan, making an employer the most likely source of health insurance. Furthermore, roughly forty-three of employees in the United States work for a small employer").

110. Nadim, *supra* note 42, at 307.

111. *Id.* at 308.

to permit insurers to establish their own definitions of what would be considered a medical necessity, further empowering insurers to pick and choose which mental illnesses to cover.[112] However, the MHPAEA did to slightly reel in this practice by mandating that insurers publically release the criteria used in making medical necessity determinations.[113] All in all, the MHPAEA significantly expanded the parity mandate found in the MHPA, but left in place many loopholes through which insurers could avoid having to provide full mental health parity.[114]

C. Patient Protection and Affordable Care Act

On March 23, 2010, President Barack Obama signed into law the Patient Protection and Affordable Care Act, or PPACA.[115] The law drastically renovated the American health care system, introducing sweeping changes to the health care structure designed to control costs, expand insurance coverage, and improve the overall quality of health care in the United States.[116] While not predominately focused on the issue of mental health parity, the PPACA, taken as a whole, ultimately strengthens mental health parity through a variety of mechanisms that will plug some of the gaps left by the MHPAEA.[117] For instance, one of the most hotly debated provisions of the PPACA is the individual mandate, which requires all individuals to either purchase health insurance or pay a penalty.[118] The individual mandate is projected to result in thirty-two million previously uninsured individuals obtaining health insurance coverage by 2019.[119] The PPACA also requires the development of two types of state-based exchanges, one for individuals and one for small businesses.[120] These exchanges will serve as an easily accessible location for consumers not only to view available health insurance plans, but to select and

112. Mauldin, *supra* note 3, at 200.

113. *Id.*

114. *See id.* at 201 ("One study found that of the 31% of firms bound by the MHPAEA that made changes to their mental coverage following passage of the law, only 5% cut mental health coverage altogether to achieve compliance.").

115. *Summary of New Health Reform Law*, KAISER FAMILY FOUNDATION, 1, http://www.kff.org/healthreform/upload/8061.pdf (last modified Apr. 15, 2011).

116. *Id.*

117. *See* Mauldin, *supra* note 3, at 205.

118. Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S.Ct. 2566, 2601 (2012) ("The Federal Government does have the power to impose a tax on those without health insurance."); Shamash, *supra* note 1, at 294.

119. Shamash, *supra* note 1, at 294-95.

120. *Summary of New Health Reform Law*, *supra* note 115.

purchase a suitable policy.[121] For low income individuals, defined as incomes below 400% of the Federal Poverty Level, "premium and cost-sharing credits" will be available to offset the costs of purchasing health insurance plans from the exchanges.[122]

The majority of the new plans, including those from the state-based exchange, the individual market, and the small group market, will be required to cover at least the ten essential health benefits:

> hospitalization, outpatient hospital and clinical services (including emergency services), physician services, medical services, preventive services, prescription drugs, rehabilitation services, maternity care, baby and child care for children twenty-one and under, early and periodic screening, diagnosis and treatment for children up to age 21, and mental health, behavioral health and substance use services.123

All of the plans that must comply with the PPACA's essential health benefits requirement by covering mental health services must also comply with the MHPAEA's mental health parity mandate.[124] As a result, the PPACA will interact with the MHPAEA's mental health parity mandate by transforming it into an actual mandate for most insurance plans, and will also extend the MHPAEA's parity mandate to some individuals who were previously out of reach.[125]

The PPACA provides several other key benefits that will impact the provision of mental health services. A major provision of the PPACA prohibits insurance companies from discriminating against and denying coverage to individuals with preexisting conditions, including mental disabilities and substance abuse disorders.[126] The PPACA expands access to health care by allowing dependents to remain on their parents' health insurance plan until the age of twenty-six.[127] Finally, the PPACA and sets aside money to train mental health professionals, and to create intervention programs, school-based health clinics and community mental health centers.[128]

As for public insurance, the PPACA affords states the opportunity to choose whether or not to expand their Medicaid

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121. *Summary of New Health Reform Law*, *supra* note 115.

122. *Id.* at 1-2.

123. Clark, *supra* note 4, at 370; Shamash, *supra* note 1, at 296.

124. Shamash, *supra* note 1, at 317 ("PPACA explicitly requires that health plans comply with the provision of the Equity Act").

125. *See* Mauldin, *supra* note 3, at 206.

