

Intellectual Property Brief

Volume 1
Issue 1 *Spring 2010*

Article 9

1-1-2010

Volume 1, Issue 1

AU Intellectual Property Brief

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Recommended Citation

American University Intellectual Property Brief, Spring 2010, 1-58.

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INTELLECTUAL PROPERTY BRIEF

IPBRIEF.NET

VOLUME 1 ISSUE 1

SPRING 2010



IN THIS ISSUE:

Software Patents: The Case for Harmonization of European and American Law Through American Decisiveness and Leadership
By Andrew G. Haberman

Virtual Confusion: How the Lanham Act Can Protect Athletes from the Unauthorized Use of Their Likenesses in Sports Video Games
By Lindsay Coleman

Pharmaceutical Patents, Paragraph IV, and Pay-for-Delay: The Landscape of Drug Patent Litigation and the Lessons Provided for the Recently Passed Biosimilar Approval Pathway
By Brett Havranek

South Africa's Movie Piracy Challenges
By Matilda Bilstein

Settling for Less? An Analysis of the Possibility of Positive Legal Precedent on the Internet if the Google Book Search Litigation Had Not Reached a Settlement
By Brooke Ericson

Regulation of Medicine Patents by the Anti-Counterfeiting Trade Agreement to Broaden Access to Medicine
By Daniel Lee

Online Auction Sites and Inconsistencies: A Case Study of France, China, and the United States
By Won Hee Elaine Lee



2009-2010 STAFF

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Daniel Lee

Elaine Lee

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Software Patents: The Case for Harmonization of European and American Law Through American Decisiveness and Leadership

By Andrew G. Haberman

4

Virtual Confusion: How the Lanham Act Can Protect Athletes from the Unauthorized Use of Their Likenesses in Sports Video Games

By Lindsay Coleman

9

Pharmaceutical Patents, Paragraph IV, and Pay-for-Delay: The Landscape of Drug Patent Litigation and the Lessons Provided for the Recently Passed Biosimilar Approval Pathway

By Brett Havranek

16

South Africa's Movie Piracy Challenges

By Matilda Bilstein

27

Settling for Less? An Analysis of the Possibility of Positive Legal Precedent on the Internet if the Google Book Search Litigation Had Not Reached a Settlement

By Brooke Ericson

33

Regulation of Medicine Patents by the Anti-Counterfeiting Trade Agreement to Broaden Access to Medicine

By Daniel Lee

44

Online Auction Sites and Inconsistencies: A Case Study of France, China, and the United States

By Won Hee Elaine Lee

50

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Software Patents: The Case for Harmonization of European and American Law Through American Decisiveness and Leadership

By Andrew G. Haberman¹

I. Introduction

In 2005, the owner of patents for a method of enabling users to receive e-mail over a wireless network sued a competitor for infringement.² Patent protection for the method derived from a conglomerate of patents in multiple nations, but the owner sued in the United States.³ Despite the fact that this invention was the same worldwide, the patent owner was unable to seek damages for its foreign patents in American courts due to the court's reluctance to exercise supplemental jurisdiction. The court further questioned the ability of the patent owner to even receive compensation for the violation since the competitor's infringing software was relayed through Canada.⁴ This type of transnational patent litigation costs corporations, like NTP, Inc., millions of dollars to protect their inventions worldwide, and exemplifies the necessity for change.

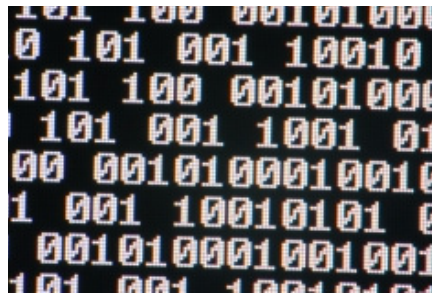
The combination of jurisdictional boundaries and subtle differences between many countries' national laws concerning protection of software patents makes protecting software patents a formidable task. Although the ideal solution would be a harmonized — solitary standard of law — worldwide patent system to protect innovations, multilateral negotiations have proven fruitless. As such, the United States should attempt to lead the way in international harmonization by beginning to align their patent laws with those of foreign nations, even if this requires lowering the protection afforded to American inventors, in order to alleviate the

difficulties in multilateral negotiations. Alignment can be accomplished through efforts by the legislature and the judiciary to clarify and synchronize American law with the law of other world leaders.

II. Background

Because software patenting is a highly debated topic worldwide, the laws surrounding it constantly shift and evolve over time.⁵ Further, software innovations are, by definition, innovations in electronic form, making them exceedingly easy to move across borders.⁶ Thus, software patents exemplify the problem with a non-harmonized system of international patent law.⁷ Specifically, if infringement occurs within a country that does not offer the same protection as the patent-granting nation, the inventor will lose his exclusive right, and he or she will have no remedy due to jurisdictional complications.⁸

In Europe, the differences between countries' software patent laws may seem subtle, but the differences affect the patentability of all computer-implemented



1. Andrew Haberman is a second year law student at American University's Washington College of Law. This article is a shortened version of a comment written for the Journal of Gender, Social Policy and the Law.

2. See *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282 (Fed. Cir. 2005) (deciding a suit based on NTP's BlackBerry technology).

3. See *id.* at 1287-92. (pursuing infringement in Virginian courts for a system relayed through Canada).

4. See *id.* at 1293, 1313 (asserting that although NTP's global patents stem from one "parent" patent, RIM cannot be held liable for their extraterritorial activities under 35 U.S.C. § 271).

5. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments-Results of the Uruguay Round, Apr. 15, 1994, 33 I.L.M. 81 (1994) [hereinafter TRIPs Agreement], available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf, at arts. 68, 71(1) (including a basis for further negotiation which authorizes the TRIPs Council, established in Article 68, to undertake reviews if necessary to remain consistent with current law).

6. See A Report by the Business Software Alliance, October 2009 at 1, available at http://global.bsa.org/internet_report2009/2009internetpiracyreport.pdf (asserting that software and computers have become "indispensable tools in our businesses, school and personal lives").

7. See Business Software Alliance, Sixth Annual BSA-IDC Global Software Piracy Study 1 (May 2009) (estimating that the software business lost \$53 Billion in 2008 based on a study on 110 countries).

8. See, e.g., *NTP, Inc.*, 418 F.3d at 1313-18 (allowing NTP to recover for infringement on its method patent, despite questioning whether this was possible because the infringed process relayed through Canada and NTP was unable to recover on its other claims abroad); see also *id.* (documenting losses sustained when no remedy is available).

subject matter.⁹ Until 2007, the European Patent Office (EPO) had statutorily banned patents for software and business methods, but awarded patents to this subject matter under the “as such” language contained within the European Patent Commission (EPC).¹⁰ The Board of Appeals, established under the EPC, took the approach that the role of the patent office was to give protection to technological developments, and that since such developments were happening in software, they should be protected.¹¹

Despite the addition of the phrase “all fields of technology” to the EPC in 2007, the EPO still requires a “technical aspect”, while the United Kingdom requires a “new and novel” analysis that implicitly considers the technical effect and Germany requires “technical character”.¹² Although these analyses usually reach similar results, the analyses are all somewhat different, and it remains possible that they may arrive at different conclusions about the patentability of the same invention.¹³

Meanwhile, in the United States, the courts began to broaden the scope of patent protection in 1998 with the *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.* decision, which allowed patents for software innovations and business methods so long as the inventions had a useful purpose.¹⁴ This decision made

patent protection available for almost any invention, and was extended when the courts eliminated the need for a business method to be linked to a machine.¹⁵ These two decisions expanded patentable subject matter to a point at which almost anything became patentable.¹⁶ Further, the combination of the patent office’s limited experience with software and business method patents and the severe increase in applications in the art area caused an over-granting of patents.¹⁷

However, in 2008, the Federal Circuit heard *In re Bilski* and rejected the usefulness test employed in *State Street*. Instead, it implemented the “machine-or-transformation” test.¹⁸ In order to satisfy the “transformation” requirement, a process must “transform any article to a different state or thing.”¹⁹ In contrast, the “machine” half of the test is less defined. It allows a claimed process to be patent-eligible if it is “tied to a particular machine or apparatus”, but does not specify whether this requires machine involvement in the process, or mere machine implementation in the transformation.²⁰

III. Analysis

Although the majority of developed countries seem to believe that the ideal solution for global

9. Compare *In re CFPH L.L.C.’s Applications*, [2005] EWHC 1589 (Pat), [2006] R.P.C. 5 [hereinafter CFPH Applications], available at <http://www.bailii.org/ew/cases/EWHC/Patents/2005/1589.html>, at ¶ 104 (requiring software innovations to be new and useful regardless of their technical character), with Convention on the Grant of European Patents, Oct. 5, 1973, 13 I.L.M. 268 [hereinafter EPC], available at <http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/contents.html>, at art. 52 (requiring a technical effect to be incorporated in the inventive step of a software patent).

10. See EPC, *supra* note 9, at art. 52. See *Vicom*, 1987 E.P.O.R. 74 (EPO Tech. Bd. App. 1986), available at <http://legal.european-patent-office.org/dg3/biblio/t840208ep1.htm> [hereinafter *Vicom*] (assessing software patents for the first time, the EPO granted a patent for digitally processing images stored in a digital format).

11. See, e.g., *Vicom*, *supra* note 10, at 75 (protecting a method for image enhancement on a computer based off of a mathematical formula, but not the formula itself).

12. See EPC, *supra* note 9, at art. 52 (determining patentable subject matter under the EPC); CFPH Applications, *supra* note 9, at ¶ 104 (holding that all inventions, technical or not, must be new and novel); Johannes Lang, *Computer-Implemented Inventions – The German View*, Intellectual Asset Management, May/June 2009, at 93, 96 (determining patentable subject matter in Germany based off of German case law).

13. See Robert E. Thomas & Larry A. DiMatteo, *Harmonizing The International Law Of Business Method And Software Patents: Following Europe’s Lead*, 16 *Tex Intell. Prop. L.J.* 1, 14 (Fall 2007) (analyzing how three tests would result in similar but still different outcomes for the Amazon “one-click” patent).

14. See *State St. Bank & Trust Co. v. Signature Fin. Group, Inc.*,

149 F.3d 1368, 1369 (Fed. Cir. 1998) (holding that business software designed to perform financial calculations for an investment fund was patentable).

15. See *AT&T Corp. v. Excel Commc’ns, Inc.*, 172 F.3d 1352, 1357 (Fed. Cir. 1999) (reaffirming *State Street* and stating that the scope of patentable subject is independent of the whether the patent is a machine or a process).

16. See, e.g., *Method of Swinging on a Swing*, U.S. Patent No. 6,368,227 (filed Nov. 17, 2000) (granting a patent for a method for one person to swing him or herself on a swing involving nothing but the person and the swing).

17. See United States Patent and Trademark Office, *Class 705 Application Filing and Patents Issued Data, January 2009*, <http://www.uspto.gov/patents/resources/methods/applicationfiling.jsp> (reporting 13,779 business method patent filings in 2008, up from 1,300 in 1998); see also Carl Shapiro, *Patent System Reform: Economic Analysis and Critique*, 19 *Berkeley Tech. L.J.* 1017, 1018 (2004) (arguing that the lack of examples in the subject matter caused extreme over-granting).

18. See *In re Bilski*, 545 F.3d 943, 964 (Fed. Cir. 2008) (rejecting a patent claim for a method of hedging risk in the field of commodities for failure to satisfy the “machine-or-transformation” test).

19. See *id.* at 965 (holding that an alleged transformation of “public or private legal obligations or relationships, business risks or other such abstractions” does not satisfy the test because it does transform the data into anything of physical substance).

20. See *id.* (comparing *Diamond v. Diehr*, 450 U.S. 175, 184-92 (1981), which involved a process operated on a computerized rubber curing apparatus with *Parker v. Flook*, 437 U.S. 584, 586 (1978) which involved a mathematical formula to create an “alarm limit” for chemical reactions and finding that the former, but not the latter, would not meet the machine formulation).

harmonization of software patents, as well as patents in general, is a centralized system, this is not being achieved.²¹ As such, the United States should use its status, not only as a world power, but as a leader in intellectual property law, to lead the harmonization of software patent law, and eventually patent law in general. Through legislative efforts, Congress can articulate specific standards and commit both developed and under-developed countries to specific standards through the ratification of treaties.²² Similarly, through judicial efforts, courts can exert supplemental jurisdiction over foreign patents with duplicate patents in the United State in order to enhance worldwide protection.²³

1. A. The Legislature's Role

Congress has already obtained "TRIPS-plus" intellectual property provisions in bilateral trade agreement through negotiations stemming from "Special 301" review.²⁴ However, Congress must also consider that although the United States may be in the best position to force things to move forward through trade pressures, "TRIPS-plus" may not be a viable global standard, since U.S. law, as it was under *State Street*, may be less like that of most other countries.²⁵

21. See International Bureau, World Intellectual Property Organization Standing Committee on the Law of Patents, *Draft Substantive Patent Law Treaty*, Tenth Session, SCP/10/2, Geneva May 10 to 14, 2004 [hereinafter Substantive Patent Law Treaty], available at http://www.wipo.int/edocs/mdocs/scp/en/scp_10/scp_10_2.pdf, at art.3 (providing an example of a failed attempt to achieve harmonization); Commission of the European Communities, *Proposal for a Directive of the European Parliament and of the Council on the Patentability of Computer-Implemented Inventions*, COM(2002) 92 final, at 3, Feb. 20, 2002, available at http://eur-lex.europa.eu/LexUriServ/site/en/com/2002/com2002_0092en01.pdf [hereinafter Proposed Directive] (revealing the European desire to take action towards harmonization as discovered through a survey of Member Countries).

22. Cf., KORUS Free Trade Agreement, U.S.-S. Korea, art. 18.4, June 30, 2007, 46 I.L.M. 642, available at <http://www.ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text> (requiring the implementation of "TRIPs-plus" IP protection, such as enhanced border authority)

23. Cf., *Cambridge Literary Props., Ltd. v. W. Goebel Porzellanfabrik G.m.b.H. & Co.*, 295 F.3d 59, 64 (1st Cir. 2002) (applying U.S. copyright law, German contract law and Austrian inheritance law); *Ortman v. Stanray Corp.*, 371 F.2d 154, 160 (7th Cir. 1967) (approving the exercise of supplemental jurisdiction over corresponding Canadian, Brazilian and Mexican patents).

24. See Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, §§ 1301-03, 102 Stat. 1107, (codified as amended in 19 U.S.C. §§ 2411-2419, 2420, 2241-2242 (1994)) [hereinafter 301 Trade Act] (requiring countries to agree to patent protection in exchange for trade agreements). See KORUS FTA, *supra* note 22, at art. 18 (requiring heightened intellectual property protections).

25. Compare *State St. Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1380 (Fed. Cir. 1998) (allowing all business methods, so long as they are useful), with EPC, *supra* note 9, at art

Therefore, harmonizing U.S. law "down" may be more likely to achieve worldwide harmonization than trying to harmonize the rest of the world "up."

In order to accomplish this, the Supreme Court would have to affirm the Federal Circuit's decision in *Bilski* and restrict the patentability of business-method and software patents in the United States, as the EPO currently does.²⁶ Although the Federal Circuit's rule in *Bilski* and the EPO's standard for patentable subject matter are not the same, a Supreme Court affirmation would make the Federal Circuit's test appear permanent and allow American inventors to confidently determine what constitutes patentable subject matter. The public would gain even more confidence if *Bilski* was codified by the legislature. However, codification may be more difficult due to the political pressures and business influences that are more prevalent in a politically-accountable Congress.²⁷

Even so, American pressure may not be sufficient to force other countries to agree to harmonized standards. To date, American pressure in intellectual property negotiations has not been sufficient to force the World Trade Organization (WTO) to adopt substantive international patent laws.²⁸ However, pressure may not be vital if the U.S. can merely bring its standard close enough to the European standard as to make negotiations easier, as the United States has seemed to do with *In re Bilski*.²⁹ Further, the United States could even lead the way in harmonization by lowering its standard from the transformation-or-machine test to the "technical affect" test, but this would likely be a secondary and possibly desperate option.

52 (requiring a business method or software patent to have a technical effect).

26. Compare *In re Bilski*, 545 F.3d 943, 960 (Fed. Cir. 2008) (requiring a technical aspect under the machine-or-transformation test), with EPC, *supra* note 9, at art. 52 (requiring a technical contribution in the inventive step).

27. See, e.g., Brief of Double Rock Corp. et al. as Amici Curiae Supporting Petitioners, *Bilski v. Doll*, 545 F.3d (2009) (No. 08-964), 2009 WL 2445751 at *7 (arguing against limiting the patentability of software innovations due to the negative effects on business).

28. See, e.g., Substantive Patent Law Treaty, *supra* note 21 (demonstrating the U.S.' inability to force other countries to agree to international patent law treaties). But see World Intellectual Property Organization Copyright Treaty, Dec. 20, 1996, 36 I.L.M. 65 (1997), available at www.wipo.int/treaties/en/ip/wct/trtdocs_wo033.html (providing international standards for protecting access-controlled digital information).

29. See *In re Bilski*, 545 F.3d at 943 (declining to implement the *State Street* test, and instead applying the machine-or-transformation test, which more closely resembles the EPC test); see also EPC, *supra* note 20, at art. 9.

1. B. *The Judiciary's Role*

While the legislature begins to assert itself in international negotiations, the judicial branch could begin to protect American corporations by exercising supplemental jurisdiction. However, the courts have been reluctant to assert supplemental jurisdiction over foreign software patent infringement, or even over foreign patent infringement in general, due in part to concerns of comity.³⁰

Although software patent law has yet to become harmonized, the Patent Cooperation Treaty (PCT), EPO, and TRIPS agreement have achieved some success. For example, one patent can be filed under the PCT in multiple different countries, as well as the EPO.³¹ Due to the increasing similarity between the standards applied in the United Kingdom, Germany, the EPO, and the United States under *In re Bilski*, it will be easier for American courts to exercise supplemental jurisdiction over foreign patents.³² Under the PCT, the same patent is filed, albeit translated, in every nation where the inventor seeks protection. With similar standards in place, and identical patents being litigated, American courts could exercise supplemental jurisdiction without having to expend a tremendous amount of time and resources on the trial.

American courts have asserted that comity is reason enough not to preempt foreign courts — courts that have not been proven inadequate to handle law — and that doing so could prejudice the rights of foreign governments.³³ Additionally, American courts have expressed a belief that exercising jurisdiction over cases involving foreign patents would destroy Congress' intent to foster uniformity and preclude forum shopping.³⁴

30. See, e.g., *Voda v. Cordis Corp.*, 476 F.3d 887, 900 (Fed. Cir. 2007) (refusing to exercise supplemental jurisdiction and add the claims involving an EPO patent of the catheter involved in a U.S. patent infringement case out of concerns for comity).

31. See Patent Co-operation Treaty (PCT), June 19, 1970, 1160 U.N.T.S. 231, at ch. 1, amended on Sept. 28, 1979 and modified on Feb. 3, 1984 [Hereinafter PCT], available at <http://www.wipo.int/pct/en/texts/articles/atoc.htm> (allowing innovators to file one patent application for patents in multiple nations or the EPO).

32. Compare *In re Bilski*, 545 F.3d 943, 964 (Fed. Cir. 2008) (applying the machine-or-transformation test), with *CFH Applications*, *supra* note 9, at 46 (requiring the innovation to be new and novel regardless of the technical aspect, but returning similar results to the EPO), and *EPC*, *supra* note 9, at art. 52 (requiring a technical link), and *Lang*, *supra* note 55 (asserting that Germany requires technical character).

33. See *Voda*, 476 F.3d at 900-02 (asserting that there is no international duty requiring the court to exercise supplemental jurisdiction over EPO catheter patents identical to the U.S. patent in question).

34. See *F. Hoffmann-La Roche Ltd. v. Empagran S.A.*, 542 U.S.

However, this logic is called into question by the number of cases in which the court has had authority to decide questions requiring the application of foreign law.³⁵ American courts have continually and frequently applied foreign laws, and concerns of comity should not prevent courts from exercising supplemental jurisdiction.

Courts may exercise supplemental jurisdiction at their discretion, and use it in order to prevent forum shopping and increase efficiency.³⁶ Courts have reasoned that the patents issued in foreign nations are not identical, and the exercise of supplemental jurisdiction would effectively unilaterally determine the adjudicating body for international disputes.³⁷ Further, American courts have argued that the exercise of supplemental jurisdiction would require extensive resources that the courts do not feel are warranted.³⁸ However, although adjudicating disputes involving foreign patents may require American courts to expend a larger amount of resources, that increase is infinitesimal compared to the amount of resources expended by the courts, parties, and countries involved in suits around the globe over the same patent.³⁹

Adjudicating disputes over the same patent in one court should increase efficiency, and possibly help to exemplify the value of a worldwide patent court and system.⁴⁰ Applying supplemental jurisdiction will not necessarily harmonize patent laws, but it will allow one

155, 166-67 (2004) (arguing that exercising supplemental jurisdiction would allow the plaintiff to choose U.S. courts instead of foreign courts in an antitrust case).

35. See, e.g., *Distillers Co. v. Standard Oil Co.*, 150 USPQ 42 (N.D. Ohio 1964) (settling a dispute over various patents on the manufacture of acrylonitrile and concluding that, "this Court is empowered to consider claims arising under foreign patents").

36. See 28 U.S.C. § 1367 (1988) (allowing supplemental jurisdiction for all claims arising from the same case or controversy).

37. See, e.g., *Voda*, 476 F.3d at 887 (asserting that the district court's exercise of supplemental jurisdiction would undermine the obligation of the United States under its treaties).

38. See, e.g., *Stein Assoc's, Inc. v. Heat and Control, Inc.*, 748 F.2d 653, 658 (Fed. Cir. 1984) (arguing that actions are not the same where one action involves an American patent and the other involves a British patent, as each would require separate claims construction and infringement determinations, which adjudication would string the courts resources).

39. See Genetic Engineering & Biotechnology News, Patent Litigation: Is it Worth the Expense? If Rights Are Uncertain, Pursuing Licensing with Alleged Infringer Might Be Best Option, Apr 1 2006 (Vol. 26, No. 7), <http://www.genengnews.com/articles/chitem.aspx?aid=1454&chid=0> (reporting that the average litigation cost was \$769,000 per party in cases where less than \$1 million was at risk, and over \$2.6 million where \$1 million or more was at risk).

40. See *Voda v. Cordis Corp.*, 476 F.3d 877 (Fed. Cir. 2007) (Newman, J., Dissenting) (arguing for the exercise of supplemental jurisdiction and offering efficiency as a benefit).

court to rule on, in the case of software patents, multiple standards that differ only slightly. In an ideal world, this would eventually lead to the adoption of a single standard. At the least, it should shed some light on the differences between the standards and provide a starting point for international negotiations.

IV. Conclusion

In order to protect and promote innovation, patents, especially software patents, must be protected by an extensive system of intellectual property laws.⁴¹ Although the software laws in European countries, the EPO, and the United States currently differ slightly, these are differences that must be reconciled. The ideal solution to clarify these inconsistencies is global harmonization, but the failure of international and even inter-European negotiations over the past decades has proven that this solution is unattainable.

As such, the United States must decisively clarify its software patent laws, ideally along the lines of *In re Bilski*, in order to enforce patentability standards as similar to European software patent law as possible, and must begin to claim jurisdiction over foreign patents with corresponding U.S. patents.⁴² Coupled with legislative efforts to align as many national patent laws as possible, these efforts will begin to harmonize international software patent law while avoiding the downfalls of multi-lateral negotiation. Any success will begin to provide inventors, as well as the courts, with clarification on patentable subject matter and efficient methods to protect these patents.

41. See U.S. Const. art. I, § 8 (giving Congress the power to protect innovation); Merges et al., *supra* note 9 (offering philosophical justifications for the grant of exclusive patent rights).

42. Compare *In re Bilski*, 545 F.3d at 943, 946 (implementing the “machine-or-transformation” test), with EPC, *supra* note 20, at art. 52 (requiring a technical link in the innovation).

Virtual Confusion: How the Lanham Act Can Protect Athletes from the Unauthorized Use of Their Likenesses in Sports Video Games

By Lindsay Coleman¹

Sports in the United States has transformed from a simple backyard game into a \$150 billion industry.² As a result of this transformation, athletes have evolved from mere players to business investments. Aside from developing the technical prowess of star athletes on the field, sports teams also cultivate these athletes' likenesses, personas and brands off the field. Branding athletes, particularly those athletes who become the face of the franchise, can reap lucrative rewards for the team.³ Branding develops instant recognition between fans, athletes and their teams. This strong connection of the athlete with his brand and team makes his likeness a valuable marketing tool for third party marketers looking to capitalize on the ever-growing sports industry. Accordingly, many companies, especially videogame producers, use prominent athletes to help promote their products. Within their sports games, these companies simulate the physical attributes, movements and persona of star quarterbacks, wide receivers, goalies and more to create as realistic a gaming experience as possible. While many of these athletes are compensated for the use of their image in the games, many others are not.⁴ Recently, several former college and professional athletes have filed lawsuits against these game companies and other advertisers under the Lanham Act⁵ for incorporating their likenesses into



games and marketing campaigns without compensating or receiving consent from the athletes before doing so.⁶

Although these cases include claims under the right of publicity, the Lanham Act applies federal—and therefore, more expansive—protections on the rights an athlete has in his persona and likeness. The right of publicity applies unevenly across states, with varied protection in each state based on the interpretations of state statutes governing the right of publicity. In general, a right of publicity claim is more suited to an infringement case based on an athlete's persona because it is triggered by a lower standard than the “likelihood of confusion” standard that trademark law requires.⁷ However, such a claim is limited by the inability to enforce infringement case across states, making the trademark infringement option more attractive.⁸ This article will evaluate whether Section 43(a) of the Lanham Act is broad enough to extend to infringement claims from former athletes over the unauthorized use of their likenesses by applying *Brown v. Electronic Arts, Inc.*⁹ to the analysis of Lanham Act protection.¹⁰ The article first analyzes the arguments and holding in *Brown* as a means to explain the trademark issues that video game producers like Electronic Arts (EA) raise by using realistic, recognizable players in their sports games.

1. Lindsay Coleman, 2011 J.D. Candidate, American University, Washington College of Law; M.A. European Studies, Georgetown University School of Foreign Service; B.A. History, Stanford University. Lindsay was the 2010 Senior Section Editor for Trademark and is the 2010-2011 Senior Managing Editor of the *Intellectual Property Brief*. Lindsay is also the Senior Recent Developments Editor on the *Administrative Law Review*.

2. 1 Glenn M. Wong, *Essentials of Sports Law* § 1.2 (3d ed. 2002).

3. Dannean J. Hetzel, *Professional Athletes and Sports Teams: The Nexus of their Identity Protection*, 11 *Sports Law J.* 141, 167 (2004).

4. Barbara A. Solomon, *Can the Lanham Act Protect Tiger Woods? An Analysis of Whether the Lanham Act is a Proper Substitute for a Federal Right of Publicity*, 94 *Trademark Rep.* 1202, 1202 (2004).

5. 15 U.S.C. § 1051 *et seq.* (2006).

