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COMMENTS

PROGNOSIS NEGATIVE: WHY THE LANGUAGE OF THE HATCH-WAXMAN ACT SPELLS TROUBLE FOR REVERSE PAYMENT AGREEMENTS

Catherine E. Creely[+]

"The Hatch-Waxman Act created today's generic drug industry" by eliminating previous barriers to generic drug approval.[1] The Hatch-Waxman Act's (HWA) Abbreviated New Drug Applications (ANDAs)[2] changed everything by allowing generic manufacturers to rely on results from expensive studies conducted by the pioneer manufacturer and perform their own limited tests on the drug without infringing the pioneer's

+ B.S., Chemistry, Georgia Southern University; M.S., Chemistry, Virginia Tech; J.D. Candidate, May 2007, The Catholic University of America, Columbus School of Law. The author would like to thank her adorable husband Tom for always pretending to be interested in the subject matter of this article, for packing her lunch every day, and most of all, for making all her dreams come true.

1. Robert D. Bajefsky & Gregory Chopskie, *Biting the Hand That Feeds?: Generic Drugs and Abuse of the Hatch-Waxman Law*, LEGAL BACKGROUNDER (Wash. Legal Found., Wash., D.C.), Dec. 6, 2002, *available at* http://www.wlf.org/upload/120602LBBajefsky.pdf. Generic drugs are a concern to pharmaceutical patent owners because "[p]atent protection gives brand-name companies . . . the sole right to sell a drug for a certain period of time. This allows them to fairly recoup their investment costs." Michelle Meadows, *Greater Access to Generic Drugs*, FDA CONSUMER, Sept.-Oct. 2003, *available at* http://www.fda.gov/fdac/features/2003/503_drug.html. Further, "[a] generic drug can only enter the market after the brand-name patent or other marketing exclusivities have expired and FDA approval is granted." *Id.* The Hatch-Waxman Act (HWA) provided a more efficient and cost-effective way for generic manufacturers to begin marketing generic drugs—the Abreviated New Drug Application (ANDA). *See generally* Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 35, & 42 U.S.C.).

2. Hatch-Waxman Act of 1984 § 101 (codified as amended at 21 U.S.C. § 355(j)(1) (2000 & Supp. III 2003)). Rather than requiring generic drug manufacturers to provide their own safety and efficacy studies, the ANDA permits a bioequivalency certification. 21 U.S.C. § 355(j)(2) (2000 & Supp. III 2003). The bioequivalency certification permits the generic manufacturer to rely on studies already conducted and submitted by the pioneer manufacturer. *Id.*

patent.[3] The HWA resulted from numerous attempts, beginning in the Carter administration, to compensate manufacturers for the amount of a patent term lost to the Food and Drug Administration's (FDA) extensive approval process.[4]

The ANDA includes a certification by the generic manufacturer that it is not infringing any valid patents.[5] This "paragraph IV" certification requires the applicant to inform the patent holder that it has filed an ANDA.[6] Upon notification, the patent holder has forty-five days to file a patent infringement suit against the applicant.[7] The resolution of an in-

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3. *See id.* § 355 (j)(2)(A); *see also* Bajefsky & Chopskie, *supra* note 1. None of this had been possible for drugs approved by the Food and Drug Administration (FDA) after the passage of the Drug Amendments of 1962. H.R. REP. NO. 98-857, pt. 2, at 4-5 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688-89. The HWA amended the 1962 rules by providing the ANDA option for generic manufacturers. *See* Hatch-Waxman Act of 1984 § 101. The ANDA allows generic forms to be tested for the purpose of proving bioequivalency while the pioneer drug is still on patent. H.R. REP. NO. 98-857, pt. 2, at 5.

For generics approved between 1962 and the passage of the HWA, the FDA "adopted the view that generics must virtually duplicate the same health and safety tests conducted by the original applicant for marketing approval." *Id.* at 4. Getting a generic drug approved under the 1962 rules was a long and arduous process that required many repetitive tests. *Id.* This was extremely cost-prohibitive and contributed to the anti-competitive effects of the 1962 rules. *Id.* The overall effect of the rules was "the practical extension of the monopoly position of the patent holder beyond the expiration of the patent." *Id.* The HWA brought needed reform in this area, although it did not come easily. *Cf.* Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 188-89 (1999).

4. Mossinghoff, *supra* note 3, at 188. Patent term restoration developed slowly despite President Carter's domestic policy review in the area and President Reagan's support of a patent term restoration proposal. *Id.* Eventually a bill for patent term restoration passed the Senate, but it was defeated in the House. *Id.* Although the bill obtained a simple majority in the House, it failed to gain the two-thirds majority needed to get the bill off the suspension calendar. *Id.* The failure of this bill prompted Henry Waxman to draft a patent term restoration and drug price competition bill that became the Hatch-Waxman Act of 1984. *Id.*

5. 21 U.S.C. § 355(j)(2)(A)(vii) (2000 & Supp. III 2003). Subsection (2)(A)(iv) states that the ANDA must include:

> information to show that the new drug is bioequivalent to the listed drug . . . [and] information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug . . . and the new drug can be expected to have the same therapeutic effect as the listed drug . . . ."

Id. § 355(j)(2)(A)(iv).

6. *Id.* § 355(b)(3)(C). Specifically, ANDA filers are required to notify

> each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and . . . the holder of the approved application . . . for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

Id. § 355(b)(3)(C)(i)-(ii).