126. *Id.*

127. Lawrence G. Smith & Megan Anderson, *New Direction in American Health Care: Innovations from Home and Abroad*, 39 HOFSTRA L. REV. 23, 32 (2010).

128. Cheng, *supra* note 52, at 179-80; Fish, *supra* note 14, at 217.

programs to include all childless and non-disabled individuals under the age of 65 who have incomes up to 138% of the Federal Poverty Level.[129] If a state elects to expand their Medicaid program, then the state must provide the expanded Medicaid population with coverage that includes at least the ten essential health benefits.[130] The PPACA expressly states that insurance plans must provide mental health benefits at parity to the medical and surgical benefits.[131] The PPACA also creates and finances new enterprises that will enable psychologists to engage in "community interdisciplinary teams that promote primary care," as well as participate in teams of health providers who deliver integrated services to low income individuals.[132] The PPACA's Medicaid expansion is estimated to open up mental health and substance abuse services and prescription drug coverage to an additional sixteen million people by 2019.[133] The PPACA also grants states the option to administer home health services for "individuals with chronic conditions, [including] 'persistent mental health conditions.'"[134]

Despite all of the promising changes under the PPACA, questions about mental health parity remain. Insurance companies are currently in the process of adjusting their old plans, or developing new ones, to comply with the PPACA. Thus, although the end results are not yet completely realized, the provisions which attempt to fill gaps in mental health parity provisions appears as if they may fall short in several ways. One particular failure of the PPACA is that it exempts grandfathered individual and employer-sponsored plans from covering the essential benefits package, including mental health services.[135] Thus, these plans will only have to comply with the MHPAEA's parity mandate if they provide coverage for mental

129. Sebelius, *supra* note 118, at 2607 ("What Congress is not free to do is to penalize States that choose not to participate in that new [expansion] program by taking away their existing Medicaid funding."); *Medicaid: A Primer: Key Information on the Nation's Health Coverage Program for Low-Income People*, KAISER FAMILY FOUNDATION, 16 (Mar. 1, 2013), http://www.kff.org/medicaid/upload/7334-05.pdf.

130. *Medicaid: A Primer: Key Information on the Nation's Health Coverage Program for Low-Income People*, *supra* note 129, at 18.

131. Leslie Prentice, *"At Risk for Incarceration": Women in Poverty, Post-Traumatic Stress Disorder, and Medicaid*, 32 WOMEN'S RTS. L. REP. 81, 96 (2010).

132. *Id.* at 96; *see also* Shamash, *supra* note 1, at 300 ("One preventive strategy the Task Force recommended, and therefore PPACA mandated, is the integration of mental health and substance abuse care with primary care.").

133. Fish, *supra* note 14, at 215-16.

134. Fadipe, *supra* note 25, at 585.

135. *Summary of New Health Reform Law, supra* note 115, at 6.

health services. The PPACA also continues to exempt small employers from the mental health parity mandate, even though the small employers still may be required to provide the PPACA's essential health benefits.[136] Another problem in the small employer provisions is that the PPACA defines small employers as having between one and one hundred employees, which is inconsistent with the MHPAEA's definition of between two and fifty employees.[137] Consequently, only small employers who have between fifty-one and one hundred employees will have to observe the MHPAEA's mental health parity mandate.[138]

Because the PPACA's requirements do not extend to all insurance policies, many health care providers will continue to exclude expensive mental health treatments from the "lower level coverage plans."[139] Individuals with serious mental illnesses may not receive the type of treatment that they need if they can afford only such "lower level coverage plans," which will only offer basic mental health benefits.[140] The PPACA also fails to establish a definition for mental illness, and to list the "minimum level of mental health services that must be covered by all insurance plans."[141] Analysts believe that because of these deficiencies, twenty-three million people will not be able to afford the health services that they need when the PPACA has taken complete effect in 2019.[142]

IV. Mental Health Parity Issue

As discussed above, the PPACA fails to resolve problems of mental health parity in several respects.[143] Although the PPACA moves things forward, the United States still has a long road ahead to establish a full and comprehensive mental health parity mandate. Furthermore, new insurance company practices threaten what advances the PPACA has made in achieving mental health parity. Due to "data indicat[ing] a positive correlation between behavioral [mental health] insurance parity and . . . [the] over-use of other physical health insurance benefits[,]" insurance companies now

136. Mauldin, *supra* note 3, at 106; Shamash, *supra* note 1, at 319.
137. Shamash, *supra* note 1, at 319-20.
138. *Id.*
139. Fadipe, *supra* note 25, at 589.
140. *Id.*
141. *Id*. at 592.
142. *Id*. at 590.
143. *See supra* Part IV.C.

realize that people who seek psychiatric help tend to have more physical problems than people who did not seek psychiatric help.[144] Because they require more mental health services as well as other medical services, it necessarily follows that those who seek psychiatric treatment will cost insurance companies more than those who do not seek psychiatric help.