6. See Complaint, *Brown v. Electronic Arts, Inc.*, No. 2:09-cv-01598-FMC-RZx (C.D. Cal. Mar. 6, 2009) [hereinafter *Brown Complaint*]; Keller v. Electronic Arts, Inc., No. CV-09-1967 (N.D. Cal. May 5, 2009) [hereinafter *Keller Complaint*].

7. See, e.g. Cal. Civ. Code § 3344(a) (West 2009) (“Any person who knowingly uses another’s name, voice, signature, photograph, or likeness, in any manner, on or in products, merchandise, or goods, or for purposes of advertising or selling, or soliciting purchases of, products, merchandise, goods or services, without such persons prior consent . . . shall be liable for any damages sustained by the person or persons injured as a result thereof . . .”).

8. 5 Thomas J. McCarthy, *McCarthy on Trademarks and Unfair Competition* § 28:12 (4th ed. 2009).

9. *Brown Complaint*, *supra* note 5.

10. See 15 U.S.C. § 1125 (2006) (specifying that any person may bring a civil action in relation to any goods or services that use words, terms or symbols that create a false designation of origin, false or misleading description or representation of fact).

Next, the article assesses the scope of the Lanham Act in its application to *Brown* and other similar cases. Finally, the article concludes with recommendations for video game producers and athletes on how to succeed in future cases.

The increasingly realistic sports-themed video games generate huge profits for game producers.¹¹ Sports leagues, like the National Football League (NFL) and the National Collegiate Athletics Association (NCAA), make money on these games by licensing their logos and brands to the game producer.¹² However, most of the money raised through licensing fees does not trickle down to the athletes, and this inequitable treatment has spurred lawsuits by players against video game producers. In March 2009, Jim Brown, a retired professional football player in the NFL, filed suit against EA for misappropriation of his likeness as a player on the Cleveland Browns NFL team in EA's *Madden NFL* game.¹³

In the 2009 version of *Madden NFL*—the most recent edition at issue in Brown's complaint—a user has the option to play virtual NFL football in several ways.¹⁴ The most straightforward mode of play for *Madden* users is the franchise mode, in which each user compiles a fantasy team by drafting players among other teams in the league. In this mode, users have access to all of the current NFL rosters and can select any player in the NFL. To select their teams, users flip through

pages of players that each contain an individual player's headshot, current team, height and weight, position, and game statistics.¹⁵ In franchise mode, the current players' identities are clear to the user because EA has licensed the rights to their images and likenesses. Once the team is compiled, users can play an entire season with their teams and act as team owners and managers by trading players. At the end of each season, users have another draft of the new players entering the league. The new players are fictitious, computer-generated characters that do not represent any real life players. Their player pages are also computer generated, with a graphic headshot instead of a photograph of the player, and names that do not exist in the NFL. Franchise mode allows users to act as team managers in a highly realistic setting for multiple seasons in a row. When playing in this mode, users recognize the current NFL players and understand that the computer-generated future players do not correspond to any real-life players.

In addition to franchise mode, users also have the option of playing *Madden* in exhibition mode. This allows the users to select entire teams rather than individual players, but uses historic players in addition to current NFL stars. Users can select either an "All-Time" team, composed of the best players on that team from throughout history, or the complete team from a particular year. In both of these instances, historic players like Brown are included in the game as part of a team. EA includes the same level of detail for all of these players, even the historic players who have not licensed their likeness rights to EA, but makes a few minor changes to avoid presenting an exact copy of the actual player on the player profile page and in the game. Generally, the changes include switching a number, excluding a player's name, and distorting the player's appearance. Although users may not individually select any players in exhibition mode, they can still manipulate the appearances of and add names to historic players to resemble the athletes that seem to be anonymous.¹⁶ In other words, placed in the context of either the All-Time

11. EA's top-selling game in the third quarter of 2008 was *Madden NFL*, selling 2,994,000 games—2,958,000 in the U.S.—during that period, the top global seller of video games. Matt Martin, *Madden is best global seller in Q3*, Games Industry, Oct. 11, 2008, <http://www.gamesindustry.biz/articles/madden-is-best-global-seller-in-q3>.

12. EA signed a licensing deal with the NFL and the NFL Players Association for the exclusive use of official player names and likenesses. Anastasios Kaburakis et al., *NCAA Student-Athletes' Rights of Publicity, EA Sports, and the Video Game Industry: The Keller Forecast*, 27 Ent. & Sports Law. 1, 15 (Summer 2009) (citing Tim Surette & Curt Feldman, *Big Deal: EA and NFL Ink Exclusive Licensing Agreement*, Gamespot.com, Dec. 13, 2004, 2:53 PM, http://www.gamespot.com/news/2004/12/13/news_6114977.html ("The deal . . . is an exclusive five-year licensing deal granting EA the sole rights to the NFL's teams, stadiums, and players.")). The NCAA has a similar agreement with EA, signing its most recent deal in 2004 for licensing rights to the teams, stadiums, and schools. Kaburakis, *The Keller Forecast*, 27 Ent. & Sports Law at 15 (quoting Press Release, Stage Select.com, CLC Grants EA Exclusive College Football Videogame License, Apr. 11, 2005, 2:43 PM EST, <http://www.stageselect.com/N1109-press-release-clc-grants-ea-exclusive-college-foot.aspx>).

13. Brown Complaint, *supra* note 5.

14. *Id.* at 5, 7. Although Brown first learned about the use of his likeness in the 2008 version of *Madden NFL*, he later discovered that his likeness had been used in all yearly editions dating back to 2001, in addition to the 2009 version. *Id.*

15. Madden 2008 08 2009 09 Player ratings, <http://www.youtube.com/watch?v=SlqHdYDTpYI&feature=fvw> (last visited Nov. 11, 2009) (showing the pages for each available player in the first draft of franchise mode, all of whom correspond to current NFL players).

16. See, e.g., All Time Cincinnati Bengals vs All Time Cleveland Browns Pt 1, <http://www.youtube.com/user/Franchiseplay#p/u/37/mN-4GJFKFzQ> (last visited Nov. 11, 2009) (demonstrating the match-up of two All-Time teams, one which included Jim Brown, number 32, in which the user manipulated the nameless players by adding their real names and changing their numbers to simulate as real a game as possible of these two all-star teams).

team or the team from a particular year, fans generally know the identities of the players, even when those players are not given names, have different numbers, and possibly have different appearances. With the rest of the information about the players—like position, team, and statistics—users know even the nameless players.

Brown's complaint centered around Section 43(a) of the Lanham Act, specifically the unauthorized use of his likeness in the *Madden* game and the false endorsement that followed from this use. Brown is always represented in *Madden* as a member of the team he played on during his football career, the Cleveland Browns.¹⁷ However, despite being represented anonymously, Brown's likeness is clearly apparent in the physical attributes given to the virtual player, especially because Brown is such a famous and celebrated athlete and actor. While the current players have already agreed to be compensated for the use of their likenesses at the start of their careers with the NFL, older players like Brown never had the opportunity to negotiate such terms, leaving their likenesses uncontrolled by the NFL and its licensees.¹⁸ Without prior agreement as to the control of their likenesses, players like Brown maintain propriety over their own personas and are not precluded from bringing complaints against video game manufacturers. This distinction is important because current NFL athletes license their images at the time of contract signing and cannot bring lawsuits like *Brown*, but NCAA athletes do not sign away the rights to their likenesses¹⁹ and can therefore continue to file trademark claims against video game producers.²⁰ NCAA athletes retain control over their likenesses, but the

debate continues to rage on over whether they should be allowed to receive compensation for their playing time.²¹ NFL athletes, on the other hand, have perhaps signed away too many of their rights by agreeing to a playing contract in the league, and future players may challenge the inclusion of likeness rights in the contracts, particularly if the athlete is extraordinarily famous and could command much more money in licensing fees than the NFL is willing to concede.

Based on the theory that he has control over his own likeness, Brown argued that EA used his image without consent or compensation in the *Madden* game, which constitutes false endorsement. Section 43(a) provides for civil remedies for anyone damaged by the use of "any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact."²² To prove a claim for false endorsement under Section 43(a), plaintiffs must prove three main elements: "(1) the mark is legally protectable, (2) the plaintiff owns the mark, and (3) the defendant's use of the mark to identify goods or services is likely to create confusion concerning the plaintiff's sponsorship."²³ Additionally, courts have adopted a grab bag of requirements that help them assess the merits of the false endorsement situation. For example, the Ninth Circuit considers the following factors, each of which carries a different amount of weight in the infringement analysis: (1) the level of recognition that the plaintiff has among the segment of the society for whom the defendant's product is intended; (2) the relatedness of the fame or success of the plaintiff to the defendant's product; (3) the similarity of the likeness used by the defendant to the actual plaintiff; (4) evidence of actual confusion; (5) marketing channels used; (6) likely degree of purchaser care; (7) defendant's intent on selecting the plaintiff; and (8) likelihood of expansion of the product lines.²⁴ In his complaint, Brown applied only a few of

17. *Id.* Brown's likeness is used as a part of the 1965 Cleveland Browns "historical" team and on the "All-Browns" team. His character is anonymous in the sense that his number is changed in the game to 37, where he played with number 32, but that is the only substantive change to the character. See Katie Thomas, *Retired N.F.L. Player Jim Brown Loses Lawsuit Against Video Game Publisher*, N. Y. Times, September 30, 2009, available at <http://www.nytimes.com/2009/09/30/sports/ncaafotball/30colleges.html>.

18. Brown Complaint, *supra* note 5, at 5-6.

19. Under NCAA rules, all college athletes competing in the NCAA are strictly prohibited from receiving remuneration for their activities as college athletes, including compensation for the use of their names, images, or likenesses. College athletes are also barred from authorizing the use of their names and images in commercial use. See Matthew G. Matzkin, *Getting' Played: How the Video Game Industry Violates College Athletes' Rights of Publicity By Not Paying for their Likenesses*, 21 Loy. L.A. Ent. L. Rev. 227, 228 (2001).

20. Former Arizona State University quarterback, Sam Keller, filed a class-action lawsuit July 2009 against EA for the unauthorized use of his likeness in its *NCAA Football* game, but did not state a claim under the Lanham Act and instead claimed infringement under the right of publicity theory. See Keller Complaint, *supra* note 5.

21. See Kristine Mueller, *No Control Over Their Rights of Publicity: College Athletes Left Sitting on the Bench*, 2 DePaul J. Sports L. & Pol'y 70, 86 (2004) (arguing that most athletes should be compensated for their skills at the college level because most will not make it to professional leagues, forcing them to lose out on the profits their universities made from their performances and personas).

22. 15 U.S.C. § 1125(a)(1) (2006).

23. Anastasios Kaburakis et al., *NCAA Student-Athletes' Rights of Publicity, EA Sports, and the Video Game Industry: The Keller Forecast*, 27 Ent. & Sports Law. 1, 29 (Summer 2009).

24. *Downing v. Abercrombie & Fitch*, 265 F.3d 994, 1007-08 (9th Cir. 2001) (adapting the factors set forth in *AMF, Inc. v. Sleekcraft Boats*, 599 F.2d 341, 348-49 (9th Cir. 1979) as they apply to cases involving celebrity personas).

the main elements required to prove false endorsement.

Brown could have strengthened his complaint by applying the *Abercrombie* factors to his Lanham Act discussion.²⁵ Widely considered the greatest football player of all time,²⁶ Jim Brown was selected to play in the Pro Bowl in each of the nine seasons he played in the NFL and was subsequently inducted into the Pro Football Hall of Fame in 1971.²⁷ Based on the fame and success that Brown achieved while in the NFL, he is widely recognized among football fans as the greatest football player of all time. The connection between Brown's success on the field and EA's use of his image in *Madden NFL* is obviously strong, with Brown's football skills integral to the use of his likeness in the game. Simply put, Brown was a hall of fame running back for the Cleveland Browns and is represented in a football game as a running back on the Cleveland Browns.

The similarity of Brown to his likeness in *Madden* is a stretch in this case because EA only depicts Brown as a nameless player with a different number and an altered appearance. However, the similarities of his team, year played, position and other athletic attributes are enough to make him recognizable to football fans. The Ninth Circuit in *White v. Samsung Electronics*²⁸ held that a Samsung commercial depicting a robot with a blond wig, long gown, and large jewelry standing in front of a game board and in the process of turning block letters on the board was confusingly similar to Vanna White, the popular hostess of the game show "Wheel of Fortune."²⁹ The court noted that even though plenty of women have blond hair and wear long gowns and big jewelry, all of the facts put together show that consumers would recognize this robot as an impersonation of Vanna White.³⁰ To further explain its reasoning, the court analogized Samsung's advertisement to a hypothetical advertisement depicting a robot with male features, an African-American complexion, a red basketball uniform with the number twenty-three on it, black hightop sneakers, and a bald head, dunking a

basketball with one hand.³¹ Based on this description, the court is certain that everyone would understand that robot to be a depiction of Michael Jordan.³² The Michael Jordan hypothetical is largely analogous to Jim Brown's representation in *Madden*, except that Brown's character is even more realistic and lifelike because EA has created a person instead of a robot with all of the same attributes as Brown. Additionally, Brown's team, position, and athletic strengths are identical, where the Michael Jordan robot only wore his team color and number.

Continuing with the *Abercrombie* factors that Brown should have asserted to bolster his claim, there is no evidence of actual confusion on the record, and it is a difficult factor to prove without evidence. Nonetheless, users might be confused and think that Brown endorsed *Madden NFL* because they can easily recognize the presence of his character in the exhibition mode games. However, users might not be confused given the difference in presentation of the current NFL players and the historic players like Brown, particularly in use of a computer-sculpted image of Brown's headshot that is different from all other current NFL players. Without evidence of actual confusion, though, this factor would have been difficult for Brown to prove. Football fans are generally zealous followers of specific players and teams for decades, which almost assures a finding that there is a high level of consumer care about whether Jim Brown is in *Madden*. EA is aware that its historic players are also an important part of its NFL games. In addition to the exhibition mode, EA also released a special addition to the newest version of *Madden NFL* called the *AFL Legacy Pack*, which allows users to play games against the original American Football League (AFL) teams.³³ Clearly, specific players from throughout the history of professional football are just as interesting to users as the current players. It is clear that Brown's likeness was specifically targeted by EA to include in the game given his reputation as the greatest football player of all time coupled with the strong user interest in *Madden* that historic players generate. Finally, EA continues to expand its *Madden* games, and with high user interest in looking back to historic players and playing other old teams, it is clear that without any action, Brown's image would continue to be appropriated by EA without his

25. *Abercrombie*, 265 F.3d at 1007-08.

26. Ron Smith, *The Sporting News Selects Football's 100 Greatest Players: A Celebration of the 20th Century's Best* (Sporting News Publishing Company 1999), available at <http://tsn.sportingnews.com/nfl/100/1.html> (nominating Jim Brown as the number one greatest football player of the 20th Century).

27. Hall of Fame Member: Jim Brown, http://www.profootballhof.com/hof/member.aspx?player_id=33 (last visited Nov. 11, 2009).

28. 971 F.2d 1395 (9th Cir. 1992).

29. *White*, 971 F.2d at 1399.

30. *Id.*

31. *Id.*

32. *Id.*

33. Alexander Sliwinski, *Madden 10 AFL Legacy Pack Takes the Field Sept. 24*, Joystiq, Sept. 9, 2009, <http://www.joystiq.com/2009/09/09/madden-10-afl-legacy-pack-takes-the-field-sept-24/>.

approval.

Without asserting the *Abercrombie* factors, the court is left with a scaled down infringement argument that does not correspond as closely to traditional infringement analyses that apply to goods. Instead, the court applies the basic test for false endorsement laid out in the statute, which requires the plaintiff to first show that he has a legally protectable mark. Courts have held that a celebrity's persona can serve as a legally protectable mark,³⁴ especially when the celebrity's name, voice, appearance, or likeness is well known to a large portion of the public. Brown argued that he is well known to the entire football-viewing public as the "greatest football player of all time," given his induction into the NFL Hall of Fame, College Football Hall of Fame, and the Lacrosse Hall of Fame.³⁵ He also claims to have "achieved significant fame and recognition off the field as a star of both film and television over the last four decades."³⁶ Applying Brown's arguments to the general pool of athletes, it is clear that athletes only have a legally protectable mark if they have gained significant fame or have developed a recognizable and distinctive attribute or likeness. Without the added factor of fame, it would be difficult for an athlete to succeed in an infringement suit because he would have little evidence to show damage to a persona that few people recognize.

The next step of the analysis is determining whether the athlete owns the mark. When Brown was a player in the NFL, he did not have the opportunity to negotiate licensing terms of his likeness like current players do at the start of their contracts, nor could he have envisioned the evolution of the sports and video games industries into behemoth money makers that use players' images as vehicles for profits. Because Brown never licensed his persona to any video game manufacturers in connection with his role as a star athlete for the Cleveland Browns, he is the definitive owner of his mark and has "retained exclusive ownership

and control in his likeness."³⁷ Most "historical" players who are not current professional athletes but are featured in sports games likely face similar circumstances as those of Brown and have retained the exclusive ownership of their persona. Current professional athletes, however, do not maintain ownership over their likeness in several key areas, particularly when they are acting as employees or representatives of their teams.

Finally, the most crucial element in proving infringement is a showing of confusion of the plaintiff's sponsorship. Preventing consumer confusion is one of the bedrocks of trademark law, and the Lanham Act is structured around protecting consumers from confusion in the marketplace to assist in a more efficient economy. In addition to confusion, the Lanham Act also rewards mark owners for the good will they have put into the product to encourage clear and truthful advertising. With these policy goals in mind, Brown argued that EA's inclusion of such a similar character in physical attributes and team connection to Brown's real-life athletic image and exploits can create confusion as to whether Brown endorsed the product. Despite these similarities, the court in *Brown* held that EA's First Amendment right to speech through video games was a complete defense to Brown's false endorsement claim.³⁸

The confusion claim would have been boosted by a showing of other factors that the court takes into consideration when considering false endorsement claims such as Brown's. Specifically, Brown should have shown or described exactly how similar the virtual character was to the real person. Without a visual image of Brown's picture next to a screenshot of the game or a detailed description of the similarities between the two characters on factors like height, weight, and distinguishing characteristics, the court had a difficult time assessing the lengths that EA went to copy the likeness and persona of Brown.³⁹ As one of 1,500 characters in the game, Brown failed to show how EA's copy of his persona was distinct from any of the other historical players' virtual characters, despite his place in athletic history as one of the greatest players of all time.⁴⁰ By not mentioning any of these additional factors, Brown did not assert all of the issues courts look at to help them decide trademark cases. Courts are rarely

34. 5 Thomas J. McCarthy, *McCarthy on Trademarks and Unfair Competition* § 28:15 (4th ed. 2009). See also *White v. Samsung Electronic American, Inc.*, 971 F.2d 1395, 1400 (9th Cir. 1992) ("In cases involving confusion over endorsement by a celebrity plaintiff, "mark" means the celebrity's persona."); *Allen v. National Video, Inc.*, 610 F. Supp. 612, 627 (S.D.N.Y. 1985) (adopting the view that a person's name, persona and personal attributes can be considered a "mark" that can be protected if that person has built up a reputation by investing in a particular public image and if the name and likeness of the person are well-known).

35. Brown Complaint, *supra* note 5, at 3-4.

36. *Id.* at ¶ 12. See Jim Brown, *IMDB*, <http://www.imdb.com/name/nm0000987/> (listing fifty-six movies in which Brown has appeared as an actor).

37. Brown Complaint, *supra* note 5, at 7.

38. *Brown v. Electronic Arts, Inc.*, No. 2:09-cv-01598-FMC-RZx, p. 5 (C.D. Cal. Sept. 23, 2009).

39. *Id.* at p. 8 ("Mere use of the likeness, without more, is insufficient to make the use explicitly misleading.")

40. *Id.* at p. 8.

clear about how they weigh the various factors in their analysis, so by not making all the possible arguments, Brown presented a weaker case than he could have.

The failure of Brown's case is not indicative of the strength of this claim overall, though. If athletes can bring cases that have a substantial amount of evidence in their favor, and can also show that the video game manufacturers acted in bad faith and hurt the good will that the athletes have put into their mark, the First Amendment defense will likely not stand up to the trademark law. However, in this case, the court did not have any strong evidence to show that EA explicitly copied Brown's image, persona and likeness to sell more video games, an action that would obviously mislead consumers into thinking that Brown endorsed the game.⁴¹ In the absence of strong evidence to support Brown's claim of false endorsement, the court took the easy path and precluded further consideration of the Lanham Act claim by deciding that video games deserved First Amendment protection.⁴² Had Brown presented images of his character next to screenshots of his *Madden* character, the court might have better understood the possibility of confusion presented by EA's use of almost identical images and attributes. Instead, without any images of the video game, the court had to blindly follow the trademark claims. Absent these crucial images, it was easier for the court to err on the side of free speech than on an individual's right to his likeness. The *Brown* case faltered because Brown could not show how the virtual character's representation harmed his image with his fans or his future profit-making potential by altering his public persona.

Despite Brown's failure to put forth enough facts to support his claims was a critical error, but the court's eagerness to skirt the substantive issue Brown raised about protection of his likeness under the Lanham Act in favor of a weak First Amendment argument was equally erroneous. The court held that the First Amendment is a complete defense to Brown's false endorsement claim under the Lanham Act, and that video games count as a form of expression protected by the First Amendment.⁴³ The cases that the court relies upon, however, focus on the affirmative right for violent video games to exist under the First Amendment.⁴⁴

41. *Id.*

42. *Id.* at pp. 6-9

43. *Id.* at p. 5 (quoting Video Software Dealers Ass'n v. Schwarzenegger, 556 F.3d 950, 958 (9th Cir. 2009)).

44. The court cites three cases to support its statement that video games are a form of expression that can be protected by the First Amendment. See *id.*; Kirby v. Sega of America, 144 Cal. App. 4th

While some people might see football as a violent sport, the contents of *Madden*, which only simulates football game playing, does not rise to the same level of violence depicted in video games that simulate war, death and criminal activity. The subject matter of *Madden* is not in the same category of any of the games mentioned by the court. Additionally, the cases cited by the court only address the question of whether the video games are allowed to exist, and do not tackle the issue of whether the First Amendment precludes the trademark rights of a former NFL player whose likeness is appropriated in a video game.

Another argument proffered by the court is that *Madden NFL* contains enough creative elements that it qualifies as an expressive work that is protected under the First Amendment.⁴⁵ Citing the creativity of the game producers in how they "realistically replicate NFL football" and create and compile the "stadiums, athletes, coaches, fans, sound effects, music, and commentary," the court finds *Madden* to be an expressive work.⁴⁶ In the supporting case, *Romantics v. Activision Publishing, Inc.*,⁴⁷ the popular rock band, the Romantics, sued the producer of the *Guitar Hero* video game that simulates music playing. The court in *Romantics* found that the game was an expressive work because of the presence of a story line and character development.⁴⁸ *Madden* has a similar type of story line as *Guitar Hero*, in that the users control how the story line moves, but the game clearly moves from one moment in time to another, especially in the franchise mode. EA has also included a substantial amount of character development in *Madden*, studying the specific movements of each player to help mimic the athletes as realistically as possible in the game. Both the story line and character development are present in *Madden*, but it is still distinguishable from *Romantics* because the contested content in *Romantics* is a song, rather than the image of the band. Music is highly creative and easily protected under the First Amendment, but the actions of athletes in sporting events is anything but a creative endeavor. Indeed, the point of *Madden* is to create as realistic a sporting simulation as possible, whereas *Guitar Hero* encourages the creative outlet of music creation.

47, 58 (Ct. App. Cal. 2006); Interactive Digital Software Ass'n v. St. Louis, 329 F.3d 954, 956-58 (8th Cir. 2003) (holding that "violent" video games are a protected form of speech).

45. *Brown*, *supra* note 37, at 7 (citing *Romantics v. Activision Publ'g, Inc.*, 574 F. Supp. 2d 758, 765-66 (E.D. Mich. 2008)).

46. *Id.*

47. 574 F. Supp. 2d 758 (E.D. Mich. 2008).

48. *Romantics*, 574 F. Supp. 2d at 766.

Finally, the court dismisses the idea that just because *Madden* is meant to be realistic does not mean it cannot be protected under the First Amendment. Citing a case about a Tiger Woods portraitist, *ETW Corp. v. Jireh Publishing*,⁴⁹ the court concludes that realism in expression does not preclude protection of the First Amendment.⁵⁰ In *ETW*, defendant published work by an artist who created a painting called “The Masters of Augusta” that commemorated Tiger Woods’s victory at the Masters Tournament.⁵¹ The court struck down *ETW*’s Lanham Act theory of false endorsement in favor of *Jireh*’s First Amendment claim because “in general the Lanham Act should be construed to apply to artistic works only where the public interest in avoiding consumer confusion outweighs the public interest in free expression,”⁵² and consumer confusion would be minimal as a result of the painting. Although *ETW* presents a strong case for the protection of free expression under the First Amendment, it deals with a painting that was carefully recreated by hand and eye from a live event. Instead, in *Madden*, EA used facts rather than interpretations to create the video game and the players’ pages. Without interpreting and reimagining the facts, EA’s actions should be considered manufacturing instead of expression. EA manufactured aspects of Brown’s and other retired players’ likenesses to make the game more realistic and make sure that the statistics, appearances, team affiliations and positions were similar enough to such a recognizable player as Brown that the players would understand and appreciate the addition of Brown into the line-up. The First Amendment analysis could have been better suited to the specific facts of this case. Without such attention to the issues involved in Brown’s complaint, the court in this case entered an opinion without considering the full extent of the Lanham Act claims and instead jumped into a First Amendment analysis that was misplaced.

The recent lawsuits filed by former athletes for trademark infringement under the Lanham Act, though unsuccessful thus far, are important checks on the appropriation of images that sports marketers and advertisers have increasingly utilized to create more realistic video games. Athletes’ rights under Section 43(a) of the Lanham Act are the best avenue for athletes to pursue when seeking enforcement of the rights to

their valuable persona, and should not be overlooked merely because of these initial setbacks. Courts are more than willing to enforce trademark claims for celebrities and athletes, particularly when the mark infringement directly harms the plaintiff’s public image. The Lanham Act is sufficiently broad to include claims such as Brown’s given past case history, but the cases brought thus far were not strong enough to justify an infringement decision.

49. 332 F.3d 915 (6th Cir. 2003).

50. *Brown*, *supra* note 37, at 7.

51. *ETW*, 332 F.3d at 918.

52. *Id.* at 927.