7. *Id.* § 355(c)(3)(C). The statute states that "[i]f the applicant made a certification described in [paragraph IV], the [FDA] approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice . . . is received,

fringement action gives rise to the issue discussed in this Comment. A pioneer manufacturer will sometimes settle an action by ostensibly paying a generic manufacturer to delay its market entry.[8] The question then becomes whether that type of reverse payment is an impermissible extension of the statutory patent term or a valid settlement agreement.[9]

The Sixth and Eleventh Circuits have addressed reverse payments with differing results.[10] The Sixth Circuit has held that reverse payment agreements are clear violations of section 1 of the Sherman Antitrust Act (Sherman Act) and thus per se unlawful.[11] Conversely, the Eleventh Circuit has held that reverse payments should be subjected to a rule of reason analysis specific to patent cases, finding that both the per se rule and the traditional, non-patent specific rule of reason are inappropriate.[12]

This Comment first discusses both the Sherman Act and the Hatch-Waxman Act in order to develop the statutory framework for the cases giving rise to each rule. This Comment then examines the development of the competing rules through three main cases: *Louisiana Wholesale Drug Co. v. Hoechst Marion Roussel, Inc.* (*In re Cardizem CD Anitrust*

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an action is brought for infringement of the patent that is the subject of the certification." *Id.*

8. *See, e.g.*, La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896, 899 (6th Cir. 2003). The reverse payment agreement that was part of the patent infringement suit "provided, in essence, that Andrx, in exchange for quarterly payments of $10 million, would refrain from marketing its generic version of Cardizem CD even after it had received FDA approval." *Id.*; *see also* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1058-59 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006). In *Schering-Plough*, The FTC argued that the payments listed in the settlement agreement were not bona fide royalty payments but rather unreasonable restraints on trade, giving rise to its complaint before the Eleventh Circuit. *Id.* at 1061.

9. *See, e.g.*, Joblove v. Barr Labs. Inc. (*In re* Tamoxifen Citrate Antitrust Litig.), 429 F.3d 370, 374 (2d Cir. 2005), *reprinted as amended*, No. 03-7641, 2006 WL 2401244 (2d Cir. Aug. 10, 2006), *reh'g en banc denied*, No. 03-7641 (2d Cir. Sept. 14, 2006).

10. *Compare In re Cardizem CD Antitrust Litig.*, 332 F.3d at 908 (holding that reverse payment agreements were per se illegal), *with Schering-Plough*, 402 F.3d at 1076 ("[W]e fear and reject a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic's entry date, and, in an ancillary transaction, pays for other products licensed by the generic."). The Second Circuit has also rejected the per se rule in a reverse payment case on slightly different facts. *See generally In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d at 370.

11. *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 907-08 (6th Cir. 2003).

12. *Schering-Plough*, 402 F.3d at 1065 (11th Cir. 2005). Circuit Judge Fay, writing for the court, stated that "[w]e think that neither the rule of reason nor the *per se* analysis is appropriate in this context." *Id.*

Litigation)[13] and *Valley Drug Co. v. Geneva Pharmaceuticals* in the Sixth Circuit,[14] and *Schering-Plough Corp. v. FTC*[15] in the Eleventh Circuit. Next, this Comment analyzes the policy concerns arising from the nexus of patent and antitrust law. The patent-antitrust doctrine is then applied to both the per se rule and the patent rule of reason. The text of the HWA and its legislative history are then analyzed in an effort to discover whether Congress has demonstrated a preference for either the per se rule or a more fact-based patent rule of reason. This Comment concludes that the per se rule most effectively reflects the competing policy concerns arising from both patent and antitrust law as well as the purpose of the HWA. Finally, based on that conclusion, this Comment argues that courts should follow the per sue rule as applied by the Sixth Circuit.

I. THE DEVELOPMENT OF THE PER SE RULE AND THE PATENT RULE OF REASON

A. The Sherman Act Defines Anti-competitive Conduct.

Congress passed the Sherman Act in 1890 in response to increased economic domination by corporations and other business combinations.[16] It outlawed any "contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States."[17] The Sherman Act was not invoked with any real success until

13. 332 F.3d 896 (6th Cir. 2003).

14. 344 F.3d 1294 (11th Cir. 2003).

15. 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006). The Supreme Court's recent denial of certiorari in *Schering-Plough* left the Eleventh Circuit's patent rule of reason in tact. *See id.* However, the Federal Trade Commission has expressed its intention to continue challenging reverse payment agreements in order to create a more defined circuit split or to encourage Congress to act in this area. Jon Leibowitz, Comm'r, Fed. Trade Comm'n, Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck!, Remarks at the Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust (Apr. 24, 2006). In response to those remarks, four senators introduced a bill regarding reverse payment settlements. S. 3582, 109th Cong. (2006). Meanwhile, the Second Circuit has denied rehearing in *In re Tamoxifen Citrate Antitrust Litigation*, affirming its earlier rejection of the per se rule. Joblove v. Barr Labs. Inc. (*In re* Tamoxifen Citrate Antitrust Litig.), 429 F.3d 370, 374 (2d Cir. 2005), *reprinted as amended*, No. 03-7641, 2006 WL 2401244 (2d Cir. Aug. 10, 2006), *reh'g en banc denied*, No. 03-7641 (2d Cir. Sept. 14, 2006).

16. AM. BAR ASS'N SECTION OF ANTITRUST LAW, THE RULE OF REASON 20-21 (1999). The monograph attributes the growth in business combinations during the second half of the nineteenth century to "strength in numbers." *Id.* at 17. At first, there was large growth in the industry, but the growth was accompanied by "inevitable economic downturns." *Id.* With these downturns, "competition intensified [and] profit margins were threatened." *Id.* This increased competition led to "the creation of cartels or 'pools.'" *Id.* (citing N. FLIGSTEIN, THE TRANSFORMATION OF CORPORATE CONTROL 38 (1990)).