In order to discourage people who seek psychiatric help from signing on to one of their health plans, insurance companies have started utilizing a practice that requires individuals to work their way up a hierarchy of mental health care professionals, referred to in this note as a "mental health tree." Instead of immediately offering access to mental health care professionals, insurance companies ask that individuals attempt to get the mental health care that they need through their general practitioner, or primary-care physician first.[145] If a general practitioner cannot help, then a referral is made to a mental health care professional.[146] There are many different types of mental health care professionals, including psychiatrist, mental health nurse practitioner, clinical psychologist, clinical social worker, mental health counselor, family therapist, peer specialist, and others,[147] each of which costs the insurance companies a different price.[148] To reduce costs and increase profits, insurance companies prefer individuals to first utilize lower cost mental health care services before higher cost services, and thus referrals to psychiatrists are lower.[149] For example, a plausible treatment scenario is as follows. An individual who needs mental health care may first be required to talk with a general practitioner. If the general practitioner believes that the individual

144. Lorraine Schmall, *One Step Closer to Mental Health Parity*, 9 NEV. L.J. 646, 665 (2009).

145. Michelle Andrews, *For people with mental health problems, care can be elusive,* L.A. TIMES, March 21, 2011, http://articles.latimes.com/2011/mar/21/health/la-he-healthcare-mental-health-20110321.

146. *Id.*; *see also What do I need to know about my insurance benefits?*, MENTAL HEALTH AMERICA, http://www.mentalhealthamerica.net/insurance-questions (last visited Apr. 6, 2014).

147. William N. Robiner, *The mental health professions: Workforce supply and demand, issues, and challenges*, 26 Clinical Psychology Review 600, 603-12 (2006); *see also Types of Mental Health Professionals*, MENTAL HEALTH AMERICA, http://www.mentalhealthamerica.net/types-mental-health-professionals (last visited Apr. 6, 2014).

148. Robiner, *supra* note 147, at 614-15.

149. *Id.*; David E. Grembowski, Diane Martin, Donald L. Patrick, Paula Diehr, Wayne Katon, Barbara Williams, Ruth Engelberg, Louise Novak, Deborah Dickstein, Richard Deyo & Harold I. Goldberg, *Managed Care, Access to Mental Health Specialists, and Outcomes Among Primary Care Patients with Depressive Symptoms*, 17 J. of GEN. INTERNAL MED. 258, 262 (2002).

should see a mental health care professional, then the individual will be referred, most likely, to a therapist. Only if the therapist sees no improvement in the individual will the individual have a chance at a referral to a psychologist or psychiatrist. This practice subjects patients to seemingly endless and taxing exchanges of personal information to one mental health professional after another.

The effect of this type of referral tree is to encourage those who desperately need psychiatric help to sign up with other insurance companies. This new practice introduces another factor that may be relevant in evaluating mental health parity.

V. Possible Solutions to the Mental Health Parity Issue

Parity has traditionally been defined in terms of financial requirements and initial treatment.[150] Debates over the definition of parity have never factored in referrals, nor have they referred to the different kinds of mental health specialists. In order to determine whether these factors need to be included in a definition for parity, it will be necessary to assess the structure of the medical services to which mental health services are being compared. For physical ailments in today's health care system, primary care physicians generally serve as patients' "first contact" with the medical community.[151] If a primary care physician cannot provide a patient adequate treatment, the primary care physician will refer the patient to a specialist who is trained to handle specific health problems.[152] Usually, there is only one stage of referral, from general practitioner to specialist.[153] Patients almost never are referred from specialist to specialist.[154]

The referral process for physical ailments is a relatively novel practice.[155] The technological advancements of the twentieth century gave rise to health specialists, including the various types of mental health specialists.[156] Furthermore, managed care has played a

150. *See* Clark, *supra* note 4, at 363.