Pharmaceutical Patents, Paragraph IV, and Pay-for-Delay: The Landscape of Drug Patent Litigation and the Lessons Provided for the Recently Passed Biosimilar Approval Pathway

By Brett Havranek¹

The Hatch-Waxman Amendments created a three-way intersection between pharmaceutical, intellectual property, and antitrust law, but there is no stop sign, and collisions are common. The laws governing generic drug approval incentivize the filing of patent infringement suits, which often lead to reverse settlements where the manufacturers of patented drugs pay their generic competitors to remain off the market. In 1984, Congress passed the Hatch-Waxman Amendments, a major revision to the Food, Drug, and Cosmetic Act, which hoped to strike the difficult balance between encouraging research and development of new drugs and the desire for a robust generic drug industry that could supply the public with inexpensive medication.² To bolster the generic industry, Congress created a unique exception to patent exclusivity, allowing generic drug manufacturers to research, develop, and test their products to prepare them for submission to the FDA, all without infringing the innovator's patents.³ The generic's new privileges are counterbalanced in part by allowing the patent holder to immediately and unilaterally halt the FDA's approval of the generic



for up to thirty months.⁴ This gives the patentee⁵ an advantageous legal position to exploit, where, by filing for patent infringement, a competitor is automatically prevented from entering the market. The unique economics of the pharmaceutical industry provide a wide set of legal options for the patentee, from simply buying monopoly time by pursuing the infringement action, to actually paying the defendant to settle the case and refrain from competing in the drug market. These so-called “reverse settlement” or “pay-for-delay” cases have drawn the attention of government antitrust regulators⁶ and Congress,⁷ while causing some inconsistencies between the circuits and some ambiguity as to where each circuit stands on the legality of reverse payments.⁸

Part I of this Article briefly discusses pharmacoeconomics and the drug development process to elucidate why infringement actions are so common and why reverse settlements are relatively unique to the pharmaceutical industry. Part II details the generic drug approval process originally set up by the Hatch-Waxman Act and explains how the law bypasses the usual judicial balancing of equities in the preliminary injunction process, which ultimately incentivizes filing infringement suits. Part III explores the eventual results of drug patent infringement suits and the legal issues they create: Once filed, these suits are difficult for the generic to challenge and may last for a long time,

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2. *See* *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370-71 (Fed. Cir. 2002) (“Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the ‘Hatch Waxman Amendments’ to the Federal Food, Drug and Cosmetic Act (‘FFDCA’)), Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.”).

3. *See* 35 U.S.C. § 271(e)(1) (2009) (excluding the use of a patented invention for purposes related to an FDA submission from the definition of infringement).

4. 21 U.S.C. § 355(c)(3)(C) (2009).

5. This Article uses the terms “patentee,” “innovator,” and “brand” interchangeably, as is common in the drug industry. In some circumstances, a generic can actually be its own brand, and these are called “branded generics,” but here, “brand” refers only to the innovator.

6. *See, e.g.*, Health Care Div., Fed. Trade Comm’n, Overview of FTC Antitrust Actions in Pharmaceutical Services and Products (2009).

7. *See, e.g.*, Tracy Staton, *Congress Grills Generics Firms on Pay-for-Delay*, FiercePharma, June 4, 2009, available at <http://www.fiercepharma.com/story/congress-grills-generics-firms-pay-delay/2009-06-04> for excerpts of recent Congressional hearings on pay-for-delay.

8. *See infra* Part III.

thereby creating favorable conditions for the generic to enter into a mutually beneficial reverse settlement agreement with the brand. In these agreements, the brand pays the generic not to market its product, and in doing so, the brand guarantees its profitable market exclusivity. These agreements can straddle the line between an exercise of the innovator's lawful patent monopoly rights and an antitrust injury to other generic competitors and consumers. Part IV applies the lessons learned from twenty-five years under the Hatch-Waxman approval regime to Congress's latest legislation: the new approval process for generic biologic medicines. The current biosimilar pathway contains a set of provisions that can be used together in conjunction with a reverse settlement to prolong an innovator's exclusivity period while providing a defense to antitrust challenges.

Part I — Drug Development and Pharmacoeconomics

Unlike virtually all other patented products, new drugs⁹ have an especially long development¹⁰ process and require FDA approval before they can be lawfully marketed.¹¹ Three to six years before involving the FDA, the research process typically begins by screening between 5000 and 10,000 potential drug molecules, followed by further laboratory and animal studies on approximately 250 of the most promising candidates.¹² Of these 250 candidates, only about five are suitable for human trials, for which the sponsor must file an Investigational New Drug Application (IND) to notify the FDA of its intent to initiate clinical trials.¹³ Filing an IND triggers a significant set of regulatory requirements that apply throughout the remainder of the drug's testing,¹⁴ burdening the innovator without providing any guarantee of success. Once the IND is in effect, the five potential drugs are subjected to three successive

phases of clinical trials¹⁵ over the next six to seven years. Statistically, only one and a half of the candidates progress to the final stage (phase III) of the trial process¹⁶ where they are able to accumulate data demonstrating safety and substantial evidence of effectiveness¹⁷ that supports the filing of a New Drug Application (NDA) with the FDA.¹⁸ Another six months¹⁹ to two years pass during the FDA's typical review of the NDAs, and on average, only one drug ultimately receives approval for sale and marketing.²⁰ Even when the NDA is approved, the FDA requires additional post-approval (phase IV) research²¹ in 72% of new drugs.²²

The entire process, resulting in one FDA-approved drug, typically takes ten to fifteen years to complete.²³ There is some disagreement about the average cost to develop one approved new drug, but the most recent estimates include \$802 million in a 2002 study²⁴ (excluding an additional \$95 million for post-approval research costs, adjusted down to approval-year dollars),²⁵ \$1.3 billion in a 2005 study,²⁶ and \$1.7 billion in a 2002 study (including the costs of preparing

15. See 21 C.F.R. § 312.21 (2009) (listing the phases of clinical trials).

16. See Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Econ. 151, 162 (2003) (estimating that the probability of phase III entry is 31.4%).

17. See 21 U.S.C. § 355(d) (2009) (requiring that proof of safety and substantial evidence of effectiveness).

18. See 21 C.F.R. § 314.50 (2009) (listing all the requirements for an NDA).

19. See 21 U.S.C. § 355(c)(1) (2009) (requiring a decision by the FDA on drug applications within 180 days, but allowing a longer period if the applicant agrees).

20. PhRMA Profile, *supra* note 12, at 36.

21. See 21 C.F.R. § 312.85 (2009) (allowing the FDA to tie marketing approval with the applicant's agreement to conduct phase IV research).

22. See Accenture, *The Pursuit of High Performance Through Research and Development – Understanding Pharmaceutical Research and Development Cost Drivers 17* (Pharmaceutical Research Manufacturers of America 2007) available at <http://www.phrma.org/files/Accenture%20R&D%20Report-2007.pdf> (“The FDA is increasingly requiring companies to commit to post-approval activities. In 2005, 13 (72 percent) of the 18 new molecular entities approved required post-marketing activities, ranging from a single human in vivo drug interaction study to a large randomized safety study to assess major clinical outcomes.”).

23. See PhRMA Profile, *supra* note 12, at 36.

24. See DiMasi, *supra* note 16, at 166 (“Our base case out-of-pocket cost per approved new drug is US\$ 403 million, while our fully capitalized total cost estimate is US\$ 802 million.”).

25. See *id.* at 173. The total out-of-pocket capitalized cost in approval-year dollars is broken down so that the pre-approval cost is \$802 million and the post approval cost is \$95 million. The money spent on post-approval research does include an average of 15% on improvements to already-approved drugs. *Id.*

26. PhRMA Profile, *supra* note 12, at 39.

9. The terms “drug” and “pharmaceutical” are sometimes used nonspecifically in the literature and may encompass both biologics/biopharmaceuticals and traditional small-molecule drugs/pharmaceuticals. A significant part of this Article deals with the legal interactions between generic manufacturers and patentees, but as of this writing, there are no approved generic biologics. Therefore, when possible, the statistics presented here disaggregate the two markets. In this Article, “drug” and “pharmaceutical” are used to refer to traditional small-molecule drugs.

10. When discussing the development of a new drug in this Article, the author assumes the new drug to be a new chemical entity, not just a reformulation of an existing product.

11. 21 U.S.C. § 355(a) (2009).

12. Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2009* 36 (2009) [hereinafter PhRMA Profile].

13. See *id.*; see also 21 C.F.R. § 312.20 (2009) (explaining when an IND is required to be submitted to the FDA).

14. See, e.g., 21 C.F.R. pt. 312 (2009).

to market the drug).²⁷ These extremely high research and development costs are reflected in the industry's overall research spending of approximately \$52 billion in 2005.²⁸

The high cost of initial development stands in stark contrast to the relatively simple and inexpensive process of gaining approval for a generic drug. The most important element of the Hatch-Waxman Amendments to the pharmaceutical industry was its creation of an expedited method for generic manufacturers to gain FDA approval for their products.²⁹ Generic manufacturers are allowed to file an Abbreviated New Drug Application (ANDA) in which they need only to demonstrate that their generic is the same as a branded drug (bioequivalence) and do not have to re-prove that the drug is safe and effective.³⁰ Under the more lenient ANDA requirements, the cost of obtaining FDA approval for a generic drug is only a few million dollars, which creates a major dichotomy in development costs between innovators and generics.³¹

As an incentive for generic manufacturers to challenge innovator patents, the law gives the first generic applicant to submit a substantially complete ANDA 180 days of marketing exclusivity before other ANDAs can be approved by the FDA.³² Originally, the first Paragraph IV ANDA filer was required to successfully defend against a patentee's infringement suit to qualify for the 180 days of exclusivity,³³ but this

27. See Accenture, *supra* note 22, at 4 ("Though estimates differ, one source suggests that the cost of an approved pharmaceutical drug, including average launch costs, has gone up from 1.1 billion in 1995-2000 to 1.7 billion in 2000-2002.").

28. See Accenture, *supra* note 22, at 4 ("Approximately \$51.8 billion was spent by US biopharmaceutical companies alone in 2005. R&D spending by Pharmaceutical Research and Manufacturers of America (PhRMA) member companies, representing the top pharmaceutical and biotechnology companies in the United States, went up 53.5 percent, from \$26 billion in 2000 to \$39.9 billion in 2005.") (citation omitted). This aggregate statistic may include spending on the development of biologics as well as traditional drugs but is nevertheless illustrative of the massive costs of researching new medicines.

29. See 21 U.S.C. § 355(j) (2009).

30. See *id.* § 355(j)(2)(A).

31. See Henry G. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, in *Science and Cents: Exploring the Economics of Biotechnology* 87, 90 (John V. Duca & Mine K. Yucel eds., Federal Reserve Bank of Dallas) (2003) ("Generic firms can file an abbreviated new drug application (ANDA). The ANDA process only takes a few years and typically costs a few million dollars.").

32. See 21 U.S.C. § 355(j)(5)(B)(iv) (2009).

33. See 21 C.F.R. § 314.107(c)(1) (1998); see also *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1339 (Fed. Cir. 2008) ("FDA regulation in effect conditioned the first Paragraph IV

requirement was officially eliminated in 1998.³⁴ Now, successful judgment on the patent for a subsequent ANDA filer can force the first filer to either begin or forfeit its exclusivity period.³⁵

The extremely high costs associated with developing a single marketable pharmaceutical product only begin to set the stage for reverse settlements and other arguably anticompetitive behavior. The market for pharmaceuticals is extremely lopsided, where the "blockbuster" drugs comprising the top decile of the market generate eighty percent of all drug sales.³⁶ In fact, the drug market is so lopsided that eighty percent of all pharmaceuticals will never recoup their own research and development costs.³⁷ The extreme profitability of a small proportion of drugs creates a powerful incentive for brand name manufacturers to preserve their marketing exclusivity, resulting in unique legal strategies such as pay-for-delay.

While innovators have a strong financial reason to preserve their monopolies, generic manufacturers have comparatively much less to gain by entering the market. Although a generic is supposed to be equivalent in efficacy to its brand-name competitor, the prices charged by generics and brands are very different. The decrease in the innovator's profits due to the generic's arrival is normally much higher than the generic's potential profit were it to enter the market. Thus, if the innovator were to pay its potential generic competitor the entire amount of the generic's expected profit in exchange for an agreement to stay off the market or to delay entry, the innovator would still see higher profits than if it were competing with the generic.³⁸ An examination of the national drug market is illustrative: while branded

ANDA filer's right to the 180-day exclusivity period on a 'successful defense' of its Paragraph IV ANDA against the patent holder.").

34. See 63 Fed. Reg. 59710 (Nov. 5, 1998).

35. See 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA); See also *Caraco Pharm. Lab. v. Forest Lab.*, 527 F.3d 1278, 1284 (Fed. Cir. 2008) ("Only the first Paragraph IV ANDA filer can trigger its 180-day exclusivity period via the commercial-marketing trigger. However, subsequent Paragraph IV ANDA filers can trigger the first Paragraph IV ANDA filer's 180-day exclusivity period via the court-judgment trigger.") (citation omitted).

36. See Congressional Research Service, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act")*, Congressional Research Service 38-39 (2005).

37. See PhRMA Profile, *supra* note 12, at 39.

38. See FTC, *Generic Drug Entry Prior to Patent Expiration*, Federal Trade Commission viii (2002) ("a generic applicant's potential liability for lost profits on the brand-name drug usually will vastly exceed its own potential profits after market entry.").

drugs make up only 28.5% of prescriptions dispensed, they still account for 78.4% of the money spent on prescriptions.³⁹ On an individual drug level, brand name prescriptions sold for an average of 3.5 times more than their generic counterparts in 2007.⁴⁰ In only one-year's time, the 2008 innovator-to-generic price ratio has risen to 3.9⁴¹ despite the preexisting disparity.

The substantial price differences between innovators and generics, the high research and development costs associated with new pharmaceuticals, and the uncertainty that any drug candidate in the innovator's development pipeline will attain blockbuster profitability give patentees a strong incentive to preserve and prolong market exclusivity. These factors allow for reverse settlements in which the brand and the generic both make more money if the generic stays off the market. The increasing prices of branded drugs compared to their generic counterparts should make these settlements even more profitable in the future. From an economic perspective, as long as the innovator's potential loss vastly exceeds the generic manufacturer's potential gain, reverse settlements will offer a Pareto improvement⁴² for pharmaceutical suppliers when the number of potential generic entrants is small. Accordingly, the industry association representing generic manufacturers supports reverse patent settlements⁴³ as does the industry association for

innovators.⁴⁴

Part II — *The Unique Legal Status of Pharmaceutical Patents*

Patents typically afford the holder twenty years of exclusivity to market a product.⁴⁵ However, when the patented article is a drug, the patent holder must also wait for the FDA's approval before selling it.⁴⁶ For the pharmaceutical patent holder, this means the actual amount of sales exclusivity before a generic becomes available is typically between ten and fifteen years.⁴⁷ Not surprisingly, the increased incentive to challenge the patents on blockbuster drugs results in these drugs having average exclusivity periods toward the bottom of this range.⁴⁸

As part of the tradeoff for allowing generics to rely on the original safety and efficacy data in the innovator's NDA, the generic is required to submit:

(A) a certification . . . with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed . . .

(i) that such patent information has not been filed,
(ii) that such patent has expired,
(iii) of the date on which such patent will expire,
or

(iv) *that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . .*⁴⁹

To generic manufacturers, the most important of these certifications is the Paragraph IV certification because it potentially leads to a challenge

39. See Generic Pharmaceutical Association, *Celebrating the Past Defining the Future* 28 (2009).

40. See Facts at a Glance | Generic Pharmaceutical Association, available at <http://www.gphaonline.org/about-gpha/about-generics/facts> (last visited Nov. 5, 2009) ("In 2007, the average retail price of a generic prescription drug was \$34.34. The average retail price of a brand name prescription drug was \$119.51. (source: The National Association of Chain Drug Stores, 2007)").

41. See Industry Facts-at-a-Glance, National Association of Chain Drug Stores, <http://www.nacds.org/wmspage.cfm?parm1=6536> (last visited Nov. 5, 2009) (stating that the average brand name prescription price in 2008 was \$137.90, and the average generic price in 2008 was \$35.22).

42. A Pareto improvement is a situation where resources are allocated to make one entity better off without hurting anyone else. Here, the brand can afford to pay its generic competitors all of the money they would have made by selling their products, or could even agree to pay *more* money than the generics could have possibly made in the market, all while still remaining better off than if it were competing with the generics. Because no one is worse off and some (or all) are better off, these reverse settlement agreements that create a Pareto improvement are a natural occurrence. The allocations analyzed here which result in a Pareto improvement are only the potential supply allocations and resulting profits among drug manufacturers, not the allocations among suppliers and consumers.

43. Patent Settlements | Generic Pharmaceutical Association, <http://www.gphaonline.org/issues/patent-settlements> (last visited Oct. 18, 2009) ("GPhA opposes an outright ban on settlements as a means of resolving patent litigation.").

44. See PHRMA – PhRMA Statement on Authorized Generics, http://www.phrma.org/news_room/press_releases/phrma_statement_on_authorized_generics (last visited Nov. 5, 2009) ("[I]t is unfortunate that the FTC used this potentially valuable report . . . to further its attack on patent settlements. Neither authorized generics nor patent settlements have discouraged the availability of generics to patients.").

45. 35 U.S.C. § 154(a)(2) (2009).

46. See 21 U.S.C. § 355(a) (2009).

47. See Henry G. Grabowskia & Margaret Kyleb, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 *Managerial & Decision Econ.* 491, 493 (2007) ("The NMEs [(New Molecular Entities)] in the two smallest [market] size categories have the longest MEPs [(Market Exclusivity Periods)] with averages of approximately 15 years. By contrast, the average MEPs for market size categories above \$100 million are in the 10.5–12.5 year range.").

48. See *id.*

49. 21 U.S.C. § 355(b)(2)(A) (2009) (emphasis added).

of the innovator's patent.⁵⁰ When generics make this certification, they must agree to notify the patent holder of their intention to seek approval of the drug.⁵¹ This notice must include a statement of the legal and factual basis for the generic's belief that it will not infringe the innovator's patent.⁵² When the generic makes a Paragraph IV certification, the FDA cannot make any approval effective for forty-five days, giving the patentee an opportunity to file an infringement suit.⁵³ If the patentee files an infringement suit against the generic, the FDA cannot approve the generic's ANDA for thirty months,⁵⁴ unless the generic wins the infringement case.⁵⁵

The key effect of Paragraph IV is to dramatically increase the innovator's incentive to file suit because the existence of an infringement suit alone has the same ultimate effect as a judicially-granted injunction: the generic manufacturer is prevented from selling its product because it cannot gain the necessary approval.⁵⁶ The law does not provide any way for a generic with a strong case for non-infringement to continue with the approval process, except to get a ruling that the patent is invalid or has not been infringed.⁵⁷ Still, a ruling may take considerable time, usually not less than thirty months.⁵⁸ By contrast, in a normal patent infringement proceeding, the patentee would have to petition the court for a preliminary injunction, and the court would weigh the following four factors, the first two of which are required: "(1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest."⁵⁹ A recent case illustrated the inconsistency of the two approaches when an innovator pharmaceutical company's thirty-month Hatch-Waxman "injunction" expired, and the innovator had to request a judicially-

imposed preliminary injunction.⁶⁰ The district court found that the patentee failed to establish a likelihood of success on the merits and irreparable harm,⁶¹ and on appeal, the Federal Circuit affirmed the district court's denial of injunctive relief.⁶² In this case, the automatic thirty-month stay gave the patentee a significant amount of market exclusivity that would have never been available to a non-pharmaceutical patentee.

Part III — Pay-for-Delay and Antitrust

The economics of the pharmaceutical market combine with the Hatch-Waxman generic approval scheme to incentivize and facilitate reverse settlement payments from patentees to generics. In any case, innovators can decide to file an infringement suit irrespective of any intent to settle, opting simply to prolong the litigation and enjoy thirty months of exclusivity before the FDA can approve the generic. In either of these situations, little recourse is available to competing generics and the public.

Challenges to the legality of reverse payments have been made on antitrust grounds, and challenges to the patentee's filing of an infringement suit have been made on both antitrust and Rule 11 grounds. Except in cases where fraud is alleged, neither approach has been particularly successful. If the innovator's initial filing of an infringement suit is fought under an antitrust theory of delaying generic competitors from coming to market, the innovator is often immunized from antitrust liability because it is only trying to enforce its constitutional patent exclusivity rights.⁶³ If the filing of suit is contested under Rule 11, two legal facts, that patents are presumed valid and that filing an ANDA is a technical act of

50. *See id.* § 355(b)(2)(A)(iv).

51. *See id.* § 355(b)(3)(A); *id.* § 355(b)(3)(C).

52. *See id.* § 355(b)(3)(D)(ii).

53. *See id.* § 355(c)(3)(C).

54. *Id.*

55. *See id.* § 355(c)(3)(C)(i).

56. *See id.* § 355(c)(3)(C); *id.* § 355(a).

57. *See id.* § 355(c)(3)(C)(i).

58. *See* FTC, *supra* note 38, at iv ("The data also do not indicate that court decisions in ANDA-related patent litigation typically are reached much earlier than 30 months from notice of the generic's ANDA."). *See also*, for example, *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999 (Fed. Cir. 2009), where the infringement proceedings were still in progress after the expiration of the Hatch-Waxman stay.

59. *See Altana*, 566 F.3d at 1005.

60. *See id.* at 1004 ("On or about April 6, 2004, Teva filed an Abbreviated New Drug Application ('ANDA') pursuant to the Hatch-Waxman Act Sun filed similarly directed ANDA applications on or about March 1, 2005, and June 25, 2005. Both Teva and Sun filed paragraph IV certifications in conjunction with their respective ANDA applications. . . . Altana filed a motion for preliminary injunction on June 22, 2007.")

61. *See id.* at 1005 ("Based on Altana's failure to establish either a likelihood of success on the merits or irreparable harm, the district court denied the motion for preliminary injunction.")

62. *See id.* at 1011.

63. *See* *Andrx Pharm., Inc. v. Elan Corp.*, 421 F.3d 1227, 1234 (11th Cir. 2005) ("Based on this precedent, we agree with the district court that the Noerr-Pennington doctrine shields Elan from antitrust liability for filing two patent infringement suits against Andrx in relation to the manufacture and sale of controlled release naproxen. The United States Constitution expressly permits the government to grant exclusive monopolies in the form of patents, and therefore the Sherman Act cannot be read to impede a litigant from seeking to defend constitutionally-permitted patent rights.") (citation omitted).

infringement, combine such that there is usually a non-frivolous basis for filing suit.⁶⁴ Therefore, in many cases, the act of filing an infringement suit cannot be challenged with any reasonable expectation of success, leaving only the settlement agreements themselves potentially vulnerable to attack.

By the very nature of a lawsuit, a claimant files suit alleging some harm in the hopes of getting a favorable legal determination, money, or both. Therefore, when a claimant alleging patent infringement in a Paragraph IV suit offers money to the alleged wrongdoer, the settlement seems puzzling. When the patentee actually pays the infringing generic more money to settle the case than the generic could possibly have made selling its product, the result becomes downright “suspicious”⁶⁵ in light of the Sherman Act, which bars contracts and combinations that restrain trade⁶⁶ and prohibits any attempt to monopolize commerce.⁶⁷ Nevertheless, the courts of appeals, except possibly the Sixth Circuit whose position is particularly ambiguous,⁶⁸ have upheld the legality of some of these agreements, as long as their terms stay “within the exclusionary zone of the patent.”⁶⁹

The confusion over pay-for-delay began when the Sixth Circuit first declared a reverse settlement agreement illegal. The Sixth Circuit decided the first Paragraph IV settlement antitrust case, *In re Cardizem*

64. See, e.g., *Celgene Corp. v. KV Pharm. Co.*, No. 07-4819, 2008 WL 2856469 at *3 (D.N.J. July 22, 2008) (“[T]he act of infringement alleged in the complaint is the filing of an ANDA—not the manufacture or sale of the product. Because the Act has made the act of submitting an ANDA itself an act of infringement, in a Hatch-Waxman ANDA case, the attorney can conduct a reasonable and competent inquiry into the act of infringement by investigating whether a relevant ANDA has been filed.”).

65. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 208 (Fed. Cir. 2006) (“There is something on the face of it that does seem ‘suspicious’ about a patent holder settling patent litigation against a potential generic manufacturer by paying that manufacturer more than either party anticipates the manufacturer would earn by winning the lawsuit and entering the newly competitive market in competition with the patent holder. Why, after all—viewing the settlement through an antitrust lens—should the potential competitor be permitted to receive such a windfall at the ultimate expense of drug purchasers?”).

66. See 15 U.S.C. § 1 (2009).

67. See *id.* § 2.

68. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1335 (Fed. Cir. 2008) (“To the extent that the Sixth Circuit may have found a per se antitrust violation based solely on the reverse payments, we respectfully disagree.”).

69. See *id.* at 1336 (“The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and the Eleventh Circuits . . . and we find it to be completely consistent with Supreme Court precedent.”).

CD Antitrust Litigation, where an innovator agreed to pay the first-filing generic manufacturer \$40 million per year not to sell any generic equivalent of the patented drug and to not relinquish its right to the 180-day exclusivity period.⁷⁰ The court classified the agreement as a per se antitrust violation, noting that the 180-day exclusivity provision acted to delay other potential entrants and that the agreement inhibited competition by paying the innovator’s only potential competitor to stay out of the market.⁷¹ The court said that “HMR’s agreement to pay Andrx \$40 million per year not to bring its generic product to market . . . is a naked, horizontal restraint of trade that is per se illegal.”⁷² The Sixth Circuit’s reasoning looks more to the character of the settlement agreement and its actual effects on competition, rather than focusing as intently on the scope of the agreement with respect to the patent.

Unlike the Sixth Circuit, the Eleventh Circuit took a more lenient stance on reverse settlements. Shortly after the Sixth Circuit’s decision, the Eleventh Circuit weighed in on reverse settlements in *Valley Drug Co. v. Geneva Pharmaceuticals Inc.*, when an innovator entered into reverse payment settlements with two of its generic competitors.⁷³ Though the terms of these settlements were similar to those in *Cardizem*,⁷⁴ the Eleventh Circuit decided that settlements were not per se antitrust violations.⁷⁵ When determining if there was antitrust liability, the court examined whether the settlement agreements extended beyond the exclusionary power granted by the patent.⁷⁶ Although at least one agreement contained a provision protecting the generic’s 180-day exclusivity⁷⁷ and the agreements might have gone beyond prohibiting only infringing generics, the court felt the per se label was still not appropriate.⁷⁸ On its face, the Eleventh Circuit’s precedent appears to conflict with the Sixth Circuit’s holding. The Eleventh Circuit noted that “[t]he failure to produce the

70. 332 F.3d 896, 902 (6th Cir. 2003).

71. *Id.* at 907-08.

72. *Id.* at 911.

73. 344 F.3d 1294, 1300 (11th Cir. 2003).

74. *Id.* at 1311 n.25.

75. *Id.* at 1309.

76. See *id.* at 1305-06.

77. See *id.* at 1300 (“Geneva agreed not to transfer or sell its rights under its ANDAs, including its right to the 180-day exclusivity period. Geneva also agreed to oppose any subsequent ANDA applicant’s attempt to seek approval of its application based on Geneva’s failure to satisfy the then-existing successful defense requirement and to join and support any attempt by Abbott to seek an extension of the 30-month stay of FDA approval on Geneva’s tablet ANDA.”).

78. *Id.* at 1306 n.18.

competing . . . drug, rather than the payment of money, is the exclusionary effect,”⁷⁹ highlighting the Eleventh Circuit’s interest in the scope of the agreements rather than the size of the payments or their practical effect.