17. Sherman Antitrust Act, 15 U.S.C. § 1 (2000), *amended by* Antitrust Criminal Penalty Enhancement and Reform Act of 2004, 15 U.S.C.A. § 1 (West Supp. 2006). The Sherman Act currently imposes hefty penalties for violations, including fines up to one

Northern Securities Co. v. United States, a 1904 case where the United States Supreme Court found activity in restraint of trade, and ruled in favor of the government in its action to break up the Northern Securities Company, a combination of two formerly competing railroads.[18]

Since that time, the Supreme Court has identified several categories of conduct that are per se violations of the Sherman Act, including price fixing, tying, and market allocation schemes.[19] The per se rule only requires the plaintiff to show that the defendant has engaged in prohibited conduct.[20] Thus, no matter how small the anti-competitive effect or how innocent the defendant's intent, a court will find illegality as a matter of law.[21]

In addition to the per se rule, the Supreme Court has applied the rule of reason to anti-competitive conduct.[22] The rule of reason balances the pro-competitive effects of the conduct with the anti-competitive effects.[23]

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hundred million dollars for corporations, one million dollars for individuals, and prison terms of up to ten years. *See id.*; Antitrust Criminal Penalty Enhancement and Reform Act of 2004, Pub. L. No. 108-237, § 215, 118 Stat. 661, 668 (to be codified at 15 U.S.C. §§ 1-3, 16).

18. *See* N. Secs. Co. v. United States, 193 U.S. 197, 321, 360 (1904). In 1901, the Great Northern Railway Company and the Northern Pacific Railway Company combined to form the Northern Securities Company. *Id.* at 321-22. The stockholders of each company were given a substantial interest in the other, thereby forming what the Court found to be an impermissible combination. *Id.* at 323-25. The Court reasoned that since the stockholders had interest in both railroads, it eliminated any motivation for competition between the companies. *Id.* at 326-27.

19. Candice Jones, David S. Lee & Adrian Shin, *Antitrust Violations*, 38 AM. CRIM. L. REV. 431, 435 & n.22, 436 & n.25 (2001). The article cites several cases where the per se rule was applied to conduct that had pernicious anti-competitive effects, limited potential for pro-competitive benefit, had obvious negative economic impact, had no redeeming value, or conduct that was manifestly anti-competitive. *Id.* at 436 n.25.

20. AM. BAR ASS'N SECTION OF ANTITRUST LAW, *supra* note 16, at 3. The monograph further points out that "[a]pplication of the per se approach frees the court from an inquiry into whether the arrangement at issue has actually harmed consumers or thwarted free market competitive forces." *Id.*

21. Richard M. Steuer, Executive Summary of the Antitrust Laws (1999), http://library.findlaw.com/1999/Jan/1/241454.html.

22. AM. BAR ASS'N SECTION OF ANTITRUST LAW, *supra* note 16, at 5. The monograph also recognizes criticisms of the rule of reason analysis. *Id.* Justice Brandeis stated that under the rule of reason, "[t]he true test of illegality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition." *Id.* (quoting Chi. Bd. of Trade v. United States, 246 U.S. 231, 238 (1918)). The monograph points out that "[c]ommentators have long criticized the breadth of Brandeis' statement in *Board of Trade* as 'legitimiz[ing] the "big case" in antitrust.'" *Id.* (alteration in original) (citing Thomas C. Arthur, *Farewell to a Sea of Doubt: Jettisoning the Constitutional Sherman Act*, 74 CAL. L. REV. 263, 303 (1986)); *see also infra* note 71 (containing Justice Brandeis' complete articulation of the rule of reason from *Board of Trade*).

23. *See* AM. BAR ASS'N SECTION OF ANTITRUST LAW, *supra* note 16, at 102. The monograph recognizes that the balancing test used by courts in their application of the rule of reason is "still condemn[ed] . . . as indefinite and unworkable." *Id.* at 102-03. The

The Supreme Court has stated that, under the rule of reason, parties to a patent dispute may exchange consideration to settle their litigation without necessarily engaging in a Sherman Act violation.[24] The basis for the Court's reasoning is that the exchange of rights and royalties in a settlement agreement promotes competition.[25]

B. The Hatch-Waxman Act Amends the 1962 FDA's Generic Drug Approval Process by Establishing Amended New Drug Applications and New Procedures for Obtaining Limited Patent Term Extensions.

Congress passed the HWA in 1984 "to amend the Federal Food, Drug, and Cosmetic Act."[26] In doing so, Congress established the ANDA for equivalent generic drugs, attempted to correct the anti-competitive effects of the 1962 FDA rules on generic drug approval, and provided for a limited patent term extension to compensate pioneer manufacturers for the portion of their patent term consumed by regulatory review.[27]

The HWA contains two relevant titles.[28] The first title specifically authorizes the use of ANDAs by generic drug applicants.[29] It also includes the paragraph IV certification that requires an ANDA filer to certify that

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monograph recognizes two main criticisms: "[f]irst, the nebulous nature of the rule can lead to inconsistent results . . . [s]econd, the modern-day rule is still open-ended and can be unworkable." *Id.* at 103.

24. Standard Oil Co. v. United States, 283 U.S. 163, 170-71 (1931). In *Standard Oil*, the government admitted that it was "not illegal for the primary defendants to cross-license each other and the respective licensees; and that adequate consideration can legally be demanded for such grants." *Id.* at 170.

25. *Id.* at 171. It is important to stress the word "royalties" here. Because reverse payments are not always royalty payments, the *Standard Oil* decision does not always apply in the cases discussed. *See generally* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1075 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006); La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896, 908 (6th Cir. 2003).

26. H.R. REP. NO. 98-857, pt. 2, at 1, 11 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2686, 2695.

27. *Id.* at 4-6. Congress passed the HWA after a long and arduous legislative process. Mossinghoff, *supra* note 3, at 187-88. With this struggle came a wealth of commentary "but not a great deal of coherent legislative history." *Id.* at 187.