151. *Primary Care*, AMERICAN ACADEMY OF FAMILY PHYSICIANS, http://www.aafp.org/online/en/home/policy/policies/p/primarycare.html (last visited Mar. 31, 2013).

152. Cheng, *supra* note 52, at 165.

153. Caroline Y. Lin, *Improving Care Coordination in the Specialty Referral Process Between Primary and Specialty Care*, 73(1) N.C. MED. J. 61, 61 (2012), available at http://www.ncmedicaljournal.com/wp-content/uploads/2012/01/73115-web.pdf.

154. *Id.*

155. Cheng, *supra* note 52, at 168.

156. *See id.* at 160-61.

significant role in "how patients seek specialty care."[157] As mental health parity is striding closer and closer to becoming a reality, even if it does so haltingly, other factors need to be taken into account, most notably the ever-changing atmosphere of the medical field. If comprehensive parity is to be achieved, parity can no longer be defined solely in financial terms. Parity must be defined as closely as possible in relation to the other medical services provided. Under this definition, the emerging mental health tree practice undermines mental health parity. Accordingly, under a more comprehensive definition, parity between mental health and other medical services would require that there be only one stage of referral between mental health professionals, barring extremely serious and unique mental disorders. Because patients need not go through a cycle of several referrals in obtaining medical care for physical ailments, to achieve comprehensive mental health parity insurers should be prohibited from requiring patients to suffer through such a cycle in obtaining mental health care.

Conclusion

For thousands of years, individuals with mental illnesses have struggled to gain access to adequate treatment for their disorders. Stigmatization, beliefs concerning the underlying cause of mental illness, and the intrinsic nature of mental illness have all compounded the difficulties faced by those who suffer from mental illness. Once treatments were designed to actually assist the mentally ill in acclimating to and succeeding in life, insurers started offering mental health coverage. However, mental health coverage has never been offered on an equal basis with that for other services.

In the 1990s, a variety of factors culminated in persuading people to demand that insurance companies cover mental health services on par with other medical services. One of the most persuasive reasons was the cost to society of not treating individuals with mental health problems. For instance, in 2007 "[e]stimated costs to [the] U.S. government and businesses from untreated mental disorders [were] over $100 billion annually in terms of lost productivity and unemployment."[158] With this understanding, Congress passed the Mental Health Parity Act of 1996, and later the Mental Health Parity

157. Christopher B. Forrest & Robert J. Reid, *Passing The Baton: HMOs' Influence On Referrals To Specialty Care*, 16 HEALTH AFF. 157, 159 (1997), available at http://content.healthaffairs.org/content/16/6/157.

158. STEPHEN P. HINSHAW, THE MARK OF SHAME: STIGMA OF MENTAL ILLNESS AND AN AGENDA FOR CHANGE 179 (2007).

and Addiction Equity Act of 2008. Both of these acts constituted significant victories for mental health parity, but both ultimately failed to establish a comprehensive parity mandate for mental health services.

Enacted in 2010, the Patient Protection and Affordable Care Act both expanded access to health insurance and filled many of the parity gaps left by the MHPAEA. However, the PPACA also failed to truly achieve parity. Grandfathered individual and employer-sponsored insurance plans need not comply with the essential health benefits requirement. Both must offer mental health benefits on par with other medical benefits only if the plans offer mental health benefits in the first place. In addition, the PPACA failed to provide insurance plans with a definition for mental illness and minimum standards for what types of mental health benefits to cover.

Finally, a new issue has emerged in mental health parity. Likely as a result of studies showing that those who seek psychiatric help are more likely to consume other benefits offered under insurance plans, insurance companies have begun to require patients to climb a mental health tree for services. Because people who seek psychiatric help are more expensive for insurance companies than people who do not, insurance companies may be imposing this mental health services tree in order to discourage people who need psychiatric help from purchasing their plans in the first place. A critical question then becomes whether insurance companies who are requiring patients to see lower level mental health professionals first are in compliance with the parity mandate.

Determination of mental health parity requires examination of the medical services against which mental health services are to be compared, and the comparison must account for more than the traditional financial and treatment terms. For example, traditional physical health care services typically involve only one referral step, from primary care physician to specialist. To achieve parity, insurance companies should only be allowed to require one referral step for mental health services, not several. Accordingly, Congress must address the above-mentioned failures of the PPACA and create a rubric that accounts for the ever-changing structure of the health care field before full and comprehensive mental health parity can be realized.

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