The Second Circuit was the next court to decide a pay-for-delay case, and it followed the Eleventh Circuit’s approach. The Second Circuit made its ruling on reverse settlements in *In re Tamoxifen Citrate Antitrust Litigation*, when an innovator agreed to pay a generic manufacturer \$9.5 million dollars immediately and \$35.9 million over ten years for the generic to change its Paragraph IV certification to a Paragraph III certification, thereby allowing the generic to market the infringing drug only after the innovator’s patent had officially expired.⁸⁰ The settlement occurred while an appeal was pending after a district court had declared that the patent was invalid,⁸¹ the agreement did not cover non-infringing products,⁸² and the agreement was made while the 180-day exclusivity period’s successful defense requirement was in effect.⁸³

The Second Circuit followed the Eleventh Circuit and decided that reverse payments by a patentee designed to protect its patent monopoly were not per se antitrust violations,⁸⁴ even though the settlement took place after the patent was declared invalid but was on appeal.⁸⁵ The court noted that the successful defense requirement meant the generic would not block other competitors,⁸⁶ but even if the agreement was “designed to manipulate the 180-day exclusivity period,” any injury was caused by the “valid patent and the inability of other generic manufacturers to establish that the patent was either invalid or not infringed.”⁸⁷ As long as the original infringement suit is not objectively baseless, the settlement does not expand the patentee’s monopoly beyond the patent’s scope, and there is no fraud, then “[p]ayments, even ‘excessive’ payments, . . . [are] not necessarily unlawful.”⁸⁸ Like the Eleventh Circuit, the Second Circuit’s analysis focused primarily on the scope of the agreement, not the size of the payments or the effect on competition.

In the most recent precedential case decided by

an appeals court, the Federal Circuit also upheld a pay-for-delay agreement. *In re Ciprofloxacin Hydrochloride Antitrust Litigation* was the Federal Circuit’s chance to speak on reverse payments, when it took an appeal involving a settlement agreement worth \$398.1 million.⁸⁹ The generic agreed to change its Paragraph IV certification to a Paragraph III certification,⁹⁰ reserved the right to revert to Paragraph IV if a court ever declared the patent invalid or unenforceable,⁹¹ and agreed “not to market a generic version of Cipro until the” patent at issue expired.⁹² Although the generic retained its right to change certifications, the Federal Circuit ignored this factor in its antitrust analysis because the settlement agreement predated the change in the successful defense requirement, and a prior court had already determined the generic had lost its exclusivity right under the law at the time.⁹³

With this “bottleneck” element out of the way, the Federal Circuit decided the agreement was not a violation of antitrust law and essentially adopted the Second and Eleventh Circuits’ holdings that reverse payments alone were not per se antitrust violations.⁹⁴ Also, it explicitly held that:

[when] all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent.⁹⁵

With this statement, the Federal Circuit foreclosed the possibility of using its exclusive jurisdiction over patent cases⁹⁶ to funnel Paragraph IV antitrust cases away from the other circuits.⁹⁷

89. 544 F.3d 1323, 1329 n.5 (Fed. Cir. 2008).

90. *Id.* at 1328-29.

91. *Id.* at 1329 n.4.

92. *Id.* at 1333.

93. *Id.* at 1339.

94. *See id.* at 1335-36.

95. *Id.* at 1336.

96. 28 U.S.C. § 1295(a)(1) (2009).

97. *See Ciprofloxacin*, 544 F.3d at 1336 (“[T]he court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment.”). Because the basis of a reverse settlement is a generic’s technical infringement of an innovator’s patent by filing the ANDA and Paragraph IV certification, if the Federal Circuit had ruled that patent validity mattered when analyzing a reverse settlement, the Federal Circuit’s exclusive jurisdiction over patent cases would have brought all future pay-for-delay cases to it. The possible exception would be if a case somehow did not raise substantial issues of patent law.

79. *Id.* at 1309.

80. 466 F.3d 187, 193-94 (Fed. Cir. 2006).

81. *Id.* at 193.

82. *Id.* at 213-14.

83. *Id.* at 219.

84. *Id.* at 205.

85. *Id.* at 206.

86. *Id.* at 214.

87. *Id.* at 219.

88. *Id.* at 213.

There is confusion among the courts⁹⁸ and even strong disagreement among commentators⁹⁹ concerning the state of the law in each circuit on reverse payments. Some commentators characterize the Sixth Circuit as employing the per se approach against the practice of the Second and Eleventh Circuits,¹⁰⁰ others lump the Sixth and Eleventh Circuits' approaches together and contrast them with the Second and Federal Circuits' holdings,¹⁰¹ and still others argue that all the circuits' holdings are consistent.¹⁰² One of the chief impediments to comparing the different circuits' approaches is that the slightly different features of the settlement agreements in each case may be significant to each court's respective holding, but the opinions do not disentangle and separately analyze the elements of the agreements clearly enough to allow for a convenient comparison. For example, the Federal Circuit attempted to distinguish its *Cipro* decision from the Sixth Circuit's per se holding in *Cardizem* by pointing out that in *Cardizem* the generic had agreed not to market non-infringing versions of

98. See *id.* at 1335 (“To the extent that the Sixth Circuit may have found a per se antitrust violation based solely on the reverse payments, we respectfully disagree.”).

99. Compare Wansheng Jerry Liu, *Balancing Accessibility and Sustainability: How to Achieve the Dual Objectives of the Hatch-Waxman Act While Resolving Antitrust Issues in Pharmaceutical Patent Settlement Cases* 18 Alb. L.J. Sci. & Tech. 441, 462-63 (2008) (“In addressing the antitrust issues of the patent settlement agreements between brand-name and generic pharmaceutical companies, the federal courts have adopted two different approaches. The Court of Appeals for the Sixth Circuit held that a settlement agreement between a brand-name drug company and a generic drug company to delay marketing until resolution of the patent infringement case in exchange for a ‘reverse payment’ is classical restraint of trade and per se illegal. The Eleventh and Second Circuits rejected this ‘per se rule’ but instead considered the exclusionary power of the patent and addressed whether the settlement agreements exceeded the exclusionary power awarded by the patent law.”) (citations omitted), with Brief Amici Curiae of 54 Intellectual Property Law, Antitrust Law, Economics, and Business Professors, the American Antitrust Institute, the Public Patent Foundation, and the AARP in Support of the Petitioner, *Arkansas Carpenters Health and Welfare Fund v. Bayer*, 129 S. Ct. 2828, 2 (2009) (No. 08-1194), 2009 WL 1144190, cert. denied, [hereinafter Brief Amici Curiae] (“The Second/Federal Circuit Rule Is Unprecedented and Conflicts With the Approaches of the Sixth Circuit, the Eleventh Circuit, and the Federal Trade Commission”). But see Christopher M. Holman, Patently-O, *Holman: A Contrarian Law Professor’s Two Cents on the Arkansas Carpenter’s (Ciprofloxacin) Petition for Certiorari*, <http://www.patentlyo.com/patent/2009/05/holman-a-contrarian-law-professors-two-cents-on-the-arkansas-carpenters-ciprofloxacin-petition-for-certiorari.html> (last visited Oct. 18, 2009) (“[T]he decisions by the Second Circuit and the Federal Circuit in *Tamoxifen* and *Ciprofloxacin* are both entirely consistent with earlier decisions by the other circuits . . .”).

100. Liu, *supra* note 99.

101. Brief Amici Curiae, *supra* note 99.

102. Holman, *supra* note 99.

the drug.¹⁰³ The difficulty with this approach is that the Federal Circuit characterizes the settlement agreement in *Cipro* as preventing the generic from manufacturing or marketing “a generic version” of the drug, language that appears to prevent non-infringing versions as well.¹⁰⁴ One way to reconcile the Federal Circuit’s characterization of the *Cipro* agreement with its holding is to assume the court was relying on the fact that the patent in *Cipro* was on the underlying drug molecule¹⁰⁵ and not the pharmaceutical’s formulation. Therefore, presumably, a non-infringing generic was not possible,¹⁰⁶ and the settlement agreement could cover all possible generics without exceeding the scope of the patent. Nevertheless, the exact basis for the court’s holding is ambiguous.

An analysis of each circuit’s antitrust approach reveals that, despite the conflicting interpretations, there appear to be a set of settlement terms that would satisfy each court, including the Sixth Circuit, whose per se holding was the strictest. The Sixth Circuit’s per se holding rests on only two facts: the reverse payments to keep the generic off the market and the use of the 180-day exclusivity period to prevent additional entrants to the market.¹⁰⁷ The Sixth Circuit does not necessarily declare all patent settlements per se illegal; rather, it appears that the per se label attaches once the agreement goes beyond enforcing patent rights and “bolster[s] the patent’s effectiveness,”¹⁰⁸ because, in *Cardizem*, the

103. *Ciprofloxacin*, 544 F.3d at 1335.

104. See *id.* at 1329 (“In return, Barr agreed not to manufacture, or have manufactured, a generic version of Cipro in the United States.”). See also *id.* at 1333 (“[T]he generic defendants agreed not to market a generic version of Cipro until the ‘444 patent expired . . .”).

105. See *id.* at 1329.

106. See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 214 (Fed. Cir. 2006) (“Like the patent for the compound ciprofloxacin hydrochloride, which was the subject of dispute in the *Cipro* cases, and unlike the patents at issue in *Cardizem* and *Valley Drug*, Zeneca’s tamoxifen patent is not a formulation patent, which covers only specific formulations or delivery methods of compounds; rather, it is a patent on a compound that, by its nature, excludes all generic versions of the drug.”).

107. See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907 (6th Cir. 2003) (“[T]he following facts are undisputed and dispositive. The Agreement guaranteed to HMR that its only potential competitor at that time, Andrx, would, for the price of \$10 million per quarter, refrain from marketing its generic . . . the Agreement also delayed the entry of other generic competitors, who could not enter until the expiration of Andrx’s 180-day period of marketing exclusivity, which Andrx had agreed not to relinquish or transfer.”).

108. See *id.* at 908 (“[T]he Agreement cannot be fairly characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation. As the plaintiffs point out, it is one thing to take advantage of a monopoly that naturally arises

“agreement’s restrictions extended to non-infringing and/or potentially non-infringing versions of generic Cardizem.”¹⁰⁹ A reverse settlement agreement would probably withstand the tests set forth by any of the circuits, including the Sixth, if it promised *only* that the generic would not infringe the listed patents, did not block non-infringing generics from being marketed, and forced the generic to abandon its Paragraph IV certification and 180-day exclusivity period. In cases where the listed patents included one on the drug molecule itself, this settlement effectively prevents the generic’s entry into the market without incurring antitrust liability under the Sixth Circuit’s logic. The result is that competitors and other affected parties have little ability to challenge properly designed reverse payments under an antitrust theory.

Part IV — Lessons from Hatch-Waxman for the New Biosimilar Pathway

For over twenty years, drug companies have lived with the compromises built into the Hatch-Waxman Amendments, but the new healthcare reform bill passed by Congress created an approval pathway for biosimilars¹¹⁰ and is the future of generic medicines. Spending on biologic products is growing by fifteen to twenty percent annually and has already risen to about \$40 billion in 2006.¹¹¹ Congress failed to learn from the weaknesses of the Hatch-Waxman regime when designing the new biosimilar approval process, but Congress still has the opportunity to amend the pathway before biosimilars begin to utilize the new system. Presently, the biosimilar pathway contains a set of provisions that can be used together to facilitate reverse settlements and to help justify them to courts.

For perspective, it is helpful to compare the current biosimilar pathway with an older proposal that was not enacted. During the 111th Congress, the House of Representatives’ approach to biosimilars in H.R. 1548 grants twelve years of marketing exclusivity to new biologics¹¹² and gives a twenty-four-month exclusivity

period to the *first biosimilar*.¹¹³ When a generic biologic submits an application to the FDA, it must send detailed information about the biogeneric and its production,¹¹⁴ and the reference product sponsor (i.e., the innovator biologic) responds with a list of its patents¹¹⁵ and reasons why they have been infringed.¹¹⁶ In turn, the biosimilar either decides not to go to market before the innovator’s patent expires, or certifies that it believes that the innovator’s patent will not be infringed, is invalid, or is unenforceable.¹¹⁷ The House bill makes submitting the certification an act of infringement.¹¹⁸ Importantly, the House bill only empowers the FDA to delay approval of the generic biologic *after* a court has ruled against the biosimilar.¹¹⁹

The new biosimilar pathway passed by Congress is similar to the House bill but with two important additions. First, it requires participation in negotiations over which patent claims should be litigated before the alleged infringer can be subject to an infringement action.¹²⁰ Second, the current biosimilar pathway offers variable amounts of exclusivity for the *first biosimilar* to be approved: the first biosimilar never has more than one year of actual marketing exclusivity, but biogenerics seeking approval afterward can be delayed up to forty-two months if the first is involved in infringement litigation and decides not to risk marketing its product.¹²¹

Both the failed House bill and the enacted biosimilar legislation make several important improvements over the generic drug approval scheme. First, they eliminate the delays associated with Paragraph IV certification by allowing biosimilars to be approved without facing a statutorily-mandated halt in the FDA’s issuance of an approval in response to an innovator’s infringement suit. Once approved, biogenerics can market their potentially infringing products at their own

from a patent, but another thing altogether to bolster the patent’s effectiveness.”).

109. *See id.* at 909 n.13.

110. In this Article, the terms “biosimilar,” “biogeneric,” and “generic biologic” are used interchangeably.

111. Congressional Budget Office, Congressional Budget Office Cost Estimate S. 1695 Biologics Price Competition and Innovation Act of 2007 5 (2008).

112. Pathway for Biosimilars Act, H.R. 1548, 111th Cong. § 101(a)(2) (2009) (amending § 351(k)(7) of the Public Health Service Act) (as introduced in the House on Mar. 17, 2009).

113. *See id.* (adding § 351(k)(6) to the Public Health Service Act).

114. *See id.* (adding § 351(l)(4)(A)(i) to the Public Health Service Act).

115. *See id.* (adding § 351(l)(4)(A)(ii) to the Public Health Service Act).

116. *See id.* (adding § 351(l)(4)(C)(i) to the Public Health Service Act).

117. *See id.* (adding § 351(l)(4)(D) to the Public Health Service Act).

118. *See id.* § 201(3) (amending 35 U.S.C. § 271(e)(2)).

119. *See id.* § 101(a)(2) (adding § 351(l)(5) to the Public Health Service Act).

120. Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, sec. 7002, § 351(l)(4), 124 Stat. 119, 811 (to be codified at 29 U.S.C. § 262).

121. *See id.* § 351(k)(6)(C)(i) at 806.

risk, similar to all other non-pharmaceutical products, and the equitable injunctive power of the court hearing the patentee's infringement case will presumably ensure that biogenerics with weak claims will not take away an innovator's rightful market share. Both bills have long exclusivity periods for the first biosimilar, which provides a strong incentive for these companies to develop their products quickly.

Unlike the unsuccessful House legislation, the actual biosimilar pathway affords innovators extra incentives to game the system and gain extra exclusivity time over second-to-file biogenerics. For example, if the infringement action by the innovator against the first biosimilar is dismissed or a final decision is reached, the first biogenic's total potential exclusivity time is actually extended to eighteen months *after* the dismissal or decision, provided the biogenic does not come to market.¹²² Therefore, the strategy that is beneficial for both the first generic biologic and the innovator is to settle an ancillary patent to begin the reverse payment process and then move toward a final decision or dismissal. From this point, the parties would have a reverse payment regime in place, with the biosimilar qualified for the extended eighteen-month exclusivity period. The settlement would provide the innovator with at least eighteen months of exclusivity and the first biosimilar with at least eighteen months of reverse payments. Unless the economics of the biogenic market diverge dramatically from the traditional generic drug market, reverse payments exchanged for eighteen months of innovator monopoly should clearly result in an improved financial outcome for both the biogenic and innovator when compared with the alternative: twelve months of shared marketing exclusivity.

These reverse payments would avoid accruing antitrust liability because the heightened exclusivity period attaches even if the first biosimilar loses the infringement suit brought by the innovator.¹²³ There is no certification analogous to Paragraph IV on file with the FDA for the first biosimilar to amend that would relinquish its right to exclusivity, so a biosimilar that chose not to come to market may not be at fault for delaying others. However, even if a court decides that a biosimilar violates antitrust law if it accepts reverse payments without beginning its marketing exclusivity period as soon as permitted, the enacted biosimilar approval pathway provides a way to escape liability. A

biogenic could strategically use a statutorily-mandated 180 days notice to the innovator prior to commercial marketing¹²⁴ to ensure that its minimum of one year of market exclusivity¹²⁵ plus the additional 180 days of required waiting results in exactly the same eighteen-month delay¹²⁶ for all other generic entrants regardless of whether reverse payments are made. This prevents the biogenic from accruing antitrust liability for causing a bottleneck in the approval of additional biogenerics. In this situation, a court could not justly hold the biosimilar responsible for the delay because the statute requires the biogenic to give the notice, which prevents the biogenic from initiating its marketing exclusivity period sooner.

Under this strategy, all additional entrants can be delayed eighteen months, but the only way for the generic biologic to get eighteen months of heightened profit instead of twelve months of shared exclusivity is to enter into a reverse settlement. By providing a longer exclusivity period for biogenerics that do not immediately enter the market, the current biosimilar law sets up an approval process that strongly incentivizes reverse payments.

Conclusion

The ANDA process under Hatch-Waxman, especially Paragraph IV, facilitates reverse settlements. The result is an explosion of litigation: patent infringement suits, followed by reverse payments, followed by antitrust suits. Pharmaceutical companies reasonably respond to the incentives created by the law, and this process, beginning with an infringement suit and ending in murky antitrust waters, is unlikely to abate any time soon. It appears as though all the circuits allow at least some reverse settlements, and short of new legislation banning them, they will remain prominent in pharmaceutical patent litigation. The new biosimilar

124. *See id.* § 351(l)(8)(A) at 813 ("Notice of commercial marketing. The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)."). The applicant can give notice after submitting an application, and must give the innovator 180 days before marketing the biogenic, but the applicant should otherwise be able to choose when to give this notice, and it is reasonable for the biogenic to wait if it is embroiled in a lawsuit with the innovator. If the biogenic does not give notice until a settlement agreement with reverse payments is in place, the notice requirement can act to preclude the biogenic from ending its exclusivity period for eighteen months, whether it does eighteen months of reverse payments or six months of required waiting and then twelve months of shared exclusivity.

125. *See id.* § 351(k)(6)(A) at 806.

126. *See id.* § 351(k)(6)(B) at 806.

122. *See id.* § 351(k)(6)(B) at 806.

123. *See id.*

approval process passed by Congress is designed in a way that encourages reverse settlements, so biogenerics will probably be subjected to the same quantity of unnecessary litigation as ANDA generic drugs.

If Congress chooses to reexamine the biosimilar pathway it passed as part of healthcare reform, it should avoid incentivizing reverse settlements. Pay-for-delay agreements should be discouraged by giving the first biosimilar extra exclusivity time if it begins selling its product immediately upon FDA approval. If the biosimilar either accepts reverse payments and stays off the market or waits for any infringement litigation to conclude before coming to market, it should be ineligible for extra exclusivity time. Under this scheme, at least one generic product will reach the market quickly, lowering prices for consumers. A longer exclusivity period for the first biogeneric will partially mitigate the loss to the innovator, because the innovator will have half of a duopoly for the lengthened exclusivity period and will be able to postpone the full onslaught of generic competition. A longer exclusivity period for the first biosimilar, applying only if it comes to market quickly, will shift the economic incentives away from reverse settlements.

The three-way intersection between patent, antitrust, and drug law exists because the road to generic drug approval was not ideally designed. The new biosimilar pathway had the chance to become a detour to innovation and efficiency, but is currently just another road at the intersection.

South Africa's Move Piracy Challenge

By Matilda Bilstein¹

South Africa faces many challenges in the areas of copyright protection and enforcement, especially in combating movie piracy. According to the International Intellectual Property Alliance (“IIPA”),² South Africa fails to reach the mandated levels of copyright protection under the Agreement on Trade Related Aspects of Intellectual Property Rights (“TRIPS”) of the Uruguay Round of the General Agreement on Tariffs and Trade (“GATT”)³, especially regarding enforcement.⁴ South Africa is a lucrative market for counterfeit goods due to several key factors: its relatively high per-capita GDP compared to other countries in the region; its high levels of imported western media, technology, and lifestyles; its under-resourced law enforcement agencies; and its high unemployment rate.⁵ In 2006, pirated movie sales accounted for 60% percent of South Africa's DVD market.⁶ This cost the South African film industry an

annual R500 million, approximately \$65 million.⁷ The South African film industry loses approximately R50 (\$6.20) in local currency for every fake DVD sold on the street.⁸ While South Africa's local movie industries suffer great revenue losses due to piracy, initiatives by private organizations in conjunction with law enforcement officials for stronger enforcement of intellectual property protection will provide great benefits to both the foreign and domestic film industries. Part I of this article will discuss South Africa's current levels of and societal views on piracy. Part II will discuss South Africa's awareness, enforcement and remedial initiatives. Part III will discuss current changes in legislation. Lastly, Part IV will discuss the benefits of strong copyright enforcement for the South African film industry.

I. South Africa's Piracy Levels and Societal Views

The current invasion of pirated DVDs, especially of movies not legitimately available on DVDs or in theaters anywhere else in the world, accounted for over 50% of the pirated South African market in 2005.⁹ Before 2001, pirated DVDs accounted for 10% of the pirated South African market.¹⁰ According to the South African Federation Against Copyright Theft (SAFACT),

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2. IIPA is a private sector coalition of trade associations representing United States based copyright industries working to improve international protection and enforcement of copyrighted materials.

3. From 1948 to 1994, the General Agreement on Tariffs and Trade (GATT) regulated world trade and presided over periods that saw some of the highest growth rates in international commerce. The Uruguay Round of GATT led to various international agreements, including the TRIPS agreement, and created the World Trade Organization. See World Trade Organization, *Roots: From Havana to Marrakesh*, available at http://www.wto.org/trade_resources/history/wto/roots.htm.

4. International Intellectual Property Alliance, *Filing of the International Intellectual Property Alliance (IIPA) Re: African Growth and Opportunity Act Implementation Subcommittee of the Trade Policy Staff Committee; Public Comments on Annual Review of Country Eligibility for Benefits Under the African Growth and Opportunity Act*, 74 Fed. Reg. 48622-23, at 5 (Oct. 22, 2007), <http://www.iipa.com/pdf/IIPAAGOAFilingtoUSTRfinal10222007.pdf>.

5. South African Federation Against Copyright Theft, *Piracy in South Africa*, http://www.safact.co.za/piracy_facts.htm (last visited Sept. 7, 2009).

6. Bhavna Sookha, “Piracy costing SA industries R50m annually,” Daily News (November 22, 2006); http://www.iol.co.za/index.php?art_id=vn20061122095246188C185140&click_id=13&set_id=1; accessed September 7, 2009.

7. SouthAfrica.info, *Fighting Fake DVDs – with Fakes*, May 19, 2006, http://www.southafrica.info/ess_info/sa_glance/media/dvd-piracy-190506.htm. See also Bhavna Sookha, *Piracy Costing SA Industries R50m Annually*, Daily News, Nov. 22, 2006, http://www.iol.co.za/index.php?art_id=vn20061122095246188C185140&click_id=13&set_id=1 (discussing how legitimate video and DVD rental stores, overwhelmed by the amount of piracy, are now being accused of dealing in pirated products).

8. Tonight, *DVD Piracy 'is not cool'*, June 10, 2009, <http://www.tonight.co.za/index.php?fSectionId=347&fArticleId=5029544>. See also Joe Karaganis, Program Director, Media, Technology and Culture, Social Science Research Council in *Beyond TRIPS: The Evolving Law of International Enforcement of Intellectual Property*, Panel 2 – American Efforts to Strengthen International IP Enforcement, available at <http://www.wcl.american.edu/pijip/go/events/beyond-trips> (discussing the disagreement on whether losses can be measured and the problems regarding the delegitimation of some industries and much of the research concerning losses is unnecessarily proprietary).

9. South African Federation Against Copyright Theft, *Piracy in South Africa*, http://www.safact.co.za/piracy_facts.htm (last visited September 7, 2009).

10. *Id.*

a local industry-driven enforcement group, this level of piracy equates to a loss of approximately 3 million unit sales.¹¹ In 2004, South Africa had an estimated trade loss of \$35 million due to motion film copyright piracy alone.¹²

South African film distributors and cinemas are not the only businesses feeling the effects of pirated movies.¹³ Video shop owners complain about how they cannot keep “customers happy if customers can easily get a movie title that has not even appeared in cinemas, for R100 (\$16.59), across the road.”¹⁴ According to SAFACT Chairperson Fay Amaral, despite that 50% of DVDs in South Africa were pirated in 2005, there were only 76 convictions.¹⁵ While enforcement raids have increased and almost half a million pirated DVDs have been taken off the streets, this figure represents only 10% of the illegal products actually in circulation.¹⁶ Involvement with the pirated movie business remains lucrative, with insubstantial risk of any repercussions.¹⁷ Since South Africans generally do not understand what intellectual property rights entail, people seem to disregard the fact that it is wrong to buy counterfeit movies and “feel they would rather see a man selling pirate DVDs on the street than breaking into their houses.”¹⁸

SAFACT emphasizes that pirating of movies causes considerable damage to the viability and sustainability of thousands of jobs in South Africa at a time when there is increased pressure on businesses due to the economic slowdown.¹⁹ For example, “in the US, it only takes six rentals for a video shop, with the same customer base . . . to get back the money it’s been

purchased with. But it takes . . . 40 times in South Africa.”²⁰ But some vendors, desperate for a job, did “not think it would be a problem selling pirated DVDs because they are making money for food and supporting their families.”²¹

II. Implementing Awareness, Enforcement, and Remedial Initiatives

SAFACT is in almost daily contact with various law enforcement agencies involved in combating piracy.²² The organization is currently implementing awareness campaigns to reduce the demand for pirated movies and increase the involvement of the general population in combating this crime.²³ In 2006, following the success of the 2005 “Stop Piracy, Stop Crime” television and radio campaign, SAFACT launched smaller targeted campaigns.²⁴ These initiatives include: (1) the distribution of anti-piracy material at major areas where street vendors selling pirated products proliferated; (2) the launch of the “Fake Fakes” campaign, involving the sale of DVDs containing anti-piracy messages disguised as newly released films, with the proceeds donated to the Anti-Piracy Foundation; and (3) the establishment of Local Anti-Piracy forums, which brought together parties like video rental and retail outlets, cinemas and the police on a regular basis to discuss piracy problems in their immediate areas.²⁵

Video piracy’s devastating effect on South Africa’s economy has led local copyright owners to mobilize and take a stand against piracy.²⁶ For example, producers of the recent domestic film *White Wedding* created a

20. Mzolisi Witbooi, *Pirate DVDs Dealing a Huge Blow to Cinemas*, *The Cape Argus*, Jan. 14, 2005, http://www.iol.co.za/index.php?set_id=1&click_id=13&art_id=vn20050114110948303C405481.

21. Janine du Plessis, *Pirated DVD Sellers Dealt Crushing Blow*, *The Pretoria News*, Oct. 6, 2006, <http://www.thestar.co.za/index.php?fSectionId=&fArticleId=vn20061006042719185C235907>.

22. International Intellectual Property Alliance, *IIPA 2007 Special 301 Report Special Mention South Africa*, at 520 (Feb. 12, 2007), <http://www.iipa.com/rbc/2007/2007SPEC301SOUTHAFRICA.pdf>.