28. Hatch-Waxman Act of 1984, Pub. L. No. 98-417, §§ 101, 201, 98 Stat. 1585, 1585, 1598 (1984) (codified as amended at 21 U.S.C. § 355(j) (2000 & Supp. III 2003); 35 U.S.C. § 156 (2000 & Supp. III 2003)). Title I addresses the Abbreviated New Drug Application (ANDA) while Title II concerns patent term extension. *Id.*

29. 21 U.S.C. § 355(j) (2000 & Supp. III 2003). The HWA states that "[a]ny person may file with the Secretary an abbreviated application for the approval of a new drug." *Id.* § 355(j)(1). Further, the ANDA may "show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved" for a listed drug. *Id.* § 355(j)(2)(A)(i). In other words, the ANDA filer can rely on the approval of the pioneer drug to further the approval of the generic drug, which was impossible under the 1962 FDA approval rules. *See supra* note 3 and accompanying text.

its product does not infringe any valid patents.[30] The second title provides for a patent term restoration of up to fourteen years to reimburse the patent holder for the time it takes the FDA to approve a new drug.[31]

While both titles encountered their share of tribulations,[32] Title I was especially contentious due to the paragraph IV certification requirement.[33] The certification must be made to the FDA and any pioneer manufacturer whose product contains a bioequivalent compound.[34] Upon receipt of the certification, a pioneer manufacturer has forty-five days to file a patent infringement suit against the ANDA filer.[35]

If a suit is filed, the FDA imposes a thirty-month stay on approval of the generic drug.[36] If the thirty-month period expires without an unappealable resolution to the patent infringement suit, the FDA may approve the generic product for marketing.[37] The HWA also provides that the patent holder may bring an action for damages if the patent in question is later found valid and infringed.[38]

Reverse payments are, at least in part, attempts by the pioneer patent holder to maintain market share for as long as possible.[39] They work well

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30. 21 U.S.C. § 355(b)(2)(A)(iv). To fully comply with the statute, the ANDA filer must submit a certification "with respect to each patent which claims the drug for which . . . investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection." *Id.* § 355(b)(2)(A). Each certification must include a good faith assertion that either there are no patents claiming the drug, that any existing patents are expired as of the ANDA filing date, or that any existing patents are "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* § 355(b)(2)(A)(i)-(iv).

31. 35 U.S.C. § 156 (2000 & Supp. III 2003).

32. *See* H.R. REP. NO. 98-857, pt. 2, at 3. The HWA first came before Congress during the Ninety-Seventh Congress. *Id.* It was subjected to many hearings and amendments, but still failed to achieve the necessary majority to pass the Senate. *Id.*

33. Mossinghoff, *supra* note 3, at 189.

34. 21 U.S.C. § 355(b)(1), (b)(3)(C) (2000).

35. *Id.* § 355(c)(3)(C). The HWA states that FDA approval will "be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) of this section is received, an action is brought for infringement of the patent that is the subject of the certification" is received. *Id.*

36. *Id.* § 355(j)(5)(B)(iii). While the official committee reports set out an eighteen-month waiting period, this was changed to thirty months prior to passage of the HWA based on recommendations from the pharmaceutical research industry. Mossinghoff, *supra* note 3, at 190.

37. 21 U.S.C. § 355(j)(5)(B)(iii). The HWA mandates that FDA approval become effective prior to thirty months if a court decides that the patent in question is invalid or not infringed, that the patent is infringed, or the court grants a preliminary injunction "prohibiting the applicant from engaging in the commercial manufacture or sale of the drug." *Id.* § 355(j)(5)(B)(iii)(I)-(III).

38. *See* H.R. REP. NO. 98-857, pt. 2, at 9 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2693.

39. Thomas B. Leary, Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II, http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.htm (last visited Sept. 25, 2006).

as settlement tools because, even though the generic manufacturer has great incentive to enter the market, "it will not make as much as the pioneer will lose."[40] Therefore, reverse payments achieve exactly what settlements are supposed to achieve—"peace between the parties."[41] However, they do so with potential negative consequences that extend beyond the parties involved.[42] If the pioneer patent is invalid, the reverse payment may cause consumer harm.[43] But for the settlement, the generic form of the drug could have entered the market sooner, granting greater consumer access and lowering consumer costs.[44] Courts have reached different outcomes in their efforts to balance the competing policy aspects of reverse payments in the context of the HWA.[45]

C. The Sixth Circuit Finds that Reverse Payments Are Per Se Illegal Due to Their Anti-competitive Effects.

The Supreme Court has found restraints of trade that have a "pernicious effect on competition" and a "lack of any redeeming virtue" per se unlawful.[46] *In re Cardizem CD Anitrust Litigation* illustrates how the Sixth Circuit applies the per se rule.[47] The court examined a reverse payment agreement between Andrx Pharmaceuticals and Hoechst Marion Roussel, finding it anti-competitive as a matter of law.[48]

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40. *Id.*

41. Owen M. Fiss, *Against Settlement*, 93 YALE L.J. 1073, 1085 (1984); *see also* Leandra Lederman, *Precedent Lost: Why Encourage Settlement, and Why Permit Non-Party Involvement in Settlements?*, 75 NOTRE DAME L. REV. 221, 224 n.22 (1999).

42. *See* Thomas B. Leary, Comm'r, Fed. Trade Comm'n, Antitrust Issues in Settlement of Pharmaceutical Patent Disputes, Remarks at Northwestern University School of Law, Sixth Annual Health Care Antitrust Forum (Nov. 3, 2000), http://www.ftc.gov/speeches/leary/learypharma.htm.

43. *Id.* Commissioner Leary stated that "[t]he patent system grants investors a twenty-year monopoly and tolerates *immediate consumer harm*, based on the expectation that this incentive will stimulate innovation both in the industries involved and throughout the entire economy, for *ultimate long-term benefit of consumers*." *Id.* (emphasis added).

44. *See id.* Commissioner Leary disagrees with reverse payment agreements on this basis, stating that "[i]f the patent is invalid, . . . the settlement can obviously cause consumer harm because it buys off a likely challenger and perpetuates a stream of improper monopoly profits." *Id.*

45. *See, e.g.*, Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006); La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896 (6th Cir. 2003).

46. N. Pac. Ry. v. United States, 356 U.S. 1, 5 (1958).

47. *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 907.

48. *Id.* at 899, 908. The Supreme Court denied certiorari, at least in part, based on an amicus curiae brief filed for the United States by the Solicitor General. *See* Andrx Pharms. v. Kroger Co., 543 U.S. 939 (2004). The Solicitor General reasoned that Supreme Court review was unnecessary because the decision below did not conflict with any other circuits at the time, that the case arose "in a somewhat atypical factual setting, and statutory changes post-dating the events at issue here may affect the frequency with which similar questions will arise in the future." Brief for the United States as Amicus Curiae

Hoechst Marion Roussel (HMR) manufactured and marketed the brand name drug Cardizem CD, used primarily to treat angina and high blood pressure.[49] HMR's original patent for Cardizem CD expired in November 1992.[50] In September 1995, Andrx became the first manufacturer to seek FDA approval for a generic form of Cardizem CD.[51] Approximately one month later, the United States Patent and Trademark Office (USPTO) issued a patent ('584 patent) for a particular drug delivery method, to Carderm Capital, L.P. (Carderm).[52] Carderm then licensed the technology to HMR.[53]

Upon receipt of Andrx's paragraph IV certification, HMR and Carderm filed a patent infringement suit claiming that Andrx's generic form infringed the '584 patent for the time release mechanism.[54] As required by the HWA,[55] a thirty-month stay immediately went into effect, during which Andrx could not proceed with the approval and marketing process for its generic drug.[56] Three months after the suit was filed, Andrx amended its ANDA to specifically distinguish its claimed dissolution mechanism from the one claimed in the '584 patent.[57] Based on the amendment, the FDA tentatively approved the ANDA with the approval becoming final once either the thirty-month stay had expired, or there was a finding that the '584 patent was invalid or not infringed.[58]

Just over a week later, Andrx and HMR entered into a settlement agreement, which provided that Andrx would not market the generic product in the United States until one of the following occurred: Andrx obtained a favorable and unappealable judgment on the patent infringement issue, Andrx entered into a license agreement with HMR, or HMR entered into a license agreement with a third party.[59] As consideration, HMR agreed to pay Andrx forty million dollars per year beginning on the date of FDA approval of the generic form.[60] HMR also agreed to pay an additional one hundred million dollars per year to delay marketing of the generic if there was either: a final and unappealable judgment in

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Supporting Respondents at 1, Andrx Pharmaceuticals, Inc. v. Kroger Co., 543 U.S. 939 (2004) (No. 03-779).

49. *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 901.

50. *Id.*

51. *Id.* at 902.

52. *Id.*

53. *Id.*

54. *Id.*

55. 21 U.S.C. § 355 (j)(5)(B)(iii) (Supp. III 2003).

56. *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 902.

57. *Id.* The '584 patent claimed a 0-45% total drug release within eighteen hours while the amended ANDA claimed no less than 55% total drug release within eighteen hours. *Id.*

58. *Id.*

59. *Id.*

60. *Id.*

Andrx's favor, a dismissal of the patent infringement suit, or an unappealable judgment that did not include a ruling on the '584 patent's "validity, enforcement, or infringement."[61]

The generic form was approved as scheduled upon the expiration of the thirty-month waiting period.[62] As agreed, HMR began making payments to Andrx and Andrx delayed its market entry accordingly.[63] By the time the agreement was terminated, HMR had paid Andrx a total of almost ninety million dollars.[64]

When direct and indirect purchasers of Cardizem CD challenged the agreement, the district court held that it "was a naked, horizontal restraint of trade and, as such, *per se* illegal."[65] The Sixth Circuit agreed, finding "[n]one of the defendants' attempts to avoid *per se* treatment" persuasive.[66] The court found it dispositive that the reverse payment agreement assured that HMR's only competitor at the time would not bring its competing product to market and also prevented other competitors from entering the market because of Andrx's 180-day market exclusivity right included with the ANDA approval.[67] District Judge Oberdorfer, sitting by designation, reasoned that "tak[ing] advantage of a monopoly that naturally arises from a patent" is different than "bolster[ing] the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market."[68] He further stated that "'[t]he anticompetitive potential inherent in all price-fixing agreements justifies their facial invalidation even if procompetitive justifications are offered for some.'"[69] As a result, the defendants' arguments that there were no anti-competitive effects were moot because the per se rule, by its nature, makes the showing of such effects superfluous.[70]

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61. *Id.* at 903.

62. *Id.*

63. *Id.*

64. *Id.* at 903. Multiple complaints alleging that the agreement was a violation of the Sherman Act were consolidated into the case that eventually came before the Sixth Circuit as *In re Cardizem CD Antitrust Litigation*. *Id.* The consolidated plaintiffs fell into three groups: (1) indirect purchasers and class representatives who initially filed in state courts but whose complaints, alleging violations of state consumer protection and antitrust statutes, were removed to federal court by the defendants ("'State Law Plaintiffs'"); (2) direct purchasers and class representatives whose complaints were initially filed in federal court and allege violations of the Sherman Act ("'Sherman Act Class Plaintiffs'"); and (3) non-class member plaintiffs whose complaints were filed in federal court alleging Sherman Act violations ("'Individual Sherman Act Plaintiffs'"). *Id.* at 903-04 n.7.

65. *Id.* at 900, 905.

66. *Id.* at 908.

67. *Id.* at 907.

68. *Id.* at 908 (footnote omitted).

69. *Id.* at 909 (quoting Arizona v. Maricopa County Med. Soc'y, 457 U.S. 332, 351 (1982)).