23. South African Federation Against Copyright Theft, *Awareness Campaigns*, http://www.safact.co.za/media_awareness.htm (last visited Sept. 7, 2009).

24. *Id.*

25. *Id.* See also SouthAfrica.info, *Fighting Fake DVDs – with Fakes*, May 19, 2006, http://www.southafrica.info/ess_info/sa_glance/media/dvd-piracy-190506.htm (describing how the “Fake Fakes” campaign combats the problem of copyright theft, disrupts the piracy market, and educates consumers about piracy).

26. International Intellectual Property Alliance, *IIPA 2007 Special 301 Report Special Mention South Africa*, at 520 (Feb. 12, 2007), <http://www.iipa.com/rbc/2007/2007SPEC301SOUTHAFRICA.pdf> (citing *First Anti-Piracy Concert to Kick Off in Joburg*, at <http://www.bizcommunity.com/Article/196/40/12012.html>).

11. *Id.*

12. International Intellectual Property Alliance, *IIPA 2007 Special 301 Report Special Mention South Africa*, at 521 (Feb. 12, 2007), <http://www.iipa.com/rbc/2007/2007SPEC301SOUTHAFRICA.pdf>.

13. Mzolisi Witbooi, *Pirate DVDs Dealing a Huge Blow to Cinemas*, *The Cape Argus*, Jan. 14, 2005, http://www.iol.co.za/index.php?set_id=1&click_id=13&art_id=vn20050114110948303C405481.

14. *Id.*

15. Barbara Cole, *DVD Piracy Hard to Stop*, *The Daily News*, June 22, 2005, http://www.iol.co.za/index.php?set_id=1&click_id=13&art_id=vn20050622092440567C697461.

16. See *id.*, (discussing a special initiative, Business Action to Stop Counterfeit and Piracy (BASCAP), launched by the International Chamber of Commerce to fight movie piracy, which is costing companies around the world \$600 billion a year).

17. *Id.*

18. *Id.*

19. South African Federation Against Copyright Theft, *Consumers Getting Ripped off Twice with Fake Mr. Bones 2*, Dec. 12, 2008, http://www.safact.co.za/press/PR_20081212.htm.

series of public service announcements against movie piracy.²⁷ In the announcements, the co-writers and co-stars of *White Wedding*, Kenneth Nkosi and Rapulana Seiphemo, announced that people buying pirated DVDs were effectively stealing from them and harming not only their business but also the local film industry.²⁸

Moreover, on December 15, 2005, the National Prosecuting Authority (South Africa's Specialized Commercial Crime Courts) and SAFACT signed a Memorandum of Understanding, which established relationships with local law enforcement agencies to create judicial capacity for the effective prosecution of piracy offenses, particularly films.²⁹ In order to fulfill this objective, SAFACT is currently training state employees to engage in intellectual property protection.³⁰ Specific training included: (1) product identification workshops to differentiate between genuine and pirated versions of film for members of the police force and the prosecution service; (2) training for customs officials at points of entry to help recognize counterfeit products; and (3) in-depth legal workshops for South African prosecutors, held in conjunction with the Department of Trade and Industry and the National Prosecuting Authority.³¹ Because South Africans purchase pirated DVDs off the street,³² the South African Police Service ("SAPS") and the South African Revenue Service ("SARS") have joined SAFACT in conducting raids, inspections, and search and seizure operations of markets selling and distributing pirated products.³³ In 2007 alone, there were 609 raids, which resulted in the confiscation of 219,926 DVDs and DVD-Rs.³⁴ In 2008, approximately 175,699 DVDs and DVD-Rs were confiscated by the first half of the

year.³⁵ Between June 2008 and February 2009, the total number of pirated films seized was over 550,000, with a value of over R27.5 million (\$2,768,563.22), which deprived legitimate business of R49 million (\$4,933,076.28).³⁶

Although seizures of pirated films have increased, with a greater number of arrests and criminal convictions due to the increased commitment by law enforcement agencies, enforcement problems remain in South African courts.³⁷ While an increasing number of cases are being referred to either the High Courts or the Specialized Commercial Crime Courts that have been established to combat white-collar crimes³⁸, prosecutors and judges in the non-specialized courts fail to view piracy as a serious crime.³⁹ Under the Berne Convention, existence of a copyright and copyright ownership by the claimant is presumed unless the defendant alleges facts, which place doubt on the claimant's ownership.⁴⁰ In South Africa, defendants have been able to reverse the burden of proving copyright ownership simply by bringing up the issue of ownership in judicial proceedings, which is not in line with the Berne Convention presumption.⁴¹

Another major issue with enforcing copyright is that monetary remedies are insufficient to deter infringement.⁴² South Africa's "copyright laws should provide (and courts should routinely award) financial remedies that make piracy too financially risky" because remedies that merely deprive the pirate of profits or even

35. South African Federation Against Copyright Theft, *Content Seizure Analysis Q1 & Q2 2008*, http://www.safact.co.za/images/Content_Seizure_Analysis_Q2_2008.pdf.

36. South African Federation Against Copyright Theft, *Multi Million Rand Haul of Pirated Films*, Feb. 15, 2009, http://www.safact.co.za/press/PR_20090215.htm.

37. International Intellectual Property Alliance, *IIPA 2007 Special 301 Report Special Mention South Africa*, at 523 (February 12, 2007), <http://www.iipa.com/rbc/2007/2007SPEC301SOUTHAFRICA.pdf>.

38. Republic of South Africa Department of Justice and Constitutional Development, *Press Statement: Opening of the Johannesburg Specialised Commercial Crime Court*, January 24, 2003, available at http://www.justice.gov.za/m_statements/2003/2003_01_24bac_statement.htm.

39. International Intellectual Property Alliance, *IIPA 2007 Special 301 Report Special Mention South Africa*, at 523 (February 12, 2007), <http://www.iipa.com/rbc/2007/2007SPEC301SOUTHAFRICA.pdf>.

40. *Id.* at 525.

41. *Id.* at 525 ("Expressing in the law a presumption of ownership is needed to (sic) satisfy South Africa's international obligations and a presumption of subsistence of copyright will greatly reduce the procedural burdens on rights holders in proving their cases.")

42. Mark Schultz and Alec van Gelder, *Creative Development: Helping Poor Countries by Building Creative Industries*, 97 Ky. L.J. 79, 139 (2008).

27. Tonight, *DVD Piracy 'is Not Cool'*, June 10, 2009, <http://www.tonight.co.za/index.php?fSectionId=347&fArticleId=5029544>.

28. *Id.*

29. *Enforcement Partners*, SAFACT, http://www.safact.co.za/about_enforcement.htm; accessed September 7, 2009.

30. *Id.*

31. *Id.*

32. My Broadband, *Broadband and Piracy*, Oct. 7, 2009, <http://mybroadband.co.za/news/Internet/9911.html>. See also South African Federation Against Copyright Theft, *Statistics 2008*, http://www.safact.co.za/activities_2008.htm, available at http://www.safact.co.za/images/Actions_Analysis_Q1_Q2_2008.pdf (last visited Sept. 7, 2009) (demonstrating that most raids occur on street vendors and flea markets, thus showing copyright infringement consists of pirated DVDs).

33. South African Federation Against Copyright Theft, *Multi Million Rand Haul of Pirated Films*, Feb. 15, 2009, http://www.safact.co.za/press/PR_20090215.htm.

34. South African Federation Against Copyright Theft, *SAFACT Statistics Archives: Summary Statistics 1997-2007*, http://www.safact.co.za/statistics_archives.htm (last visited Sept. 7, 2009).

of gross remedies are sometimes ineffective deterrents.⁴³ However, even after winning a case and being awarded costs, the chances of collecting from a defendant are almost nonexistent. Following trial, the defendant will likely dispose of or transfer their assets and leave the country, thus leaving the right-holder without recourse to collect the damages awarded in the judgment.⁴⁴

III. Changing Current Copyright Legislation

Because South Africa is a party to most international conventions protecting intellectual property, it is determined to uphold its commitments to the World Trade Organization and to support the rights of local and foreign companies.⁴⁵ South Africa enacted the Intellectual Property Laws Amendment Act and the Counterfeit Goods Act (“CGA”) to ensure compliance with the TRIPS Agreement.⁴⁶ However, the Intellectual Property Alliance (“IIPA”) still has many recommendations that the South African government needs to implement in order to comply with TRIPS, such as:

(1) Reinstating police powers under the CGA: The IIPA recommends amending the CGA to clarify and simplify police procedures; ease time limits that do not allow cases to be reasonably prepared for the courts; reinstate powers of arrest; and include complainant’s right to submit evidence of economic damages for consideration in sentencing.

(2) Running Ex Officio Raids: The IIPA states that current on the spot raids amount to the cost of doing business.

(3) Adopting copyright legislation that complies with TRIPS and joining the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty: The IIPA urges South Africa to enact copyright legislation that would improve the enforcement landscape and bring the national law in compliance with the TRIPS Agreement.⁴⁷ Others believe that “simply honoring international obligations is not enough” and in order to benefit local creators, South Africa’s intellectual

property rights laws ought to include features beyond the minimum TRIPS requirements.⁴⁸ For example, end-user piracy (the copying of software without obtaining a license⁴⁹) is also not a criminal offense in South Africa, giving rise to questions about South Africa’s TRIPS compliance under Article 61, which requires criminalization of at least all copyright piracy on a commercial scale.⁵⁰ The IIPA also recommends that other modernizing measures should be taken in addition to this legislation, including adequate protection of copyright materials on the Internet, such as notice and takedown measures and incentives for Internet service providers to cooperate in fighting infringement.⁵¹

(4) Developing joint intellectual property rights enforcement public awareness campaigns: The South African Government should work with copyright industries to inform the public on the detrimental effects of piracy and illegal downloading on South Africa’s domestic creative community.⁵²

IV. Benefits of Strong Copyright Protection

Since the implementation of the TRIPS agreement, there have been two major views regarding intellectual property protection for developing countries. First, that intellectual property protection is necessary for the advancement of developing countries. Second, that current international intellectual property laws do not properly serve developing countries’ needs.⁵³ The arguments supporting the first view states that strong protection “is essential to the successful operation of a system that promotes global innovation” because the economic nature of intellectual property strengthens the incentive for domestic innovation and creativity, and encourages foreign direct investment, thus promoting a country’s development.⁵⁴

The primary advantages for a film industry with a strong copyright system are that it:

(1) decentralizes and widely distributes control

43. *Id.* at 140.

44. International Intellectual Property Alliance, *IIPA 2007 Special 301 Report Special Mention South Africa*, at 523 (February 12, 2007), <http://www.iipa.com/rbc/2007/2007SPEC301SOUTHAFRICA.pdf>.

45. South African Federation Against Copyright Theft, *Anti-Piracy Legislation in South Africa*, www.safact.co.za/piracy_legislation.htm (last visited Sept. 7, 2009).

46. *Id.*

47. International Intellectual Property Alliance, *IIPA 2007 Special 301 Report Special Mention South Africa*, at 520 (February 12, 2007), <http://www.iipa.com/rbc/2007/2007SPEC301SOUTHAFRICA.pdf>.

48. Mark Schultz and Alec van Gelder, *Creative Development: Helping Poor Countries by Building Creative Industries*, 97 Ky. L.J. 79, 139 (2008).

49. <http://www.corel.com/servlet/Satellite/us/en/Content/1152796558890>

50. International Intellectual Property Alliance, *IIPA 2007 Special 301 Report Special Mention South Africa*, at 524 (February 12, 2007), <http://www.iipa.com/rbc/2007/2007SPEC301SOUTHAFRICA.pdf>.

51. *Id.* at 520-21.

52. *Id.* at 520-21.

53. Lauren Loew, *Creative Industries in Developing Countries and Intellectual Property Protection*, 9 Vand. J. Ent. & Tech. L. 171, 179-80 (2006).

54. *Id.* at 180.

over decisions about producing and paying for creative works, making it more likely to foster a popular, commercially successful industry;

(2) vests ownership in the original creator of the work, with the resulting independence and control providing greater economic and creative opportunities; and,

(3) enables creators and their collaborators in the film industry to use their own resources to finance their own creativity.⁵⁵

“Intellectual property protection benefits indigenous creativity in developing countries,” and the South Africa’s local film industry is an example of the indigenous creativity argument that intellectual property protection can assist countries escape lesser-developed status.⁵⁶

The alternative suggestion, made by those against imposing the current system of intellectual property protection on developing countries, is “that piracy helps lay the foundation for a developing country’s infrastructure, and, once in place, the developed infrastructure enables the developing country to benefit from increased protection.”⁵⁷ Piracy permits access to the technology needed for growth at low prices, develops critical skills in a developing country’s workforce, earns foreign exchange, produces and mobilizes domestic capital, and provides employment and cheaper products for the population.⁵⁸ Piracy, however, is one of the major problems, along with a host of infrastructure problems, which hinder indigenous creativity. Since almost all African countries have a piracy level over 25%, with some estimates reaching 85% to 90%, artists are hesitant to create new works.⁵⁹ Lack of effective enforcement against piracy hurts local creators and the development of local creative clusters since piracy:

deprives creators and legitimate distributors of sales, and it also creates a number of other deficiencies that impeded the development of local creative clusters, including preventing creators from securing capital to finance their work, pushing the surviving movie industry

to developed countries, and undermining local trade.⁶⁰ Thus, “a commercial industry that supports the creation of mass market films, books, and recorded music has little prospect of developing without its copyright and its enforcement.”⁶¹

Strong, effective copyright enforcement is the institution that best serves the basis for the development of South Africa’s commercial film industry.⁶² Some policymakers in developing countries question the value of strong copyright since it will inevitably displace workers in industries that involve piracy.⁶³ However, when the discussion is framed as a trade-off between local jobs and greater profits for foreign movie studios, it disregards local South African filmmakers, whose efforts will benefit the local economy and culture if protected by copyright.⁶⁴ Because the works of foreign movie companies will still be produced, developing markets with high rates of piracy, such as South Africa, are flooded with pirated foreign works “subsidized” by profits from foreign consumers.⁶⁵

The new business generated by greater domestic protection of copyright is likely to benefit local creators and creative industries the most because without effective copyright protection, the market for local creative works in less-developed countries is likely to be undermined by pirated foreign works.⁶⁶ Additionally, copyright enforcement is likely to generate additional local jobs that compensate for any job losses in piracy industries because it gives talented, creative people the opportunity to remain in their native countries rather than fleeing to more hospitable business climates.⁶⁷ Furthermore, even those involved in the piracy industries will be able to redeploy their skills to more creative, higher-paying work in legitimate copyright-based industries. They can thus move from being adversaries to business partners of local creators, creating a win-win situation for their home countries.⁶⁸

South Africa will reap financial and cultural benefits from increasing enforcement against its current pervasive levels of movie piracy. Foreign movie

55. Mark Schultz and Alec van Gelder, *Creative Development: Helping Poor Countries by Building Creative Industries*, 97 Ky. L.J. 79, 119 (2008).

56. Lauren Loew, *Creative Industries in Developing Countries and Intellectual Property Protection*, 9 Vand. J. Ent. & Tech. L. 171, 181 (2006).

57. *Id.* at 183.

58. Dru Brenner-Beck, *Do As I Say, Not As I Did*, 11 UCLA Pac. Basin L.J. 84, 102 (1992).

59. Lauren Loew, *Creative Industries in Developing Countries and Intellectual Property Protection*, 9 Vand. J. Ent. & Tech. L. 171, 182 (2006).

60. Mark Schultz and Alec van Gelder, *Creative Development: Helping Poor Countries by Building Creative Industries*, 97 Ky. L.J. 79, 127 (2008).

61. *Id.* at 119.

62. *Id.* at 119.

63. *Id.* at 120-121.

64. *Id.* at 120-121.

65. *Id.* at 121.

66. *Id.* at 121.

67. *Id.* at 121.

68. *Id.* at 122.

companies will be encouraged to invest in South Africa's film industry, domestic filmmakers and producers will be able to protect their current movie projects, and the South African film industry as a whole will benefit from the ingenuity that copyright protection incentivizes.

Settling for Less? An Analysis of the Possibility of Positive Legal Precedent on the Internet if the Google Book Search Litigation Had Not Reached a Settlement

By Brooke Ericson¹

I. Introduction

A final hearing held in early February will lead to an opinion by U.S. District Judge Denny Chin for the Southern District of New York, determining whether the Google Book Search Settlement is upheld or rejected. Google's competitors argue antitrust violations,² the National Writers Union calls the settlement "grossly unfair"³ and library associations worry about the lack of guarantees to current and future access.⁴ This article will focus on another critique of the Google Book Settlement: that by settling, Google is avoiding the fight for a positive legal precedent for copyright fair use on the Internet and is only concerned with its own business interests.⁵ This logic



stems from the fact that many scholars believed Google would succeed on its fair use defense and "blaze a trail on behalf of many, less wealthy Internet companies."⁶ Instead, Google entered a settlement providing itself with a strong advantage over its book scanning competitors and a monopoly over millions of orphan books.⁷

This article will look at this argument and analyze whether Google's settlement was based on self-interest or a strategic cost-benefit analysis. Part II of this article will explain the Google Book Search Settlement. Part III will analyze the effects a Google win would have on copyright law. Then, Part IV will compare the Ninth and Second Circuits' precedents to determine if Google

really could have set this "positive legal precedent." Finally, Part V will conclude that it is likely Google would have failed in the Second Circuit leaving Google with two options – to appeal to the Supreme Court or single-handedly bring an end to online book scanning.

II. The Google Book Settlement

In 2004, Google entered into agreements to digitize books with several libraries and universities, including the New York Public Library, Harvard University, Stanford University, Oxford University and the University of Michigan. Seven million books were scanned until issues arose concerning the digitization of books protected by United States copyright law. In 2005, several authors and publishers brought a lawsuit against Google, asserting copyright infringement. Google denied such allegations, claiming that its display of "snippets" or a few lines was protected under the

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2. See Jacqui Cheng, *Microsoft, Amazon Join Opposition to Google Books Settlement*, *Ars Technica*, Aug. 21, 2009, <http://arstechnica.com/tech-policy/news/2009/08/microsoft-amazon-join-opposition-to-google-books-settlement>.

3. See Ryan Singel, *National Writers Union Opposes Google Book Settlement*, *Wired.com*, Aug. 13, 2009, <http://www.wired.com/epicenter/2009/08/national-writers-union-opposes-google-book-settlement/>.

4. See John Timmer, *Google Book Settlement Has Librarians Worried*, *Ars Technica*, May 5, 2009, <http://arstechnica.com/tech-policy/news/2009/05/librarians-weigh-in-with-worries-on-googles-book-settlement>.

5. See Juan Carlos Perez, *In Google Book Settlement, Business Trumps Ideals*, *PC World*, Oct. 30, 2008 http://www.pcworld.com/businesscenter/article/153085/in_google_book_settlement_business_trumps_ideals.html; see also Fred von Lohmann, *Google Is Done Paying Silicon Valley's Legal Bills*, *Recorder*, Nov. 14, 2008, available at <http://www.eff.org/deeplinks/2008/11/further-thoughts-google-book-search-settlement>.

6. See Perez, *supra* note 4.

7. Miguel Helft, *Opposition to Google Books Settlement Jells*, *N.Y. Times.com*, Apr. 17, 2009, available at <http://bits.blogs.nytimes.com/2009/04/17/opposition-to-google-books-settlement>.

doctrine of fair use. In 2007, however, rather than going forward with its fair use defense, a settlement was reached between the parties.

The proposed settlement establishes a \$125 million fund, providing authors who sign on to the agreement a onetime nominal payment, plus future royalties. The settlement also sets aside \$34.5 million for a Book Rights Registry, to locate rightsholders and create a database of their contact information and the copyright interests in their works. In exchange, Google will be released from liability for its scanning, searching, and displaying of books online.

Google will dedicate 63% of its net revenues from the advertising that it shows on search results and book display pages to authors. Thus, Google gets to show 20% of the book online and sell digital copies of it, keeping 37% of all revenues. Further, Google has the right to scan books in print and use them for research purposes. For books with no known authors, orphan works as they are called, Google may scan these works and hold a share of the revenues in trust for the copyright owners, if they are ever exposed. These orphan works, which according to UC Berkeley Professor Pamela Samuelson constitute 70% of books that are still in copyright,⁸ are at the center of the settlement's controversy.

III. What Could Have Been, the Consequences of a "Positive Legal Precedent"

Mixed feelings surround the Google Book Settlement, as Google's competitors point to its unfairness and researchers point to its potential. One journalist went as far as to state, "by settling a lawsuit with book authors and publishers this week, Google is looking out for itself and has avoided fighting for and possibly establishing a positive legal precedent for copyright fair use on the Internet."⁹ This section explores this assertion and imagines a copyright world where fair use is a solid defense for search engines.

A. Copyright in the Digital Age

Copyright scholars often find themselves unsatisfied with the Supreme Court's holding in *MGM Studios*,

8. Ryan Singel, *The Fight over the Google of All Libraries: A Wired.com FAQ*, *Wired.com*, Apr. 30, 2009, <http://www.wired.com/epicenter/2009/04/the-fight-over-the-worlds-greatest-library-the-wiredcom-faq/>.

9. Perez, *supra* note 4.

Inc. v. Grokster, Ltd.,¹⁰ and are left longing for more clarity in an increasingly digital world. In *Sony Corp. v. Universal City Studios, Inc.*,¹¹ the Court held that "the sale of copying equipment, like the sale of other articles of commerce, does not constitute contributory infringement if the product is widely used for legitimate, unobjectionable purposes."¹² Originally the Ninth Circuit applied *Sony* broadly in *Grokster*, finding that producers could *never* be contributorily liable for third parties' infringing uses "even when an actual purpose to cause infringing use is shown . . . unless the distributors had specific knowledge of infringement at a time when they contributed to the infringement and failed to act upon that information."¹³ The Supreme Court unanimously rejected this holding, but instead applied the inducement theory of secondary liability to reach its conclusion.¹⁴ Thus, if the Supreme Court took the Google Book Search case, not only would there be hope for more clarity after *Grokster*, but new questions that have arisen and new issues that have formed since 2005 could now be answered.

Beyond clarity, a positive legal precedent could provide a road map for how innovative technologies such as Google act on the Web. As Google continues to develop, a variety of possibilities await it on the Web and copyright law thus far has not been able to keep pace with technology.¹⁵ A precedent holding that Google's fair use defense is viable may help both Google and its competitors understand what they can do online and what they can't. Without such precedent, Internet companies are rapidly experimenting and expanding on the Web, but at their own risk. Not only would a

10. 545 U.S. 913 (2005).

11. 464 U.S. 417 (1984).

12. *Id.* at 442.

13. 545 U.S. at 933-34; see *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 380 F.3d 1154 (9th Cir. 2004) (emphasis added).

14. See *Grokster*, 545 U.S. at 934 ("we do not revisit *Sony* further, as MGM requests, to add a more quantified description of the point of balance between protection and commerce when liability rests solely on distribution with knowledge that unlawful use will occur. It is enough to note that the Ninth Circuit's judgment rested on an erroneous understanding of *Sony* and to leave further consideration of the *Sony* rule for a day when that may be required.").

15. See Steven Hetcher, *The Half-Fairness of Google's Plan to Make the World's Collection of Books Searchable*, 13 *Mich. Telecomm. & Tech. L. Rev.* 1, 9 (2006) (noting that "changes in technology are creating market opportunities for Google on a global scale" and the law hasn't had a chance to respond. "Thus, Google finds itself in a legal free zone and is seeking to do its best to exploit its opportunities. Rather than waiting for the law to adapt, Google is adopting a proactive approach, seeking to create 'private law' that stands to be maximally favorable to its interests.").

positive legal precedent induce innovation because it would wipe out the fear of potential lawsuits, but it also would serve judicial efficiency in preventing numerous test cases from arising.

Further, a positive legal precedent could help copyright law catch up with technology. “In the digital world, controlling copying is less important than controlling access to a work.”¹⁶ If this is the case, then a positive legal precedent could go as far as rewriting copyright law, focusing on preventing distribution to the public.¹⁷ Such a decision could stem out of the fact that while Google is copying entire works, the general public will only be able to access a mere snippet of the work. The positive legal precedent would allow copying or scanning of works, provided that access to the public remained limited.

B. A Change in Ownership

i. Publishers

Why do we have the Google Book Search litigation to begin with? Although publishers and authors contend it is because their livelihood is being tested, scholars argue that the answer is more basic: publishers want their fair share of the profits Google will receive from the Book Search project.¹⁸ With a positive legal precedent in Google’s favor, content ownership shifts from the possession of the publishers, to the possession of the scanners. Further, without the settlement, all Internet search engines, including Yahoo and Microsoft, would become owners and distributors of content. While many scholars understand the implications this has for publishers, they note that the purpose of copyright law is not to protect the publishers. Pursuant to the Constitution, works are protected “to promote the Progress of Science and useful Arts.”¹⁹ Books will only promote progress if they are read and will only be read if they can be located. Thus,

16. Emily Anne Proskine, Note, *Google’s Technicolor Dreamcoat: A Copyright Analysis of the Google Book Search Library Project*, 21 Berkeley Tech. L.J. 213, 238 (2006).

17. *See id.* (explaining that Copyright law should be rewritten to focus on preventing distribution to the public, rather than to continue promoting a system “that impedes ‘normal use’ and technological advancement.”).

18. *See id.* at 239 (“What is certain is that a publishing house bringing suit against Google is not in the battle to uphold its constitutional right ‘to promote the Progress of Science and useful Arts,’ but rather to obtain what it perceives to be its fair share of the Google Library Project’s profits.”).

19. U.S. Const. art. I, § 8, cl. 8.

The Google Library Project advances the public interest by making information globally accessible regardless of a user’s income, geographic location, and proximity to a library . . . The Project also simultaneously drives publishers’ incentives to create by increasing their profits based on increased exposure to book titles. Thus, the Google Library Project is consistent with copyright law.²⁰

Therefore, a positive legal precedent would not only allow Google to continue the dissemination of information and provide incentives for creation, but other companies would be able to do this as well. Essentially, the more digital libraries there are, the more the goals of copyright will be promoted.

ii. Libraries

Not only could a positive legal precedent shift the role of publishers, it also shifts the roles of public libraries: public being the key word. Google is not the first entity to want to collect the world’s knowledge. Once upon a time, the Library of Alexandria was created under this same notion, “to bring the sum total of human knowledge together in one place at one time.”²¹ If Google is allowed to create a “digital Library of Alexandria” it will be doing so as a private company. Although many may take for granted that libraries are publicly run, critics fear that a private company, ultimately driven by profit maximization, could drastically change the notion of libraries for everyone.²² Further, with legal precedent allowing the scanning, numerous digital libraries could arise. However, instead of these libraries being congenial partners on a mission to locate books and distribute them to those who seek them, these new private libraries will be competitors. Private libraries will not reach out to other digital libraries for support, instead they could be driven to oust one another. Thus, although competition could bring prices down and allow greater access to knowledge, it also could drastically change the concept of the library. While this could be a negative side to a positive legal precedent, it is important to note that no matter how drastically competition could change the landscape of libraries, it usually always alters the landscape in a better

20. Proskine, *supra* note 15, at 239.

21. Hetcher, *supra* note 14, at 1.

22. *See id.* at 6 (“An important question raised by the Google Print lawsuits, both domestically and internationally, is whether something as important as the digital Library of Alexandria should be in the control of a private company . . . driven by the motive of profit maximization.”).

way than a monopoly would. Without a positive legal precedent there will likely only be one digital library. The world does not exist under the regime of one public library. Likely, it should not exist under the regime of one digital library.