70. *Id.*; *cf.* Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 992-93 (N.D. Ill. 2003), *dismissed*, 104 F. App'x 178 (Fed. Cir. 2004). Judge Posner argued that reverse

D. The Eleventh Circuit Rejects the Per Se Rule in Favor of a Three-Factor Patent Rule of Reason.

Unlike the per se rule, the traditional rule of reason takes into account both the anti-competitive and pro-competitive effects of conduct.[71] The rule of reason typically requires elaborate factual inquiries involving expensive, complex litigation that may result in a narrow judicial determination that is of little help in other contexts.[72] However, it also provides an opportunity for the accused party to present its side of the case and demonstrate any pro-competitive effects of the questioned conduct.[73] Additionally, the result does not have the same chilling effect as the per se rule.[74]

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payments should not be inherently suspect because they are a natural byproduct of the Hatch-Waxman regulatory scheme that allows for patent issues to be litigated prior to generic entry. *Cf. id.*

71. AM. BAR ASS'N SECTION OF ANTITRUST LAW, *supra* note 16, at 2. In *Chicago Board of Trade v. United States*, Justice Brandeis articulated the factors to be examined in a rule of reason analysis:

> [T]he court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts.

Chi. Bd. of Trade v. United States, 246 U.S. 231, 238 (1918). Justice Brandeis also stated the rule of reason itself as whether the restraint of trade imposed "is such as may suppress or even destroy competition." *Id.*

72. AM. BAR ASS'N SECTION OF ANTITRUST LAW, *supra* note 16, at 6. The monograph cites a book by F. Scherer and D. Ross which argues why courts are ill suited to make judgments about the reasonableness of business practices. *Id.* at 6 n.28 (citing F. SCHERER & D. ROSS, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 336-37 (3d ed. 1990)). Scherer and Ross identify several problems with the applicability of the rule of reason in American courts:

> For one, the rules of evidence applied in antitrust cases are cumbersome in the extreme . . . . Second, jurists are seldom trained in economics, and many lack the knowledge to separate sense from nonsense in the contending parties' briefs or to get a firm analytic handle on the conduct and performance variables at issue . . . . Third, the whole adversary process on which the courts operate is best suited for reaching either-or decisions . . . . It is much less adept at ascertaining, say, how much competition is optimal out of a continuous spectrum of possibilities.

Id. (third omission in original) (quoting SCHERER & ROSS, *supra*, at 336-37).

73. *Id.* at 7.

74. *Id.* Since the rule of reason is a case-by-case analysis, the chilling effect of a per se analysis, where a certain type of conduct is always impermissible, is potentially reduced. *See id.* The per se rule has also been criticized for encouraging borderline behavior. *Id.* at 4. Essentially, a bright line test like the per se rule "tells businesses how close to the line they can safely walk before the conduct becomes clearly illegal." *Id.*

The Eleventh Circuit modified the traditional rule of reason, creating a special rule of reason specifically for patent cases.[75] This patent rule of reason is also based on a factual inquiry, but discards the traditional factors in favor of three patent-specific ones—particularly, (1) "the scope of the exclusionary potential"; (2) the extent to which the settlement agreement exceeds the scope of the patent; and (3) any anti-competitive effects of the settlement agreement.[76]

In *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, the Eleventh Circuit specifically abandoned the per se rule in the context of reverse payment agreements.[77] The facts in *Valley Drug* are similar to those in *In re Cardizem CD Antitrust Litigation* in that the defendants formed agreements wherein the pioneer manufacturer paid the generic manufacturer to delay market entry for the generic product.[78] Ultimately, Abbott Laboratories agreed to pay two different generic manufacturers nearly seven million dollars a month to delay market entry of their competing generic drugs.[79]

The district court applied the per se rule and found that the agreements were anti-competitive, impermissible restraints on trade.[80] The court concluded that the core purpose of the agreements was to "'dissuade[] Geneva and Zenith from marketing the first generic [Hytrin] drugs in the United States for an indefinite period [and] eliminate[e] the risk that ei-

75. *See* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006); Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003).

76. *Valley Drug*, 344 F.3d at 1312.

77. *Id.* at 1310-11.

78. *Id.* at 1300. The case was a consolidation of antitrust suits and resulted in two contested agreements. *See id.* The first agreement was between Abbott Laboratories and Zenith Goldline Pharmaceuticals (the Zenith agreement). *Id.* Zenith was the ANDA applicant and manufacturer of the generic equivalent of Hytrin, a drug for treating hypertension and enlarged prostate. *Id.* at 1298-99. The Zenith agreement provided that Zenith would admit to the validity of Abbott's patent for Hytrin and that any generic product marketed by Zenith would infringe that patent. *Id.* at 1300. Zenith also agreed not to market any product containing any form of the active ingredient in Hytrin until Abbott's patent expired or until someone else introduced such a product, whichever came first. *Id.* Finally, Zenith promised not to transfer any of its rights under the ANDA application to a third party, or to assist any third party in an attempt to invalidate Abbott's patent for Hytrin. *Id.* As consideration, Abbott contracted to pay Zenith "$3 million up front, $3 million after three months, and $6 million every three months thereafter . . . until the Agreement terminated by its own terms." *Id.* The second agreement was very similar, and also involved Hytrin, but was between Abbott and Geneva Pharmaceuticals (the Geneva agreement). *Id.* In the Geneva agreement, Abbott agreed to pay $4.5 million per month, "until either someone else brought a generic . . . product to market or Abbott won a favorable decision in the district court on its infringement claim." *Id.*

79. *Id.*

80. *Id.* at 1301.

ther drug maker would sell or purchase the right to introduce such drugs in the interim.'"[81]

On appeal, the defendants argued that the pro-competitive effects of the agreements warranted a rule of reason analysis.[82] The Eleventh Circuit agreed, at least in part, holding that reverse payments between patentees and alleged infringers are not "automatically condemned under the antitrust laws."[83] The court remanded the case back to the district court so that a new variation of the rule of reason could be applied to the facts.[84]

As discussed above, the new patent rule of reason focused on the exclusionary effects of the patent through the evaluation of three factors.[85] The district court boldly ignored the new rule on remand, refusing to apply the three factors, and reapplied the per se rule, once again finding that both the Zenith and Geneva agreements were anti-competitive as a matter of law.[86]

Two years later, the Eleventh Circuit got another chance to assert its position on the patent rule of reason.[87] In *Schering-Plough Corp. v. FTC*, the court reaffirmed its holding in *Valley Drug* under similar facts.[88] Under the terms of a reverse payment agreement, Schering (the pioneer) agreed to pay Upsher (the generic manufacturer) "(1) $60 million in ini-

81. *Id.* at 1302 (second alteration added) (quoting *In re* Terazosin Hydrochloride Antitrust Litig., 164 F. Supp. 2d 1340, 1349 (S.D. Fla. 2000)).

82. *Id.* at 1303.

83. *Id.* at 1310-11.

84. *Id.* at 1312-13.

85. *Id.* at 1312. The court found that a traditional rule of reason would be inappropriate because it is directed at anti-competitive effects that "cannot be seriously debated." *Id.* at 1311 n.27 (noting that reverse payment agreements do cause anti-competitive effects by their nature, but recognizing that patents entitle their owners to participate in anti-competitive conduct that is within the scope of the patent). The court reasoned instead that because the case involved a patent, any decision about the reverse payment agreements needed "an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects." *Id.*

86. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1065 n.14 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006). The *Schering-Plough* court admonished that "[o]n remand, the district court in *Valley Drug* still applied a *per se* analysis, and found [the] agreements to be illegal." *Id.*

87. *Id.* at 1076.

88. *Id.* at 1058-59, 1076. Schering-Plough is the manufacturer and marketer of the potassium supplement, K-Dur 20. *Id.* Upsher-Smith used the HWA's ANDA procedure to apply for FDA approval for a generic version of K-Dur. *See id.* at 1058, 1058-59 n.2. Schering's patent covered the K-Dur tablet's coating and Schering filed suit claiming that Upsher's product infringed on that patent. *Id.* at 1058-59. Prior to the infringement trial, Schering and Upsher engaged in settlement negotiations. *Id.* at 1059. The negotiations resulted in an agreement allowing Schering to license Upsher products besides the K-Dur generic. *Id.* In exchange for the licenses and the delayed release of Upsher's generic version of K-Dur, Schering agreed to pay Upsher millions of dollars. *Id.* at 1060.

tial royalty fees; (2) $10 million in milestone royalty payments; and (3) 10% or 15% royalties on sales."[89] The court applied the new patent rule of reason to determine "whether there is substantial evidence to support the . . . conclusion that the challenged agreements restrict competition beyond the exclusionary effects of the" patent.[90]

As to the first factor—the scope of the exclusionary potential—the court found that Schering's patent gave it "the legal right to exclude Upsher . . . from the market until [it] proved either that the . . . patent was invalid or that [the] products . . . did not infringe."[91] The court reasoned that cases involving patents are special because "application of antitrust law to markets affected by the exclusionary statutes set forth in patent law cannot discount the rights of the patent holder."[92] This means that a patent holder can sometimes exclude others without incurring antitrust liability.[93]

The court then addressed the second factor, asking "whether there [was] substantial evidence to support the Commission's conclusion that the challenged agreements restrict competition beyond the exclusionary effects of the . . . patent."[94] The Federal Trade Commission (FTC) argued that reverse payments that appear in conjunction with agreements to delay market entry raise a "red flag."[95] The FTC's arguments did not convince the court for at least two reasons.[96] First, although an administrative law judge had already found the agreements credible, the FTC chose to ignore those findings in the face of Supreme Court authority giving deference to them.[97] Second, the parties had specifically character-

89. *Id.*

90. *Id.* at 1068.

91. *Id.* at 1066-67.

92. *Id.* at 1067.

93. *Id.* This reasoning may be flawed under a Kaplow analysis of the patent-antitrust doctrine. *See* Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARV. L. REV. 1813, 1845-46 (1984). Kaplow asserts that courts justify ignoring the antitrust component by reasoning that since "patentees were legally entitled to refuse to license their patent at all, the less restrictive practice of licensing the patent subject to certain conditions was deemed unimpeachable." *Id.* at 1845. Kaplow rejects this reasoning stating that "because the lesser can indeed be more of an evil than the greater or because regulation of the lesser restriction can lead to substantial improvement in light of the unwillingness of the regulated entity to resort to the greater restriction" the argument in favor of ignoring the antitrust component has "fallen into disfavor." *Id.* at 1845-46.

94. *Schering-Plough*, 402 F.3d at 1068.

95. *Id.* at 1068 (citation and internal quotation marks omitted).

96. *See id.* at 1070-71.

97. *Id.* (citing Universal Camera Corp. v. NLRB, 340 U.S. 474, 487-88 (1951)). In *Universal Camera*, the NLRB had issued an order for Universal Camera to stop firing or disciplining employees for testifying against Universal Camera under the National Labor Relations Act. *Universal Camera*, 340 U.S. at 476. Universal Camera refused to comply with the order and the NLRB petitioned for a court order enforcing the previous administrative order. *Id.* The Second Circuit ignored the Board's findings. *Id.* Upon review at

ized the payments as "up-front royalty payments" not as compensation for delayed market entry.[98] The court found nothing in the record to counter this description of the payments.[99]

Finally, the court evaluated the anti-competitive effects of the agreements.[100] The court first pointed out that any anti-competitive effect "cannot be hypothetical or presumed," and that "'[p]ublic policy strongly favors settlement of disputes.'"[101] The court found that the agreements "demonstrate[d] an efficient narrowness" since they did not delay the market entry of any products that were not covered by the "identical reach" of Schering's patent.[102] Additionally, the court reasoned that the agreements benefited both parties and further encouraged settlement by maintaining the flow of consideration from the patent holder to the infringer.[103]

The court also found that these types of agreements actually further competition because "[a] prohibition on reverse payment settlements would 'reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement.'"[104]

Thus, the Eleventh Circuit was able to use *Schering-Plough* to emphatically reaffirm its holding in *Valley Drug* by citing policy concerns such as the expense of litigation, overcrowded dockets, and the benefits of settlements.[105] The court specifically rejected "a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic's entry date."[106] The court also successfully applied the patent rule

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the Supreme Court level, Justice Frankfurter ruled that courts "must consider the whole record" and set aside an administrative decision only when courts "cannot conscientiously find that the evidence supporting that decision is substantial." *Id.* at 488.