C. *A Chance for Competitors*

Also of importance, and mentioned throughout this section, is that with a positive legal precedent Google's competitors will also be able to scan books and create their own digital libraries. This, of course, would not only include the larger companies, Yahoo and Microsoft, but also numerous smaller companies who could never fight the copyright battle in court due to smaller budgets, but who indeed want a piece of the pie once Google adds solidity to the flimsy fair use doctrine.²³ Alas, Google was the only entity willing to risk scanning books and potential copyright infringement claims. Further, Google would be the only company paying for an extensive litigation on the fair use doctrine. Thus, Google would have to go through extensive expenses in order to get this positive legal precedent, only to find that its competitors and many no name companies could then do exactly what Google was doing before the precedent. This fact alone could explain why Google opted for the settlement over the litigation and how a positive legal precedent could benefit everyone, but Google.

D. *The Unstoppable Google*

Of course, the statement above is not entirely true. While a positive legal precedent would certainly fuel competition, competition shouldn't and doesn't scare Google. Through Google's constant creation of new applications, it has found a way to continuously be ahead of the curve and its competitors. Thus, a positive legal precedent may create more book scanners, but by the time the litigation would have ended, Google likely would have set its sights on other potentials realized after the Supreme Court held that Google's fair use defense was viable.

Google has already said it wants to collect all the information in the world. With a positive legal precedent confirming the fair use defense, what would stop Google from next putting every movie in the world on its databases, or every song? If the Court ruled in

23. *See id.* ("Should Google prevail, risks will be dramatically decreased and one can expect competitors to rush in.")

favor of Google getting permission to scan books from the libraries but not the copyright owners, why wouldn't the Court rule in favor of Google getting permission from libraries but not copyright owners to scan DVDs and CDs?²⁴ Thus, if Google's Book Search database is approved, the amount of copyrighted work that Google could exploit on its databases is infinite.

IV. *But Could Google Win?*

After a discussion of the positive legal precedent a Google win could set on the copyright landscape, the larger question unfolds: could Google even win? This section analyzes relevant precedent in the Ninth and Second Circuits. As the case would ultimately be litigated in the Second Circuit, only cases from this Circuit are binding. However, several opinions by the Ninth Circuit have dealt with cases sharing similar facts with the one at hand and this article will also explore those holdings. Further, many who argue that Google would succeed on its fair use defense have relied on cases not from the Supreme Court or Second Circuit, but from the Ninth Circuit, specifically, *Kelly v. Arriba Soft Corp.*²⁵

If Google proceeds in its litigation it will assert a fair use defense. Under the affirmative defense of fair use, Google is essentially admitting to copying, but claiming that it is permitted under the doctrine. When analyzing fair use, courts ultimately balance four factors. These are: (1) the purpose and character of the use (including if it is commercial in nature or a "transformative" use); (2) the nature of the copyrighted work; (3) the amount of the work used; and (4) the effects or potential effects on the market for the original work.²⁶

A. *Ninth Circuit Decisions*

This section will analyze cases that many Google advocates are arguing would support Google's position. However, it is important to keep in mind, that at most, this is persuasive authority only, as the Second Circuit is free to ignore the precedent established outside its jurisdiction.

i. *The Ninth Circuit and Fair Use*

24. *See id.* at 6–7 (pointing out that libraries do in fact loan out DVDs and CDs).

25. 336 F.3d 811 (9th Cir. 2003).

26. 17 U.S.C. § 107 (1992); *see* Campbell v. Acuff-Rose Music, Inc., 510 U.S. 569 (1994) ("All four factors are to be explored, and the results weighed together, in light of the purpose of copyright.")

In 2003, the Ninth Circuit decided *Kelly v. Arriba Soft Corp.* The case was brought when Leslie Kelly, a professional photographer, found thumbnail images of his photographs on Arriba Soft's search engine. The court concluded that the "creation and use of the thumbnails in the search engine is a fair use."²⁷ Going through the analysis, the court first noted that "the more transformative the new work, the less important the other factors, including commercialism, become."²⁸ To make this assertion, the court cited the Supreme Court's decision in *Campbell v. Acuff-Rose Music, Inc.*²⁹ In *Campbell*, the Court analyzed the transformative nature of the work under the first prong, noting that

The central purpose of this investigation is to see . . . whether the new work merely supersedes the objects of the original creation . . . or instead adds something new, with a further purpose or different character, altering the first with new expression, meaning, or message; it asks, in other words, whether and to what extent the new work is "transformative."³⁰

Applying *Campbell*, the court found that "although Arriba made exact replications of Kelly's images, the thumbnails were much smaller, lower-resolution images that served an entirely different function than Kelly's original images."³¹ Thus, while Kelly's images were "artistic works intended to inform and to engage the viewer in an aesthetic experience," Arriba's search engine used the images "to help index and improve access to images on the Internet and their related web sites."³² The court also noted that users were unlikely to enlarge the thumbnail images, as there constituted a much lower-resolution than the originals and an enlargement would result in a significant loss of clarity. Further, while evidence pointing towards transformative use was high, the commercial use was low, as Arriba did not profit from selling the image or use the images to directly promote its website.³³

Turning to the other prongs, the court found that although photographs are generally considered creative in nature, because Kelly published its images on the

Internet before Arriba used them in its search engine, the second prong only weighed slightly in favor of Kelly. The third prong was found to favor neither party, as it was reasonable to copy the entire image in light of Arriba's use.³⁴ Finally, the court found that not only did Arriba's use of Kelly's images not harm the market of Kelly's images; it actually helped it. By displaying the thumbnails of Kelly's images, the search engine would guide users to Kelly's website, rather than detract from it.³⁵

In 2006, the Ninth Circuit decided *Field v. Google*.³⁶ The case centered on Google's main search engine, which scans the web using a "web crawler" known as the "Googlebot."³⁷ The web crawler scans the Internet to locate, analyze, and catalog the webpages into Google's searchable index, making a temporary repository of each webpage it finds called a "cache."³⁸ When clicked, the cached link directs an Internet user to the archival copy of a webpage, rather than to the original website for that page.³⁹ Field contended that allowing Internet users to access archival copies of 51 of his copyrighted works stored by Google in an online repository violated Field's exclusive rights to reproduce copies and distribute copies of those works.⁴⁰

Looking at the purpose and character of the use, the court used *Kelly* to find that Google's cached links were transformative.⁴¹ Further, the court noted that although Google is a for-profit corporation, no evidence demonstrated that Google profited from Field's work.⁴² The court concluded, "the fact that Google is a

34. *See id.* at 821 (noting that "it was necessary for Arriba to copy the entire image to allow users to recognize the image and decide whether to pursue more information about the image or the originating web site. If Arriba only copied part of the image, it would be more difficult to identify it, thereby reducing the usefulness of the visual search engine.").

35. *Id.*

36. 412 F.Supp.2d 1106 (D. Nev. 2006).

37. *Id.* at 1110; *see also* Cameron W. Westin, *Is Kelly Shifting Under Google's Feet? New Ninth Circuit Impact on the Google Library Project Litigation*, 2007 Duke L. & Tech. Rev. 2, 26 (2007) (discussing how Google's search engine uses its web crawler to scan pages online and catalogue these pages into Google's searchable database.).

38. *Field*, 412 F. Supp. 2d at 1110–11.

39. *Id.* at 1111.

40. *Id.* at 1109.

41. *See id.* at 1118–19 ("Because Google serves different and socially important purposes in offering access to copyrighted works through 'Cached' links and does not merely supersede the objectives of the original creations, the Court concludes that Google's alleged copying and distribution of Field's Web pages containing copyrighted works was transformative.").

42. *See id.* at 1120 (noting that Field's work was among billions of

27. *Kelly v. Arriba Soft Corp.*, 336 F.3d 811, 815, 822 (2003).

28. *Id.* at 818.

29. 510 U.S. 569 (1994).

30. *Id.* at 579 (internal citations omitted).

31. *Kelly*, 336 F.3d at 818.

32. *Id.*

33. *See id.* ("Because the use of Kelly's images was not highly exploitative, the commercial nature of the use weighs only slightly against a finding of fair use.").

commercial operation is of only minor relevance in the fair use analysis. The transformative purpose of Google's use is considerably more important, and, as in *Kelly*, means the first factor of the analysis weighs heavily in favor of a fair use finding.⁴³ Although balancing the other three factors led the court to rule in the favor of fair use, the court added an additional prong to its fair use analysis: Google's good faith. The court noted that Google honors industry-standard protocols that site owners use to instruct search engines not to provide cached links for the pages of their sites. Field both failed to inform Google to not cache his site *and* took a variety of steps to get his work included in Google's search results. "Comparing Field's conduct with Google's provides further weight to the scales in favor of a finding of fair use."⁴⁴

Finally, in 2007, the Ninth Circuit decided *Perfect 10, Inc. v. Amazon.com, Inc.*,⁴⁵ a case focusing on Google's "Google Images" feature. Perfect 10 markets and sells copyrighted images of nude models. The issue arose in this case when Google's search engine automatically indexed the webpages of websites that republished Perfect 10's images without authorization. Thus, Google users could click on the thumbnail image provided by Google's search engine and access third-party webpages with full-sized infringing images.⁴⁶

Under the fair use analysis the court used *Kelly* to hold that "Google's use of thumbnails is highly transformative."⁴⁷ Thus, per *Kelly*, "even making an exact copy of a work may be transformative so long as the copy serves a different function than the original work."⁴⁸ The court further rejected the district court's finding that since Google's thumbnails "lead users to

works in the Google database and no advertisements were placed on the cached pages).

43. *Id.*

44. *Id.* at 1122–23.

45. 487 F.3d 701 (9th Cir. 2007).

46. Legal action was sought against Amazon.com because of the agreement between Google and Amazon.com, in which Amazon.com is allowed to in-line link to Google's search results. As the court explains, "Amazon.com gave its users the impression that Amazon.com was providing search results, but Google communicated the search results directly to Amazon.com's users. Amazon.com routed users' search queries to Google and automatically transmitted Google's responses (i.e., HTML instructions for linking to Google's search results) back to its users." *Id.* at 712.

47. *See id.* at 721 (noting that "a search engine puts images 'in a different context' so that they are 'transformed into a new creation.'").

48. *Id.* at 721–22 (citing *Kelly v. Arriba Soft Corp.*, 336 F.3d at 818–19).

sites that directly benefit Google's bottom line," the AdSense program increased the commercial nature of Google's use of Perfect 10's images.⁴⁹ Instead, the court concluded that the "significantly transformative nature of Google's search engine, particularly in light of its public benefit, outweighs Google's superseding and commercial uses of the thumbnails in this case."⁵⁰ Balancing the other factors led the court to hold in favor of fair use.

ii. The Google Book Search and Fair Use

Kelly has already allowed Google to prevail in *Field* and *Perfect 10*, and many advocates argue it could have likely given the Google Book Search the capacity to prevail on its fair use defense. If these cases were used as controlling, on the first factor it is very likely that the court would have found Google's use transformative in nature. Google is not simply reproducing the books and allowing the public to access them in their entirety. Instead, Google displays "snippets" of the books used for locating materials relevant to search queries and "keyword" searches. It, therefore, serves a purpose and function very different than that of the original book. Further, the ability to search for keyword results has enormous potentials for researchers, making the project a clear public benefit.⁵¹ Therefore, it is likely that the court would find, as it did in *Perfect 10*, that the "significantly transformative nature of Google's search engine, particularly in light of its public benefit, outweighs Google's superseding and commercial uses of the books in this case."⁵²

Moving to the nature and character of the use, while many of the books Google copies are creative, they have all been published and therefore do not encroach on the author's right of first publication.⁵³ Further,

49. *Id.* at 722–23; *see Perfect 10 v. Google, Inc.*, 416 F. Supp. 2d 828, 847 (C.D. Cal. 2006).

50. *Perfect 10*, 487 F.3d at 723; *see also id.* ("Accordingly, we disagree with the district court's conclusion that because Google's use of the thumbnails could supersede Perfect 10's cell phone download use and because the use was more commercial than Arriba's, this fair use factor weighed 'slightly' in favor of Perfect 10. Instead, we conclude that the transformative nature of Google's use is more significant than any incidental superseding use or the minor commercial aspects of Google's search engine and website. Therefore, the district court erred in determining this factor weighed in favor of Perfect 10.")

51. *See Westin, supra* note 36, at 48.

52. *Perfect 10*, 487 F.3d at 723.

53. *Westin, supra* note 36, at 49; *see Kelly v. Arriba Soft Corp.*, 336 F.3d 811, 820 (9th Cir. 2003) ("The fact that a work is published or unpublished also is a critical element of its nature. Published works

while as in *Kelly*, Google copies the works in full, such wholesale copying is necessary to create a functional search engine.⁵⁴ Finally, while it is arguable whether the content-owners of library books may lose the licensing value of their works due to Google's actions, the search-engine is not created to replace the demand for full books and is instead designed to lead users to locations for purchasing the original works. As in *Kelly*, it can be argued that this not only *does not* detract from the market, it instead enhances it.⁵⁵ Finally, the court could choose to look at the additional good faith prong added by the court in *Field*. Such good faith efforts in the Google Book Search include the opt-out provision that Google has designed. Thus, while providing an "opt-out" method alone would not immunize a defendant from copyright infringement claims, "volunteering a relatively simple and effective method for content owners to prevent their works from being included in a vast project may lessen the image of authors' works being wrestled from their grasp."⁵⁶

B. Second Circuit Decisions

While Google defenders rest on *Kelly* and subsequent case law, it is important to remember that it is the Second Circuit, and not the Ninth Circuit, that would decide this case. Thus, there is a different body of case law that the Second Circuit would look to in order to reach its decision. Further, the East Coast's Second Circuit has proven much less pragmatic than the West Coast's Ninth Circuit.⁵⁷ This section will analyze relevant precedent set in the Second Circuit and analyze how such precedent would have guided the court in the current Google litigation.

are more likely to qualify as fair use because the first appearance of the artist's expression has already occurred. Kelly's images appeared on the Internet before Arriba used them in its search image."); see also *Perfect 10, Inc. v. Amazon.com, Inc.*, 487 F.3d 701, 723 (9th Cir. 2007) ("Once Perfect 10 has exploited this commercially valuable right of first publication by putting its images on the Internet for paid subscribers, Perfect 10 is no longer entitled to the enhanced protection available for an unpublished work."); *Field v. Google*, 412 F.Supp.2d 1106, 1120 (D. Nev. 2006) (holding that the nature of the copyrighted works weighed only slightly in favor of Field because "even assuming Field's copyrighted works are as creative as the works at issue in *Kelly*, like *Kelly*, Field published his works on the Internet, thereby making them available to the world for free at his Web site.").

54. See Westin, *supra* note 36, at 49

55. See *id.*

56. *Id.* at 54.

57. Siva Vaidhyanathan, *The Googilization of Everything and the Future of Copyright*, 40 U.C. Davis L. Rev. 1207, 1225 (2007).

In the Google Book Search Settlement, the East Coast and West Coast house two different interests. In this case, the East Coast is home to authors and publishers.⁵⁸ Here, "content is king," and therefore its protection is a powerful interest.⁵⁹ Across the country, however, the West Coast is home to Google and content distributors, rather than content creators.⁶⁰ Thus, Google's litigation in the Second Circuit gives its adversaries – authors and publishers – home court advantage.⁶¹ With this natural bias in mind, it is then important to turn to case law and binding precedent.

i. The Second Circuit and Fair Use

In the same year that the Supreme Court was debating contributory liability in *Sony*, the Second Circuit reached its decision in *Fin. Info., Inc. v. Moody's Investors Servs., Inc.*⁶² In this case, Financial Information Inc. ("FII"), a publisher of financial information, contended that Moody's stole its copyrighted material from its Bond Service. At trial, FII demonstrated that there was a 95% certainty that Moody's had copied at least 40–50% of FFI's information in the years 1980 and 1981.⁶³ Laying out the fair use factors, the court found that Moody's did not make out a proper defense. The court began its analysis by finding "there is no argument and of course can be no doubt but that Moody's use is commercial, and thus presumptively unfair."⁶⁴ Further, the court rejected the "public function" of Moody's use.⁶⁵ Thus, based on the presumption of unfair use, the court found in favor of FII on the first factor.

Placing little emphasis on the second factor, which the court found to favor fair use, the court placed significant emphasis on the third factor. The court found significant evidence offered at trial by Professor Herbert Robbins, Professor of Mathematical Statistics at Columbia University, that it was statistically certain (95–99% probable) that Moody's had copied at the 40–50% level.⁶⁶ The court considered this "substantial, if not wholesale copying by Moody's from FII."⁶⁷ Finally, with respect to the fourth factor, the court found that

58. Westin, *supra* note 36, at 12.

59. *Id.*

60. *Id.*

61. *Id.* at 13.

62. 751 F.2d 501 (2d Cir. 1984).

63. *Id.* at 503.

64. *Id.* at 508.

65. *Id.*

66. *Id.* at 509.

67. *Id.*

FII might be in a position to license the infringed use for a fee and noted that harm to the copyright owner “may be presumed.”⁶⁸

In 2000, the Southern District of New York found itself faced with a copyright infringement claim concerning downloading music on the Internet. In *UMG Recordings, Inc. v. MP3.com, Inc.*⁶⁹ the court began by asserting that, “The complex marvels of cyberspatial communication may create difficult legal issues; but not in this case. Defendant’s infringement of plaintiffs’ copyrights is clear.”⁷⁰ Employing the fair use factors, the court found the purpose and the character of the use to be commercial.⁷¹ Further the court found that retransmitting the copies into another medium was insufficient to constitute as transformative.⁷² Thus, as MP3.com failed to add “new aesthetics, new insights and understandings” to the original music recordings it copied, but instead “simply repackages those recordings to facilitate their transmission through another medium,” its works could be considered innovative, but not transformative.⁷³ Balancing the other three facts, the court found MP3.com’s fair use defense indefensible as a matter of law and ruled in favor of the copyright owners.

More recently, the Second Circuit has ruled in favor of fair use. In 2005, *Blanch v. Koons*⁷⁴ decided an infringement claim of a copyrighted photograph. In this case, Andrea Blanch, copyright owner of her photograph “Silk Sandals by Gucci,” alleged that Jeff Koons copied the model’s legs, feet, and Gucci sandals from the photograph in his painting entitled, “Niagara.” Undertaking a fair use analysis the court first found Koons’ use of the work to be transformative, finding “no original creative or imaginative aspect of Blanch’s photograph . . . included in Koons’ painting.”⁷⁵ Under

the nature of the copyrighted work, the court found that the photograph was sufficiently creative and its publication in a magazine throughout the United States favored fair use. On the third factor, the court found that because the quality of the copyright protection for crossed legs is weak, the third factor was neutral between the parties. Finally, on the fourth factor the court found in favor of defendants as “Niagara” was not a substitute for Blanch’s photograph and was in no way competitive with it.

In 2006, the Second Circuit found in *Bill Graham Archives. v. Dorling Kindersely Ltd.*⁷⁶ a viable fair use defense. In 2003, Dorling Kindersley Ltd (“DK”) published a 480-page coffee table book entitled “Grateful Dead: the Illustrated Trip.” Issue arose when Bill Graham Archives (“BGA”) claimed to own the copyright to seven images displayed in the book. Employing the fair use test, the court found that by placing the photographs in chronological order, DK’s use was “transformatively different from the mere expressive use of images on concert posters or tickets.”⁷⁷ Regarding the second fair use factor, the court found against DK because BGA’s images were creative artworks. However, the court noted that where the work is found to be transformative under the first factor, the second factor becomes of limited use.⁷⁸

Next, the court found that even though the images were reproduced in their entirety, “the third fair use factor weighed in favor of DK because the images were displayed in reduced size and scattered among many other images and texts.”⁷⁹ In reaching this decision, the court noted that sister circuits “have concluded that such copying does not necessarily weigh against fair use because copying the entirety of a work is sometimes necessary to make a fair use of the image.”⁸⁰ Similar to *Kelly*, the court noted that while the copyrighted images were copied in its entirety, the visual impact of its artistic expression was significantly limited due to its reduced size. This led the court to conclude, “that such use by DK is tailored to further its transformative purpose

68. *Id.* at 510 (citing *Sony Corp. v. Universal City Studios, Inc.*, 464 U.S. 417 (1984)).

69. 92 F. Supp. 2d 349 (S.D.N.Y. 2000).

70. *Id.* at 350.

71. *See id.* at 351 (“for while subscribers to My.MP3.com are not currently charged a fee, defendant seeks to attract a sufficiently large subscription base to draw advertising and otherwise make a profit.”).

72. *See id.* (“Here, although defendant recites that My.MP3.com provides a transformative ‘space shift’ by which subscribers can enjoy the sound recordings contained on their CDs without lugging around the physical discs themselves, this is simply another way of saying that the unauthorized copies are being retransmitted in another medium—an insufficient basis for any legitimate claim of transformation.”).

73. *Id.*

74. 396 F.Supp.2d 476 (S.D.N.Y. 2005).

75. *Id.* at 481.

76. 448 F.3d 605 (2d Cir. 2006).

77. *Id.* at 609.

78. *Id.* at 613; *see also id.* at 612–13 (“Accordingly, we hold that even though BGA’s images are creative works, which are a core concern of copyright protection, the second factor has limited weight in our analysis because the purpose of DK’s use was to emphasize the images’ historical rather than creative value.”).

79. *Id.* at 613.

80. *Id.* (citing *Kelly v. Arriba Soft Corp.*, 336 F.3d 811, 821 (9th Cir. 2003)).

because DK's reduced size reproductions of BGA's images in their entirety displayed the minimal image size and quality necessary to ensure the reader's recognition of the images as historical artifacts of Grateful Dead concert events."⁸¹ Finally, looking to the fourth factor, the court first recognized that it did not find harm to BGA's license market simply because DK did not pay a fee for the copyrighted images.⁸² Then, because DK's use of BGA's images was transformative, the court concluded that BGA did not suffer market harm due to the loss of license fees.⁸³

ii. Google Book Search and Fair Use

Looking at the Second Circuit's binding case law as a whole demonstrates that Google would likely not fair well against copyright owners and publishers of books. While newer Second Circuit decisions have allowed the fair use doctrine to prevail, its application of the transformative standard differs significantly from that held in the Ninth Circuit.⁸⁴ Both the Ninth and Second Circuits have used *Campbell* to support its transformative analysis. However, *Bill Graham Archives* and *Blanch* appear to have adopted a different transformative standard than did *Kelly*, *Field* and *Perfect 10*. The differences between the standards is based on different weights to different values, "whereas the Campbell opinion recognized the value of new creative expression containing commentary that depends of previously created expression, the Ninth Circuit saw value in improving 'access to information on the Internet.'"⁸⁵ Thus, although *Bill Graham Archives* goes as far as citing to *Kelly*, both *Bill Graham Archives* and *Blanch* involved the unauthorized uses of copyrighted material to create new authorship.⁸⁶ Further, "both opinions indicate that uses, such as Google's, that do not involve the creation of new expression containing commentary are not transformative."⁸⁷

Thus, applying the fair use doctrine in the Second Circuit comes down to how the Second Circuit will rule on the transformative nature of Google's use. Since Google's use is commercial, it will have to make a strong showing of transformation in order to overcome this prong.⁸⁸ In *Blanch*, the Second Circuit did not hold Koons' work to be transformative solely because it found a new purpose or function for Blanch's photograph. Instead, the court cautiously explained that Koons' repurposing of Blanch's work involved the creation of new expression containing commentary.⁸⁹ Further, in *Bill Graham Archives*, the defendant was able to prevail because it presented its readers with information that augmented the value and effectiveness of the commentary in its new work.⁹⁰ Thus, *Bill Graham Archives*, cites *Kelly* for the narrow principle that it is important to use copyrighted material for a new purpose that provides the public with information.⁹¹ The court did not cite *Kelly* for the broad principle that a use can be transformative for altering the function in order to increase access to information.⁹² In fact, in *MP3.Com* the court found that retransmitting copies into another medium was insufficient to constitute as transformative.⁹³ In the Google Book Search, Google did not create new authorship with commentary. Despite the new webpages, databases, and search engine programs provided by Google, none of these features provide the public with new information. Thus, because Google adds no new commentary, it likely will not be found to be transformative. The lack of transformation coupled with the commercial nature of Google's use would likely lead Google to fail under the first prong.

Succeeding on the first prong is not always critical.⁹⁴

88. See *Fin. Info. Inc. v. Moody's Investors Servs., Inc.*, 751 F.2d 501, 508 (2d Cir. 1984) (holding that commercial use is "presumptively unfair").

89. Williams, *supra* note 83, at 319.

90. *Id.* at 323.

91. *Id.* at 321.

92. *Id.* at 323-24.

93. See *UMG Recordings, Inc. v. MP3.com, Inc.*, 92 F.Supp.2d 349 (S.D.N.Y. 2000) ("Here, although defendant recites that My.MP3.com provides a transformative 'space shift' by which subscribers can enjoy the sound recordings contained on their CDs without lugging around the physical discs themselves, this is simply another way of saying that the unauthorized copies are being retransmitted in another medium-an insufficient basis for any legitimate claim of transformation").

94. *But see* *Castle Rock Entm't, Inc. v. Carol Publ'g Group*, 150 F.3d 132 (2d Cir 1998) (determining that the a trivia game of the television show *Seinfeld* was not transformative because its purpose was not to educate, criticize or expose viewers to the "nothingness" of the show, but to "repackage *Seinfeld* to entertain *Seinfeld* viewers.")

81. *Id.*

82. *Id.* at 614.

83. *Id.* at 614-15.

84. Matt Williams, *Recent Second Circuit Opinions Indicate that Google's Library Project Is Not Transformative*, 25 *Cardozo Arts & Ent. L.J.* 303, 319 (2007).

85. *Id.* at 305-06.

86. See *id.* at 319 (noting that even though *Bill Graham Archives* cited *Kelly*, both *Bill Graham Archives* and *Blanch* "involved unauthorized uses of copyrighted material to create new authorship containing commentary, and both opinions indicate that uses that do not involve the creation of new expression containing commentary are not transformative.").

87. *Id.*

The test balances each factor, and therefore if Google can come up strong on the other factors it can still succeed on fair use.⁹⁵ Unfortunately, not even Google advocates argue that Google will succeed on the second prong that looks at the nature of the work. Books are highly creative works and rest at the heart of copyright protection. Further, while the copying of an entire work has not bothered the Second Circuit, it has allowed such wholesale copying only when the work is transformative.⁹⁶ Because Google's use is probably not transformative by nature, the Second Circuit will likely compare such copying to *Moody's* rather than *Bill Graham Archives*. Finally, on the fourth factor, unlike in *Blanch* where the court found that the defendant's photograph was not a substitute for the plaintiff's photograph and was in no way competitive with it, it can be argued that Google is directly competing with books. Further, *Bill Graham Archives* will be of little use to Google, as the court concluded that BGA did not suffer market harm due to the loss of licensing fees only because DK's use of BGA's images were transformative. Here, as mentioned above, Google's use of the books is likely not transformative.⁹⁷ Therefore, although Google advocates argue it can make a strong showing that Google will not harm the copyright owners and publishers' market, based on Second Circuit case law, such a win is unlikely.

V. Conclusion

Failure at the Second Circuit might not be the end of the road for Google. With a split between the Ninth and Second Circuit on how to qualify a work as transformative, the Supreme Court may agree to take the

Ultimately, the determination that the work was not transformative had a significant role in determining the other three factors. When looking at the second factor the court held that, "the fictional nature of the copyrighted work remains significant in the instant case, where the secondary use is at best minimally transformative." On the third prong the court specifically noted, "*The SAT* does not serve a critical or otherwise transformative purpose." Finally, on the fourth factor the court stated "the more transformative the secondary use, the less likelihood that the secondary use substitutes for the original."

95. See *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569 (1994) ("All four factors are to be explored, and the results weighed together, in light of the purpose of copyright.").

96. See *Bill Graham Archives v. Dorling Kindersley Ltd.*, 448 F.3d 605, 613 (2d Cir. 2006) (concluding that where the work is found to be transformative under the first factor, the second factor becomes of limited use. "Even though the copyrighted images are copied in their entirety . . . such use by DK is tailored to further its transformative purpose . . .").

97. *Bill Graham Archives*, 448 F.3d at 614–15.

case. However, following the holding in *Campbell* it is likely that the Court will side with the Second Circuit.⁹⁸ Further, it is interesting to note that the Second Circuit is a very well respected Circuit when it comes to copyright issues, and the Supreme Court may be more willing to take its interpretation of the transformative prong seriously. Already the Supreme Court has taken copyright cases from both the Ninth Circuit (*Grokster*) and the Second Circuit (*Tasini v. New York Times Co., Inc.*⁹⁹). The difference, however, is that the Supreme Court upheld the Second Circuit's ruling and sided with the writers while it unanimously overruled the Ninth Circuit that favored the infringers.¹⁰⁰

Ultimately the question of whether the Supreme Court would take the Google Book Search case and whether it would rule in Google's favor is a question for another article. This article's focus was to ponder the possibility of a positive legal precedent, and then conclude that despite the sweeping changes that would come with new precedent, the likelihood of actually getting the Second Circuit to rule in Google's favor is slim. Thus, if the Second Circuit ruled against Google and the Supreme Court took the case and agreed with the Second Circuit, the Ninth Circuit would have to change its pattern of ruling in favor of fair use, at least to the extent of deeming a work transformative merely because it has been placed online. What would be the effects of a negative legal precedent?

Before Google entered settlement negotiations in 2007, a scholar described Google as "an intellectual property owner's worst enemy: a risk-taking iconoclast with deep pockets, seemingly unafraid to litigate licensing issues all the way to the Supreme Court."¹⁰¹ Perhaps the scholar got it wrong; perhaps Google was afraid to litigate fair use "all the way to the Supreme Court." Or maybe Google realized that this was a battle it could only win

98. See *Campbell*, 510 U.S. at 583 (finding a parody transformative because the song at issue "reasonably could be perceived as commenting on the original or criticizing it to some degree."); see also *Harper & Row, Publishers, Inc. v. Nation Enterprises*, 471 U.S. 539, 543 (1985) (noting that defendant "attempted no independent commentary, research or criticism").

99. 533 U.S. 483 (2001).

100. See also *Sony Corp. v. Universal City Studios, Inc.*, 464 U.S. 417 (1984) (reversing the Ninth Circuit's holding that petitioners were liable for contributory infringement); *Accord Harper & Row*, 471 U.S. at 542 (reversing the Second Circuit's decision that *The Nation's* act constituted a fair use.)

101. James Gibson, *Accidental Rights*, 116 Yale L.J. Pocket Part 348, 349 (2007).

by settling rather than fighting.¹⁰²

102. See Hetcher, *supra* note 14 at 9. (“Google may believe that, by engaging in an all-out legal battle, the publishing industry will be forced into submission through a settlement on terms favorable to the Google Print project.”).

Regulation of Medicine Patents by the Anti-Counterfeiting Trade Agreement to Broaden Access to Medicine

By Daniel Lee¹

One of the most concerning areas of recent patent enforcement is a life or death matter for thousands of people around the world. Restricted access to vital medicines in developing countries is one of the most controversial international intellectual property issues today. There is a new international treaty called the Anti-Counterfeiting Trade Agreement (ACTA) being negotiated among developed countries, and it is expected to bring a huge impact on access to medicine in developing countries.²

This article proposes what ACTA should include in order to protect access to medicine in developing countries. It discusses the need to allow broader compulsory licensing of pharmaceutical patents to encourage increased production of generic drugs and bring down the overall prices of essential medicine in developing countries. It also examines the need to regulate counterfeit drugs in order to promote research and development from pharmaceutical companies, while correctly distinguishing generic drugs from counterfeit drugs. Lastly, this article concludes by suggesting the need for a provision in ACTA that recognizes the importance of access to medicine provisions in multinational treaties over the regional and bilateral agreements.

The most recent major agreement on international intellectual property rights enforcement is the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property (TRIPS) Agreement.³ The TRIPS Agreement is an international agreement that sets the basic norms of international intellectual property standards along with other

international agreements such as the World Intellectual Property Organization (WIPO) agreements.⁴ The TRIPS Agreement extends patent terms in all fields of technology to twenty years, and requires that all WTO states provide patent protection for all inventions.⁵ This requirement also applies to pharmaceutical patents, resulting in a significant restriction on vital medicines in developing countries.⁶

While every party involved agrees that large populations of developing countries lack meaningful access to health-related technologies, approaches to this problem differ significantly between developed countries and developing countries.⁷ The International Bill of Human Rights acknowledges that access to medicine is a fundamental right of every person.⁸ On the other hand, pharmaceutical companies must also protect their patent rights in order to secure their profit to keep producing medicines and seeking out innovations.⁹

There are some provisions in the TRIPS Agreement and the subsequent Doha Declaration that provide some flexibility to the restricted access to medicines resulting from TRIPS. Article 6 of TRIPS allows for "Parallel Importation", which happens when a patented good sold by the patentee is imported without his consent¹⁰; Article 2 of TRIPS recognizes continued application of the Paris Convention, which forces patent

4. Susy Frankel, *Challenging TRIPS-plus Agreements: The Potential Utility of Non-Violation Disputes*, 12 J. Int'l Econ. L. 1023, 1039 (2009).

5. Morgan, *supra* note 2, at 48.

6. *Id.*

7. See Tina S. Bhatt, *Amending TRIPS: A New Hope for Increased Access to Essential Medicines*, 33 Brook. J. Int'l L. 579, 598-599 (2008) (discussing the lack of meaningful access to AIDS/HIV medicine in African countries due to high price while addressing the need of profit from patent by pharmaceutical companies to promote research and development).

8. Siddhartha Rao, *Closing the Global Gap: A Pragmatic Approach to the Access to Medicines Problem*, 3 J. Legal Tech. Risk Mgmt. 1, 3 (2008) (citing to Universal Declaration of Human Rights, Art. 25 (1)).

9. See Bhatt, *supra* note 5, at 601 (arguing that "patent protection is necessary for the continued availability of drugs").

10. Morgan, *supra* note 2, at 61.

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2. Margot Kaminski, *The Origins and Potential Impact of the Anti-Counterfeiting Trade Agreement*, 34 Yale J. Int'l L. 247, 247 (2009).

3. See Maxwell R. Morgan, *Medicines for the Developing World: Promoting Access and Innovation in the Post-TRIPS Environment*, 64 U. Toronto Fac. L. Rev. 45, 48 (2006) (explaining that the access to medicine issue transcends the recent heated debate on the implementation of TRIPS Agreement and its impact on medicine prices).

holders to file foreign patent applications within a year from their domestic filing date in order to acquire an international patent;¹¹ Paragraph 7 of the Doha Declaration extends the TRIPS implementation for pharmaceutical products in the least developed countries until January 1, 2016;¹² and most importantly, Article 31 of the TRIPS Agreement allows for the compulsory licensing of pharmaceutical patents and for exportation of medicines produced under compulsory licenses to eligible importing member nations.¹³

Recently, there have been rounds of new bilateral trade agreements that impose additional enforcement of patent rights between developing nations and developed nations.¹⁴ These bilateral and regional trade agreements are called “TRIPS-plus,” and include additional intellectual property provisions in the Free Trade Agreements (FTA) among developed and developing countries.¹⁵ The TRIPS-plus agreements deter developing nations from taking full advantage of the flexibility provisions in the TRIPS, by forcing them to adopt stricter intellectual property provisions.¹⁶

ACTA is still a work in progress, and thirteen countries, including the United States, have joined in the negotiations. Although the negotiation process has been kept confidential, some released material indicates that the new agreement will contain even stricter enforcement measures, including increased criminal sanctions for infringement and stronger border measures.¹⁷ Considering ACTA’s purpose and nature, it can be predicted that the agreement will further decrease access to medicines in developing countries.¹⁸

I. Broader Compulsory Licensing and More

11. *Id.*

12. *Id.* at 63.

13. *See id.* at 60 (quoting F.M. Scherer & J. Watal, “Post-TRIPS Options for Access to Patented Medicines in Developing Countries” in Commission on Macroeconomics and Health Working Paper Series (Geneva: World Health Organization, 2001) Paper No. WG4:1 at 13).

14. *See* Bhatt, *supra* note 5, at 617-618 (arguing that new FTA Agreements made by the United States “contain provisions that far exceed the protections offered by TRIPS”).

15. *Id.* at 618.

16. *See id.* (explaining that American bilateral and multilateral FTAs include provisions that limit exclusions of patentability, require broader definition of patents, prevent parallel importation, limit scope of compulsory license, and permit prosecution of non-violation claims).

17. Kaminski, *supra* note 1, at 247.

18. *See id.* (arguing that ACTA will likely be the strictest enforcement measures among many countries).

Generic Drugs: Profit Maximizing Pricing of Medicine by Pharmaceutical Companies Creates Deadweight Loss

Pharmaceutical companies holding drug patents have almost monopolistic control over the price of their medicine.¹⁹ When pharmaceutical companies set a price for their medicine in a market, they usually pursue a profit-maximizing strategy, rather than considering what would allow for greater access to the medicine.²⁰ This strategy works because the demand for essential medicine is likely inelastic in theory, in that the demand by the consumers for the medicine will tend not to decrease as the price of the medicine increases.²¹ This profit-maximizing pricing strategy consequently creates a large dead weight loss in developing countries.²² Since the majority of the population in the least developed countries earns an income below the poverty line, a small increase of a medicine price can make medicines inaccessible for an enormous amount of people in need.²³ However, it is often more profitable and more efficient for the pharmaceutical companies in developing countries to impose a high price on their medicine and target the top percentage of a rich population, rather than selling the maximum possible quantity in a market.²⁴ Sometimes these medicine prices in developing nations are even higher than comparable drug prices in developed countries.²⁵

An example is illustrated by Professor Sean Flynn of American University in Washington, D.C. According to 2006 UNAIDS data, there are 5.5 million HIV/AIDS patients in South Africa.²⁶ Assuming that HIV prevalence is uniform in the population, with each decile containing 550,000 people in need of antiretroviral treatment, if the price of an anti-retroviral is set at \$1,481 per patient per year, only 550,000 people (10% of total HIV patients) can afford it.²⁷ The total revenue earned at this price point is \$814.6

19. *See* Morgan, *supra* note 2, at 56 (arguing that in return for granting medicine patent holders monopolistic control over their patents, society gains full disclosure of the invention).

20. Sean Flynn, Aidan Hollis & Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries* 8 (U. of Calgary Dep’t of Econ. Working Paper No. 2009-01).

21. *Id.* at 10.

22. *Id.* at 8.

23. *Id.* at 10.

24. *Id.* at 12.

25. *Id.* at 18.

26. Flynn, *supra* note 18, at 17.

27. *Id.*

million.²⁸ However, if the price of an antiretroviral is set at \$396, about half of the total HIV patients can afford the anti-retroviral with total revenue of \$435.6 million.²⁹ Further calculation by Professor Flynn shows that revenues keep falling as pharmaceutical companies reduce prices and increase production.³⁰ Thus, in South Africa, pharmaceutical companies will profit the most if they price their antiretroviral at \$1,481, so that only the top ten percent of the population can afford it.³¹ This is higher than the profit-maximizing price of \$1,468 in Norway, where 80% of the population can afford the same medication at this price level due to their relatively uniform high income.³²

II. Broader Compulsory Licenses Can Bring in More Generic Competition and Reduce the Price of Medicine and the Deadweight Loss

One of the most effective ways to bring down the cost of high priced essential medicine is to bring in more generic competition through more aggressive compulsory licensing.³³ Compulsory licensing means that a patent holder is compelled to grant a license to third parties to use the patent. It is often used in antitrust law and patent law.³⁴ As mentioned earlier, Article 31 of the TRIPS Agreement contains procedural requirements to obtain compulsory licenses. The unauthorized user must make a reasonable effort to obtain a license from the patent holder and provide adequate remuneration based on the economic value of the use.³⁵ However, TRIPS also waives these procedural requirements in case of a national emergency or other extreme urgency.³⁶

The problem with the compulsory licensing flexibility is that only some developing countries have the infrastructure to take advantage of the provision and produce generic drugs under the compulsory license.³⁷ Most developing countries rely on the export and import of generic drugs produced by the few capable developing nations.³⁸ The August 30th Agreement,

adopted by the TRIPS council in 2003 in addition to the TRIPS Agreement, outlines this import and export system procedure, but its “ad hoc, case-by-case, country-by-country procedural system” creates segmented markets.³⁹ This results in a substantial inefficiency to the compulsory licensing system and high transaction costs.⁴⁰ Entry of generic drugs into the market then becomes burdened, because demand for a generic drug by one particular segmented market often shows insufficient incentives for an overall generic entry.⁴¹

In addition, there is a growing concern regarding the seizure of generic drugs being transported from a developing country to other developing countries. European countries tend to impose local intellectual property laws on pass-through cargos, which pause briefly in these countries to refuel or change their mode of transportation on the way to their final destination.⁴² These “transit countries” take the view that pass-through generic drugs are in violation of their local intellectual property laws and can be seized, regardless of their destination.⁴³ For example, in December 2008, Dutch customs authorities seized several cargos of the generic drug Losartan Potassium in transit from India to Brazil.⁴⁴ The Dutch customs authorities released the cargos after 36 days, but they released the cargos back to India instead of allowing the cargos to ship to Brazil.⁴⁵

In order to encourage more efficient exportation and importation of generic drugs produced under compulsory license among developing countries, ACTA should simplify burdensome procedural requirements as much as possible. It should allow the generic drug market in developing countries to be viewed as a whole, in order to create enough demand for generic entry. Furthermore, ACTA should prohibit the transit countries from applying their local intellectual property laws to generic drugs in transit to developing countries,

WTO member nation that has shown insufficient or no manufacturing capacities to import medicines produced under compulsory license).

28. *Id.* at 18.

29. *Id.*

30. *Id.*

31. *Id.*

32. Flynn, *supra* note 18, at 20.

33. Rao, *supra* note 6, at 15.

34. *Id.* at 8.

35. Morgan, *supra* note 2, at 60.

36. *Id.* at 61.

37. *Id.* at 64.

38. *See id.* (explaining that the Article 31(f) of TRIPS allows a

39. *Id.* at 84.

40. *Id.*

41. Morgan, *supra* note 2, at 84.

42. ConsumerInternational.com, European Countries Imposing Local Intellectual Property Laws on Cargo Passing Through, <http://www.consumersinternational.org> (follow “member information” hyperlink; then follow “member news” hyperlink; then follow “generic drugs seized in transit: IP laws threatening access to affordable medicine” hyperlink) (last visited Nov. 1, 2009).

43. *Id.*

44. *Id.*

45. *Id.*

to ensure the fast and efficient supply of essential medicines to developing countries.

III. Funding for Innovation by Stronger Regulation on Counterfeit Drugs

Research and development of new drugs cost substantial amounts of money and involves high risks of unsuccessful products.⁴⁶ On the other hand, generic drugs bear little to no research and development costs and involve substantially fewer risks, since the drug is already proven to be successful.⁴⁷ This is why the introduction of generic alternatives of more expensive patented medicines in markets is often said to be the deterrent to research for innovative new drugs.⁴⁸ Pharmaceutical companies often view high profits as incentives for their patented technology, and when these incentives are low, they are reluctant to make investments to enter into the market and experiment with new drugs.⁴⁹

In order to promote research and development of new drugs and vaccines for neglected diseases, incentives to pharmaceutical companies are needed while keeping generic competition in place.⁵⁰ There have been many mechanisms proposed to help research and development, such as public and private research funding, advance purchasing, and bulk purchasing.⁵¹ However, these mechanisms are separate from ACTA since they involve voluntary funding and are not geared toward altering enforcement mechanisms.

One way that ACTA can help increase research and development of new drugs is by drawing a clear

46. See Bryan Mercurio, *Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines*, 5 Nw. U. J. Int'l Hum. Rts. 1, 53 (2006) (explaining that research and development cost of drugs account up to thirty percent of total production costs: only 5 of every 250 compounds enter into clinical trials where over half of the compounds fail, and additional large numbers of fail at the regulatory stage).

47. See Morgan, *supra* note 2, at 82 (explaining that a generic drug company does not incur front-end investments cost associated with researching and developing new drugs even though there are still transaction costs and capital costs).

48. See *id.* at 56 (introducing an existing theory that monopolistic incentives from patent stimulate research and development by pharmaceutical companies).

49. Flynn, *supra* note 18, at 6.

50. See Morgan, *supra* note 2, at 99 (arguing that in addition to keeping medicine prices down in developing countries, new strategies to incentivize innovation are required).

51. See *id.* at 99-105 (explaining financial strategies such as pull and push mechanism, advance purchasing and orphan drug laws to promote innovation).

line between generic drugs and counterfeit drugs and imposing strict regulations to eliminate counterfeit drugs. Regulating counterfeit drugs through ACTA can have two positive effects. First, casualties caused by dangerous counterfeit drugs can be eliminated. Second, by gaining back the market share held by counterfeit drugs, pharmaceutical companies can increase their revenue and thus have more financial support for their research and development. However, it is important not to confuse generic drugs with counterfeit drugs since elimination of generic alternatives can only cause restricted access to medicine in developing countries.

A counterfeit drug is a medicine “which is deliberately and fraudulently mislabeled with respect to identity and source.”⁵² Unlike generic drugs, counterfeit drugs can have incorrect or inactive ingredients that can cause injuries or even death, instead of curing a disease.⁵³ Counterfeit drugs are extremely profitable because there is a high demand for affordable medicine from the large poor populations in developing countries.⁵⁴ Many customers in developing countries cannot distinguish between counterfeit drugs and generic drugs.⁵⁵ In Africa, counterfeit drugs encompass up to thirty percent of all medicines sold among developing African nations.⁵⁶ Inadequate knowledge and insufficient regulations continue to contribute to the expansion of counterfeit drugs.⁵⁷

In 2006, the World Health Organization formed an international partnership called IMPACT to combat counterfeit drugs.⁵⁸ IMPACT’s goal is to “eradicate counterfeit drugs by influencing legislation and increasing awareness”.⁵⁹ There has not yet been an international treaty to regulate counterfeit drugs.⁶⁰ ACTA can be the first international treaty to regulate counterfeit drugs by imposing criminal and civil penalties for the production and distribution of counterfeit medicines, while keeping a wide door open to the production of generic drugs and compulsory

52. Amanda Chaves, *A Growing Headache: The Prevalence of International Counterfeit Pharmaceutical Trade in Developing African Nations*, 32 Suffolk Transnat'l Rev. 631, 633 (2009).

53. *Id.* at 637.

54. *Id.* at 635.

55. *Id.* at 637.

56. *Id.* at 636.

57. *Id.* at 637.

58. Chaves, *supra* note 45 at 644.

59. *Id.* at 645.

60. *Id.* at 646.

licensing.⁶¹

IV. Preemptive Power of TRIPS Over Regional Treaties

As mentioned in the introduction, flexibilities in multinational treaties such as TRIPS and ACTA can be jeopardized by bilateral and regional TRIPS-plus agreements.⁶² TRIPS-plus agreements include intellectual property provisions in Free Trade Agreements between developed countries and developing countries, and they usually impose stricter domestic intellectual property enforcement than the multinational treaties.⁶³

The TRIPS-plus provisions are usually unfair negotiations resulting from unequal economic power between the negotiating nations.⁶⁴ Developing nations are forced to agree upon the TRIPS-plus provisions in obtaining other bigger trade benefits.⁶⁵ The U.S. and the EU are known to have non-negotiable 'template' intellectual property chapters for the FTAs.⁶⁶

For example, TRIPS-plus provisions in the U.S. bilateral and multilateral Free Trade Agreements include "limiting the potential exclusions from patentability, requiring the grant of patents for 'new uses' of known compounds, requiring the extension of patent terms under certain conditions, preventing parallel importation, limiting the ground on which compulsory licenses can be granted, and permitting the prosecution of non-violation nullification or impairment claims."⁶⁷ Any country that agrees to a Free Trade Agreement with the U.S. is bound by this term, which clearly limits or eradicates the flexibility provisions provided in the TRIPS Agreement and the Doha Declaration.⁶⁸

It is true that the TRIPS Agreement allows the member nations to enact stricter enforcement provisions.⁶⁹ However, international law allows nations to make an international agreement with other nations under a condition that such agreements do not conflict with other international agreements of these nations.⁷⁰

Thus, TRIPS-plus add-on intellectual property provisions, such as the intellectual property provisions in FTAs, are international agreements that must obey the minimum standard and frameworks of the TRIPS Agreement to comply with basic international law.⁷¹ It can then be said that by enforcing stricter intellectual property standards and taking benefits of the TRIPS Agreement away from developing nations, the TRIPS-plus provisions deteriorate the TRIPS Agreement in violation of international law.⁷²

By continuing to push TRIPS-plus provisions, the U.S. and EU are violating an international treaty and standards that are viewed necessary by the rest of the world.⁷³ One way to resolve the problems caused by the TRIPS-plus agreements can be adopting a provision in ACTA that requires all of the negotiating nations to abide by the international treaties, such as ACTA and the TRIPS Agreement, prior to regional TRIPS-plus agreements. This provision will provide preemptive power to ACTA and the TRIPS Agreement over the TRIPS-plus provisions and deem conflicting TRIPS-plus provisions unenforceable.

Concerns regarding access to medicines in developing countries keep growing each day. The upcoming Anti-Counterfeiting Trade Agreement needs to demonstrate a new way to enforce intellectual property rights while preserving adequate access to medicine for developing countries. One way of supporting access to medicine is to provide wider access to generic drugs by allowing more compulsory licensing. Introduction of generic drugs in a market brings down drug prices and can offer greater access to essential medicine.

Introduction of generics lowers drug prices but also deters research and development of new drugs by pharmaceutical companies. There needs to be global research support mechanisms in place to encourage further innovation. In addition, by eradicating counterfeit drugs while carefully distinguishing them from generic drugs, ACTA can increase total revenue for pharmaceutical companies, and thus more money can be used for more research and development of new drugs.

However, all of these flexibilities and efforts for greater access to medicine can only be successful

61. *Id.* at 647.

62. Bhatt, *supra* note 5, at 618.

63. *Id.*

64. Frankel, *supra* note 3 at 1024.

65. *Id.*

66. *Id.*

67. *See also* Bhatt, *supra* note 5, at 618.

68. *Id.*

69. Frankel, *supra* note 3 at 1040.

70. *Id.*

71. *Id.*

72. *Id.*

73. Bhatt, *supra* note 5 at 619.

if all the parties to the treaty abide by it prior to other bilateral and regional agreements. If the U.S. and other members of the WTO are dedicated to increase access to medicine and the right to health, they should agree to adopt and abide by multinational treaties such as TRIPS and ACTA over the provisions in the TRIPS-plus agreements.

Online Auction Sites and Inconsistencies: A Case Study of France, China, and the United States

By Won Hee Elaine Lee¹

Globalization and the proliferation of Internet use have diluted the concept of national boundaries. Consequently, it is increasingly difficult for brand owners to enforce and protect their trademarks on the Internet, and online auction sites in particular. For instance, the leading online auction site eBay had over 90.1 million active users worldwide at the end of 2009, and generated over \$770.6 million of operating cash flow during the fourth quarter of 2010.² However, while online auction sites give consumers a wide range of choices, they have increasingly become a battleground for trademark disputes because of their sales of counterfeits.

In an attempt to protect their brands from counterfeit goods sold on online auction sites, brand owners increasingly seek relief from third-party sites such as eBay, rather than directly from sellers of counterfeits.³ Despite the global nature of Internet websites, brand owners generally need to acquire trademark rights on a country-by-country basis.⁴ Thus, in the absence of binding multilateral treaties or international law that regulates the sale of counterfeits on online auction sites, ownership of a trademark in one country does

not guarantee ownership in another unless the national prerequisites for acquiring such rights are satisfied.⁵ Such differences have recently yielded inconsistent court decisions in France, China, and the United States regarding counterfeit claims against eBay and Taobao. These inconsistent holdings suggest the need for a coherent international enforcement agenda to address counterfeit concerns in the context of e-commerce.

This article will discuss the French, Chinese, and the United States courts' inconsistent judicial interpretation over eBay and Taobao for the same conduct, namely allowing counterfeit goods to be sold on their auction sites. The article will also delineate current international protective mechanisms for brand owners to protect against counterfeits, and it will suggest possible enforcement mechanisms to resolve inconsistency in the courts' decisions regarding online auction sites.

I. The French Approach

France is home to a number of the world's most famous luxury brands, including Louis Vuitton, Chanel, and Christian Dior. Accordingly, "French regulations established a broad system to protect luxury brands from counterfeiting."⁶ The National Anti-Counterfeiting Committee was created in 1994 to "apprise the public of the 'dangers' of counterfeiting, and to ensure public compliance with anti-counterfeiting laws."⁷ Moreover, current French law not only "requires mandatory forfeiture of counterfeit goods," but also imposes fines and jail time.⁸ Consequently, trademark owners in France work closely with the French government to

5. *Id.*

6. Sofia H. Ahmed, *Life, Liberty, and the Pursuit of Luxury: eBay's Liability for Contributory Trademark Infringement in the United States, Germany, and France*, 5 *BYU Int'l L. & Mgmt. Rev.* 247, 250 (2009).

7. *Id.*

8. *Id.* In France, buying or carrying a counterfeit product is a criminal offense that can result in up to three years in prison or fines up to 300,000 euros. *Id.*

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2. Press Release, eBay, eBay Inc. Reports Fourth Quarter and Full Year 2009 Result 1, 11 (Jan. 20, 2010), http://files.shareholder.com/downloads/eBay/896102080x0x345224/b455630d-4bb9-4ba5-adb1-40dcf29e82ce/eBay_Q409EarningsRelease.pdf.

3. Eric P. Schroeder, *Trademarks, the Internet, and the New Social Media: A Fresh Battleground for Old Principles*, in *Recent Trends in Trademark Protection: Leading Lawyers on Analyzing Recent Decisions and Adapting to Evolutions in Trademark Law*, 1 (2009). Such claims are known as secondary liability in which the complainants sue "secondary" infringers, such as distributors, in addition to or instead of the direct infringer. See Mark Bartholomew & John Tehranian, *The Secret Life of Legal Doctrine: The Divergent Evolution of Secondary Liability in Trademark and Copyright Law*, 21 *Berkeley Tech. L.J.* 1363, 1364 (2006).

4. Robert W. Sacoff, *Trademark Law in the Technology-Driven Global Marketplace*, 4 *Yale Symp. on L. & Tech.* 8, 8 (2001).

fight counterfeits at every level of the distribution chain, including the consumer level.⁹ Overall, the French courts provide strong trademark protection for the many high-end designers that are based in France.¹⁰

In 2006, Louis Vuitton Moet Hennessy (LVMH) filed a lawsuit against eBay in the Paris Commercial Court (PCC).¹¹ Although France has statutory protections for online auction sites that merely act as a host for the sale of counterfeit goods,¹² the PCC found against eBay in this matter on June 30, 2008, reasoning that eBay had not taken sufficient measures to prevent transactions involving counterfeiting goods on its site.¹³ The PCC held that eBay was acting not just as a host, but also as a broker, because eBay received commissions from transactions between sellers and buyers. The PCC also stated that eBay facilitated the selling and marketing of counterfeit products on a large scale through electronic means, and such conduct made eBay responsible for the infringement that occurred on its website. The PCC particularly faulted eBay for its failure to prevent illegal sales, stating, “eBay defaulted its obligation of insuring that its business does not generate any illicit actions like] infringement.”¹⁴ In addition to equitable remedies against eBay, LVMH was awarded about eight million euros in compensatory damages for eBay’s tortious use of the rights of the owner, ten million euros for damage to the image of LVMH, and one million euros in moral damages, totaling almost twenty million euros.¹⁵

The PCC recognized the problems resulting from the imbalance between the rapid expansion of e-commerce due to globalization and the relatively slow development of enforcement in both national and international e-commerce contexts. The PCC stated that “the globalization of trade and the appearance of new means of communication connected with free trade have fostered the marketing of fraudulent products, among them those that are the result of infringement, that

scourge of the legal economy”¹⁶ The PCC’s decision could be interpreted as a judicial initiative to prevent the proliferation of counterfeit goods in the online context and to protect brand names and their accompanying values in creative industries like fashion, which are a crucial part of France’s economy and national heritage.

II. *The Chinese Approach*

The counterfeiting of trademarks and brands in the People’s Republic of China is one of the most serious counterfeiting problems in the world. Trademark and brand owners suffer estimated losses of billions—or even tens of billions—of dollars per year as a result of the counterfeit trade in China.¹⁷ Moreover, China is one of the fastest-growing markets for online auctions. For instance, in March 2007, there were no less than 601,145 auctions for seven leading brands at Taobao, and most of them were presumably counterfeit goods.¹⁸ Taobao has implemented a system in which brand owners can ask the auction site to take down auctions under certain conditions.¹⁹ However, due to the large number of auctions at any given time, the system is not sufficient to protect brand owners.

Despite a large number of counterfeits sold on China’s online auction sites, Chinese courts have been unwilling to hold auction sites, such as Taobao and eBay, liable for trademark infringement.²⁰ For instance, in *Puma AG Rudolf Dassler Sport v. Taobao.com*,²¹ the Guangzhou Intermediate People’s Court dismissed the brand owners’ claim and held for online auction sites.²² Puma registered its Puma word mark, a figurative mark, and its Puma word and device mark in China in 1978.²³ Before filing a lawsuit in 2006, Puma sent a warning letter to Taobao requesting that Taobao terminate the accounts of infringing online stores.²⁴ However, Taobao did not reply to the letter and continued to provide its

9. *Id.*

10. David P. Miranda, *Protecting Trademarks in the Global Marketplace*, 81 N.Y. St. B.J. 50, 51 (2009).

11. See *SA Louis Vuitton Malletier v. eBay*, Tribunal de Commerce de Paris T.C.] Commercial Court] Paris, June 30, 2008.. Also note that, in *Christian Dior Couture SA v. eBay, Inc. et al.*, the Paris Commercial Court (PCC) made a decision identical to the holding of *Louis Vuitton*.

12. See Miranda, *supra* note 9, at 51.

13. See *SA Louis Vuitton Malletier* at 10.

14. *Id.*

15. *Id.* at 13, 15.

16. *Id.* at 9.

17. Daniel C.K. Chow, *Counterfeiting in the People’s Republic of China*, 78 Wash. U. L.Q. 1, 3 (2000).

18. *Asia and the Internet Top Challenges for Brand Owners*, News (Marques/The Association of European Trade Mark Owners, Leicester, U.K.), Mar. 2007, at 1.

19. *Id.*

20. Xenia P. Kobylarz, *Looking For Deep Pockets: Brand Owners Look to Shift Enforcement Burdens to Third Parties*, 5 Internet L. & Strategy 4, 4 (2007).

21. See Kangxin Partners PC, *China*, World Trademark Review, Feb./Mar. 2009, at 60.

22. Kobylarz, *supra* note 21.

23. Kangxin Partners PC, *supra* note 22.

24. *Id.*

services to the online stores.²⁵

In June 2006, Puma took action against Taobao's refusal to comply with its request and sued a store owner listed on Taobao. Puma also named Taobao as a defendant because the website provided online services to the store owner, thereby enabling the store owner to sell counterfeit goods via Taobao's website.²⁶ Puma alleged that Taobao provided network services for 43,932 online stores to sell counterfeit Puma products.²⁷ Although the court found the store owner liable for trademark infringement, the court did not hold Taobao liable for any infringement, reasoning that Taobao does not have direct involvement in the sale of counterfeit goods. Puma alleged that Taobao has a duty to check whether the users of Taobao's services have the legitimate right to sell a trademarked product. The court, however, found that there is no legal basis for Puma's claim because the duty sought by Puma would extend far past Taobao's capabilities. The judges further held that online auction sites have a legal duty to remove auctions after proper notice by the trademark holder, but they have no duty to proactively monitor and investigate all the auctions or users.

In recent years, China has made significant progress toward enhancing trademark protection for brand owners in the offline context.²⁸ However, the *Puma v. Taobao.com* decision demonstrates the relatively weak and undeveloped Chinese trademark enforcement law for preventing infringement resulting from Internet sales. Currently, China has 253 million Internet users, constituting only 19 percent of the total Chinese population.²⁹ Thus, there is a reasonable expectation that the number of Internet users and activities on online auction sites will continue to rise. Consequently,

developing stronger protective mechanisms will become increasingly important in the context of e-commerce to protect brand owners from trademark infringement.

III. The American Approach

In the United States, the protection for trademark owners is largely based on the provisions of the Lanham Act,³⁰ which imposes civil penalties for trademark infringement but does not account for trafficking in counterfeit goods. However, in 2006, Congress enacted the Stop Counterfeiting in Manufactured Goods Act, which incorporates criminal laws in the Lanham Act to prevent the proliferation of counterfeit goods, especially those from Asia.³¹

Despite the heightened enforcement mechanism for trademark infringement, there are no laws that govern the selling of counterfeit goods on online auction sites. Online auction sites often do not have permission from the trademark holders to sell the products advertised on their sites. These products are frequently counterfeit, but are sold under the pretense of being the real thing, thereby confusing consumers and damaging the manufacturer's brand.

The most recent case deciding third-party hosting websites' liability for trademark infringement in the United States was the Southern District of New York's 2008 decision in *Tiffany, Inc. v. eBay, Inc.*³² Tiffany & Co., a luxury jewelry brand, sued eBay, alleging that thousands of pieces of counterfeit jewelry were offered for sale on eBay's website. Tiffany sought to hold eBay liable for trademark infringement, false advertising, and trademark dilution, on the grounds that eBay allowed and facilitated the sale of counterfeit goods on its website. The main issue in the case was not whether counterfeit Tiffany jewelry can appear on eBay, but rather, who has the burden of policing Tiffany's trademark in an e-commerce context.³³ The court held for eBay, concluding that Tiffany failed to bear its burden of protecting its trademark.³⁴ The court held

25. *Id.*

26. *Id.*

27. *Id.*

28. For instance, in 2001, China joined the World Trade Organization (WTO), which obligates China to adhere to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In order to meet the TRIPS requirements, the Chinese legislature amended the existing trademark laws. For example, the amended Article 13 of the 2001 Chinese Trademark Law closely resembles Article 16 of the TRIPS' provision regarding the recognition and protection of well-known marks. Moreover, China signed bilateral treaties with many foreign countries, such as Canada, France, and the United States, to facilitate and protect trademark registration and protection in each other's territory. See Robert H. Hu, *International Legal Protection of Trademarks in China*, 13 Marq. Intell. Prop. L. Rev. 69, 91-93 (2009).

29. Kangxin Partners PC, *supra* note 22.

30. 15 U.S.C. § 1114 *et seq.* (2005).

31. 18 U.S.C. § 2320 (2008); see also Ahmed, *supra* note 5, at 252-53.

32. 576 F. Supp. 2d 463 (S.D.N.Y. 2008).

33. *Id.* at 469. Tiffany also claimed that eBay was directly liable for trademark infringement. Tiffany alleged that the use of registered Tiffany's trademark on eBay's website constitute illegal use of its mark. However, the court held that such use of eBay constituted nominative fair use and thus, eBay is not directly liable for the trademark infringement.

34. *Id.* at 470.

that Tiffany must show that eBay had direct control and monitoring over the sale of counterfeit items.³⁵ Thus, the court rejected Tiffany's notion that liability could be premised on the generalized knowledge that eBay's site might be used as a venue for trademark infringement.³⁶

Regarding Tiffany's claim of trademark infringement, the court found that eBay was not liable for selling counterfeit goods on its website.³⁷ The court determined that the correct test was not whether eBay could reasonably anticipate possible infringement, but whether eBay continued to supply its services to sellers once it knew or had reason to know of infringement by such sellers.³⁸ Thus, following the Ninth Circuit's persuasive authority established in *Lockheed Martin Corp. v. NSI*,³⁹ the Southern District of New York held that if liability is premised on the conduct of a user of a venue, as opposed to that of a manufacturer or seller of a product, the plaintiff must make a threshold showing of direct control and monitoring over the means of infringement.⁴⁰ The court in *Tiffany* decided that eBay did not infringe Tiffany's trademark because it did not have sufficient knowledge of specific acts of infringement on its site and it acted appropriately to discontinue an infringing listing when it discovered a counterfeit product on its site.⁴¹

The Second Circuit recently affirmed the district court's decision that denied Tiffany's third party liability claim against eBay.⁴² Like the district court, the Second

Circuit delineated that for contributory trademark infringement liability to lie, a service provider must have more than a general knowledge or reason to know that its service is being used to sell counterfeit goods. The Second Circuit noted that some contemporary knowledge of which particular listings are infringing or will infringe in the future is necessary. The Second Circuit took into consideration that eBay does not have such contemporary or specific knowledge, and held that eBay is not contributorily liable for trademark infringement.

The decision in *Tiffany, Inc. v. eBay, Inc.* demonstrates the difficulty of holding online auction sites liable for trademark infringement because operators of these websites often do not have specific knowledge of counterfeiting activity on their sites. The decision also shows the lack of adequate protective measures available to brand owners to protect their trademarks in an online context under U.S. law.

IV. What Resulted in the Different Holdings on Rights for Trademark Owners

Recent court decisions in suits against online auction sites in France, China, and the United States have resulted in differing decisions, creating uncertainty and confusion about trademark infringement cases in an online context. These three countries each reached different conclusions based on the application and analysis of their respective national trademark laws.⁴³

The *Puma* court in China and the *Tiffany* court in the U.S. both found for the online auction sites; however, their reasons for reaching the decisions were relatively different from one another. The Chinese court did not find Taobao liable for infringement mainly because the court was unwilling to impose a burden on the online auction sites to proactively monitor online infringement. On the other hand, the U.S. court held

claim against eBay. However, unlike the district court, the Second Circuit did not dismiss Tiffany's direct infringement claim based on normative fair use doctrine. Instead, the Second Circuit "recognized that a defendant may lawfully use a plaintiff's trademark where doing so is necessary to describe the plaintiff's product and does not imply a false affiliation or endorsement by the plaintiff or the defendant" and agreed with the district court that eBay's use of Tiffany's mark on its website and in sponsored links was lawful. The Second Circuit noted that eBay used the mark "to describe accurately the genuine Tiffany goods offered for sale on its website. And none of eBay's uses of the mark suggested that Tiffany affiliated itself with eBay or endorsed the sale of its products through eBay's website."

43. See Ahmed, *supra* note 5.

35. *Id.* at 506.

36. *Id.* at 513.

37. *Id.* at 469.

38. *Id.*

39. 194 F.3d 980, 986-87 (9th Cir. 1999) (holding that contributory trademark infringement does not occur when the defendant neither intentionally induces a third party to infringe the plaintiff's mark nor supplies a product to a third party with actual or constructive knowledge that the product is being used to infringe the service mark).

40. *Tiffany*, 576 F. Supp. 2d at 509.

41. eBay was also relieved of liability partly because of its protective measures against counterfeiting goods, such as a Verified Rights Owner (VeRO) Program. See eBay, Summary of Our Privacy Policy – Our Disclosure of Your Information (eBay's Verified Rights Owner (VeRO) Program), <http://pages.ebay.com/help/policies/privacy-policy.html>. The Program allows brand owners, such as Tiffany, to report and have unauthorized items be removed from the site. However, unlike eBay, many other online auction and e-commerce sites do not actively deter the sale of counterfeit goods. It is unclear whether the VeRO Program effectively deters and prevents the sales of all the counterfeits on eBay.

42. *Tiffany, Inc. v. eBay, Inc.*, ___ F.3d ___, 2010 WL 1236315 (2d Cir. Apr. 1, 2010). The Second Circuit affirmed the district court's decision and dismissed Tiffany's direct trademark infringement

for eBay in *Tiffany* because the court believed that Tiffany failed to show that eBay had direct control and monitoring of the selling of counterfeit goods in its auctions.⁴⁴ Thus, the *Tiffany* holding demonstrates that the Second Circuit will not hold online auction sites liable based on a mere showing of general knowledge of counterfeit goods sales or on a showing of simple negligence on the part of the online auction sites. Further, the Second Circuit's decision demonstrates that although the court requires eBay to engage in self-monitoring, it recognizes that trademark rights are private rights most effectively enforced by trademark owners.⁴⁵

Contrary to the Guangzhou Intermediate People's Court and the Second Circuit, the PCC court enforced stricter rules against eBay and found in favor of the brand owners. In *Louis Vuitton*, the court considered eBay a broker rather than mere host of the sale of counterfeits. The PCC believed that eBay's interactive features such as marketing tools for sellers that provides information on brands, user-created virtual stores, and PowerSeller program for users⁴⁶ were sufficient to consider eBay a broker.⁴⁷ The PCC stated that the interactive features eBay offers its users demonstrate that eBay has sufficient control over the sellers on its site and was not acting merely as a host. The PCC also noted that eBay received commission from the sellers, thereby acting as an intermediary rather than just a

host. The PCC concluded that eBay's knowledge of improper activity was sufficient to establish that eBay was negligent in taking adequate measures to prevent the sales of counterfeits on its website.

These contrasting opinions recently decided in French, Chinese, and American courts indicate their different approaches to trademark infringement in the online context. While the PCC believes that the online auction site should bear the responsibility of monitoring its own site, the Chinese and the U.S. courts believe that trademark owners should be responsible for monitoring and protecting their own marks. These inconsistent holdings suggest a need for coherent international measures to govern trademark infringement cases in an online context because online auction sites are not confined by national boundaries.

V. Possible Methods to Resolve Inconsistent Holdings in the E-Commerce Context

The international trademark community has continuously made efforts to facilitate the registration and protection of trademarks. As of December 2009, more than 84 countries have signed the Madrid Protocol, which aims to reduce obstacles and costs associated with registering trademarks in multiple countries.⁴⁸ In addition, the World Intellectual Property Organization (WIPO) provides remedies for trademark owners who were injured by bad-faith registrations and the illegal use of their marks in domain names.⁴⁹ Despite the aforementioned protections for trademark owners, effective enforcement of trademark rights in the context of e-commerce still remains difficult.⁵⁰

Moreover, the inconsistencies in national trademark law regarding trademark infringement and counterfeiting on online auction sites have yielded inconsistent holdings among different countries. Currently, in the United States and China, trademark owners bear a larger burden of protecting the reputation and use of their marks than the online auction sites on which their goods are sold. On the other hand, in France, the burden of protection falls on Internet auction sites who act as brokers. These inconsistencies not only disadvantage trademark owners but also confuse online auction sites because the sites have difficulty reconciling their conduct with the trademark

44. Although both the *Puma* and *Tiffany* courts held for Taobao.com and eBay, respectively, the approaches of the two courts seem different. The *Puma* court seems more lenient toward the online auction site because even though Taobao.com did not respond to Puma's letter requiring Taobao.com to terminate services to the virtual stores selling counterfeits, the court held in favor of Taobao.com. On the other hand, in *Tiffany*, when Tiffany sent a complaint letter to eBay, eBay promptly removed the auctions involving trademark infringement and counterfeits. However, eBay rejected Tiffany's request to remove "apparently infringing" auction listings, such as a multiple listings of Tiffany items by a seller. Thus, the *Tiffany* court seems to view that eBay does not have intent to create a forum for selling counterfeits because eBay acted promptly upon the Tiffany's complaint to remove counterfeit auctions. See Kangxin Partners PC, *supra* note 22; *Tiffany*, 576 F. Supp. 2d at 506.

45. See Ahmed, *supra* note 5, at 248.

46. A PowerSeller is an eBay seller who achieves a sustained total trading volume above a set cut-off for several months in a row. PowerSellers can be identified by a "PowerSeller" logo shown after their eBay User ID in their auction listings in eBay.

47. See Ahmed, *supra* note 5, at 266. Like the U.S., France also has statutory protections for Internet websites that merely act as hosts for counterfeit sales. However, the PCC saw eBay not merely acting as a host but rather as a broker. Consequently, the PCC did not apply the statutory protections for eBay and held it liable. See Miranda, *supra* note 9, at 51.

48. See Miranda, *supra* note 9, at 50.

49. See *id.*

50. See *id.*

laws of every country in which they have a presence. In order to alleviate and reduce inconsistencies regarding trademark infringement and counterfeiting on online auction sites, the development of binding international mechanisms with both flexible and tailored standards should be implemented.

VI. The International Trademark Association (INTA)'s Alternative Dispute Resolution System

Applying a national standard to an online auction site, which is a borderless medium for commercial activities, is difficult and inadequate. Instead of litigating under domestic laws, brand owners and online auction sites may settle trademark disputes and arrive at a solution more efficiently and effectively through a mediation process supported by the International Trademark Association (INTA).⁵¹ Although INTA's mediation program currently only settles disputes regarding trademark registrations and domain names, the program could be expanded to address disputes between trademark owners and online auction sites.

While litigation is often bound by specific domestic laws, a mediation process is flexible in terms of the choice of law. Mediation allows the involved parties to reach a more satisfactory solution in a relatively short period of time. A mediation process may also cover a broad range of trademark disputes, ranging from trademark infringement claims to misappropriation. Neutral panels comprised of broad geographical diversity facilitate the mediation process, which is not limited by any court or statutory restraints. Consequently, when a dispute between brand owners and an online auction site arises, mediation could function as an effective alternative to litigation because the involved parties are

51. Mediation is one form of Alternative Dispute Resolution (ADR) for avoiding or settling litigation. It is "a non-binding negotiation between adversaries that is conducted with the assistance of, and often through, an experienced neutral third party." See Thomas M. Onda, *Navigating Trademark Trial & Appeal Board Practice 2002*, 689 PLI/Pat 61, 63, 67 (2002); one of the roles of the International Trade Association (INTA) is to protect trademark globally by curtailing counterfeiting problems in various regions and countries. INTA has developed various Alternative Dispute Resolution (ADR) Programs, such as mediation and arbitration, to provide customized options and more flexibility for parties with conflicts involving trademark and related issues. See David C. Stimson, *INTA and ASEAN or Around the World in a State-Free Haze*, 93 Trademark Rep. 105, 109 (2003); see also International Trademark Association, *Alternative Dispute Resolution (ADR)*, available at http://www.inta.org/index.php?option=com_content&task=view&id=71&Itemid=219&getcontent=4 (last visited on November 13, 2009).

not bound by a specific jurisdiction and its domestic laws. Thus, the parties would have more choices in terms of applicable laws, possible solutions, and enforcement agendas, eliminating some of the confusion about who bears the burden of policing the sales of counterfeits in an e-commerce context.

VII. Anti-Counterfeiting Trade Agreement (ACTA): A Possible Solution?

In addition to the mediation process, implementation of binding international law to protect brand owners against the mass sale of counterfeit goods in online auction sites could alleviate the effect of inconsistent international enforcement of trademark infringement disputes between brand owners and online auction sites. The international law would only apply to infringement in the online context, creating an international standard for countries to follow when applying trademark law to online auction sites selling counterfeit goods. The standard would provide a consistent standard for courts and online auctions sites to follow in cases involving online sales of counterfeit products.

The proposed multilateral Anti-Counterfeiting Trade Agreement (ACTA) would implement stronger enforcement in response to the increase in global trade of counterfeit goods and pirated copyright protected works.⁵² The scope of ACTA is broad, addressing not only counterfeit physical goods but also Internet distribution and information technology. Although the secrecy and no-open-negotiation process of ACTA generate criticism about the document, its broad scope could create a uniform and coherent enforcement mechanism regarding trademark infringement on online auction sites.

ACTA seeks to impose a stronger international enforcement agenda than that of the existing bilateral agreements. For instance, ACTA aims to create an agreement not between several countries, but rather, a global standard on copyright infringement without going through a multilateral process.⁵³ ACTA attempts to apply enforcement mechanisms from the top down rather than allowing individual countries to select their

52. Anti-Counterfeiting Trade Agreement, European Commission Trade, http://trade.ec.europa.eu/doclib/docs/2009/january/tradoc_142039.pdf.

53. See Margot Kaminski, *The Origins and Potential Impact of the Anti-Counterfeiting Trade Agreement (ACTA)*, 34 Yale J. Int'l L. 247, 250 (2009).

own adequate levels of prevention and protection.⁵⁴

Although the main focus of ACTA is copyright protection, ACTA could also be used as a tool for heightened enforcement mechanisms in the trademark realm. ACTA's goal is to establish global standards that effectively enforce intellectual property rights in order to fight the growing problem of counterfeiting and piracy more efficiently. Further, ACTA's focus is on counterfeiting and piracy activities that significantly affect commercial interests, rather than on the activities of ordinary citizens. Online auction sites are a growing hub for counterfeiting activities in the commercial context and a new battleground for trademark infringement. Thus, ACTA could set up a standard for stricter enforcement measures for trademark protection, especially on the Internet. For instance, according to the Office of the United States Trade Representative, ACTA would impose strict enforcement of intellectual property rights related to Internet activity. If ACTA proposes or implements global enforcement mechanisms for trademark infringement similar to those for copyright, then ACTA could facilitate the development of coherent or uniform standards for trademark infringement in online auction sites. Further, because ACTA is based on the rationale of heightened enforcement of intellectual property rights, creating a trademark infringement protection mechanism in the online context would encourage courts in member countries to consider the worldwide effect of their decisions and strive for globally consistent decisions. Consequently, if ACTA implemented a binding global standard to prevent trademark infringement in the online context, future decisions in online auction site cases would likely be more similar to the decision of the PCC than Guangzhou Intermediate People's Court or the Second Circuit.⁵⁵ However, one should note that stronger enforcement mechanisms that favor brand owners may place unreasonable burdens on online auction sites and on consumers who wish to sell or purchase legal products.

VIII. Responsibilities of Online Auction Sites and

54. *Feds Release Info on Plans to Stop Theft of Intellectual Property*, 26 *Andrews Computer & Internet Litig. Rep.* 5 (2009).

55. Currently, the French court imposes stricter enforcement in such context than the Chinese or the U.S. courts. One of the rationales for stricter holding in France is to dissuade online auction sites from selling counterfeits on their websites by imposing strict liabilities and burdens upon them. Such rationale seems similar to ACTA's objective, which is to pursue globally binding, stronger intellectual property protection for online counterfeiting and piracy.

Trademark Owners

In addition to implementing a uniform enforcement mechanism in the global context, online auction sites should take more vigorous measures to prevent the sale of counterfeit goods on their websites. After eBay's loss in France, John Pluhowski, eBay's Vice President of Corporate Communication, stated that eBay "devotes] more resources to fighting] counterfeits than most brands."⁵⁶ He further contended that eBay "invests] more than \$20 million a year and has] some 20,000 employees worldwide involved in monitoring eBay] . . . to fight fraud."⁵⁷ Mr. Pluhowski also pointed out that eBay shut down nearly 2.1 million listings and suspended 30,000 sellers who sold "suspicious" goods in 2008.⁵⁸ In order to prevent selling counterfeits on online auction sites, it is important to provide their users with incentives to not engage in the selling of counterfeit goods. Thus, stronger and stricter mechanisms, such as imposing fines or holding credits, could deter people from engaging in illegal activities.

Furthermore, trademark owners should acknowledge that online auction sites are the world's largest and fastest growing channels of commerce. Trademark owners must use these websites to promote brands rather than trying to suppress the proliferation of online auction sites simply to prevent the sale of counterfeit goods. Open communication between trademark owners and online auction sites is essential because online auction sites often act as "online ambassadors of the brand."⁵⁹ Trademark owners must also leverage the reporting systems implemented by the online auction sites and offer additional solutions, if necessary. Preventative steps taken by the trademark owners would at least minimize, if not prevent, the sale of counterfeit goods on online auction sites.

IX. Conclusion

Over the past two years, eBay has been involved in numerous lawsuits in multiple countries. Three courts in France, China, and the U.S. each reached conflicting conclusions on trademark infringement in the online context, and they fundamentally disagreed on the whether eBay's anti-counterfeiting efforts were

56. Robert Klara, *The Fight Against Fakes*, *Brandweek*, Jun. 27, 2009.

57. *Id.*

58. *Id.*

59. *Id.*

sufficient. Protecting trademark owners and reducing the sales of counterfeit goods on online auction sites are important goals. These goals, however, should not be achieved by destroying the business model of online auction sites. If a consistent international legal standard were created to protect trademark owners from counterfeits sold on online auction sites and to strengthen the interdependency between online auction sites and trademark owners, the sale of counterfeits could be prevented without sacrificing a burgeoning channels of commerce. Thus, brand owners and online auction sites must work together to propose a concrete way to effectively prevent the sale of counterfeit goods on online auction sites. Although litigation based on domestic laws may sometimes provide adequate remedies for trademark and brand owners, domestic laws often do not keep up with the pace of globalization. Means of commerce are constantly changing in the integrated economic world. Consequently, in order to effectively prevent trademark infringement on online auction sites, brand owners and online auction sites should try to resolve disputes through a mediation process designed for an international context rather than litigation based on domestic laws. Further, to prevent counterfeiting activities in e-commerce, the development of binding international laws is also necessary to protect brand owners, online auction sites, and consumers.