98. *Schering-Plough*, 402 F.3d at 1071.

99. *Id.*

100. *Id.* at 1072.

101. *Id.* at 1072-73 (alteration in original) (quoting Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976)).

102. *Id.* at 1073.

103. *Id.* at 1074. Judge Fay, writing for the majority, stated:

> If Schering had been able to prove damages from infringing sales, and settled before trial for a sum less than the damages, the result is a windfall to the generic manufacturers who essentially keep a portion of the profits. If this were true, then . . . such a settlement would be a violation of antitrust law because the infringer reaped the benefit of the patent holder's partial surrender of damages. Like the reverse payments at issue here, "such a rule would discourage any rational party from settling a patent case because it would be an invitation to antitrust litigation."

Id. (quoting *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003)).

104. *Id.* at 1074-75 (quoting Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 985, 994 (N.D. Ill. 2003)).

105. *Id.* at 1076.

106. *Id.*

of reason, finding, in direct opposition to the Sixth Circuit, that a reverse payment agreement is not necessarily an antitrust violation.[107]

II. COLLISION COURSE: THE INTERSECTION OF PATENT AND ANTITRUST LAW

A. The Patent-Antitrust Doctrine

In his seminal article on the intersection between patent and antitrust law, Louis Kaplow proposed a ratio test for identifying conduct on the part of the patentee that is impermissible in light of antitrust policy concerns.[108] The ratio test compares the patentee's reward from the conduct with the loss imposed on society via the monopoly.[109] Kaplow asserts that "the greater the ratio, the stronger is the case for permitting the practice."[110]

The ratio test is not problem free because it involves quantities that are sometimes unknowable.[111] Despite these potential unknowns, the ratio test can still be applied to reverse payment agreements.[112] Reverse payment agreements are settlement agreements that essentially combine patents that would have otherwise been in competition with each other.[113]

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107. *See id.*

108. Kaplow, *supra* note 93, at 1816, 1831. Professor Kaplow was prompted to develop the ratio test by his observation that "[t]he intersection of antitrust law and patent policy has proved to be a source of perpetual confusion and controversy since the passage of the Sherman Act." *Id.* at 1815. He reasons that courts and commentators are making the problem worse in three main ways: (1) by pretending that either the antitrust portion or the patent portion of the equation do not exist; (2) by "invoking formalistic constructions that are indeterminate and only superficially address the issues"; and (3) by focusing "on the relationship between the reward a patentee receives and the value of the patent." *Id.* Kaplow advocates the ratio test as a solution to the problem because it is conceptually simple, but can be applied to complex situations. *Id.* at 1816.

109. Kaplow, *supra* note 93, at 1842. Professor Kaplow proposed several factors to consider when using the ratio test, including "the extent to which the reward is a pure transfer, the portion of the reward that accrues to the patentee, and the degree to which the reward serves as an incentive." *Id.*

110. *Id.* at 1816.

111. *Id.* at 1842-45 (pointing out that the information needed for the analysis is sometimes difficult to obtain). The courts' application of the ratio test would, therefore, be case-by-case, and such a case-by-case application would not be helpful in determining "a coherent patent-antitrust doctrine." *Id.* Courts have attempted to solve this by ignoring the antitrust component and essentially granting antitrust immunity to patent holders. *Id.* at 1845-46. The article further points out that this conflict avoidance strategy has become unpopular with commentators even though the Supreme Court continues to use it. *Id.*; *see also* United States v. Gen. Elec. Co., 272 U.S. 476, 490 (1926). The problem with this conflict evasion strategy is that, sometimes, conduct that should be regulated is not. Kaplow, *supra* note 93, at 1846.

112. *See id.* at 1869-70.

113. *See id.* at 1867-70. Kaplow asserts that competition, not combination, leads to the greatest social benefit by discouraging the practice of "inventing around." *Id.* Kaplow

As the facts of the three cases demonstrate, reverse payment agreements usually arise in the context of so-called "invent-around patents."[114] Kaplow reasons that invent-around patents have significant effects on both the numerator and the denominator in the ratio of patentee reward over societal loss.[115]

With respect to the numerator, the only purpose of an invent-around patent "is to redistribute the reward from the original patentee to others."[116] Since inventing around does not provide any net benefit to the patentees when patents are combined, the effort it took to invent around was wasted.[117] If competition is required, the waste could be avoided because inventing around would be at least partially discouraged.[118]

With respect to the denominator, invent-around patents "provide[] no social benefit if the new invention is no better than the first."[119] This means that if invent-around patents are combined with pioneer patents, as is effectively the case for reverse payment settlements, the social loss comes from a decrease in competition that results in higher prices.[120] Therefore, the best way to increase the ratio and achieve a permissible practice would be to "forc[e] firms that invent around to compete."[121] This would "tend both to decrease the resources wasted on duplicative research and development and to diminish the monopoly loss incurred in providing the original inventor with a given level of reward."[122]

B. The Patent-Antitrust Doctrine Favors the Per Se Rule.

The first line of inquiry for determining whether a practice will fail the ratio test is whether it is "a subterfuge for collusion or other exclusionary conduct."[123] If the practice is not a subterfuge, the next level of inquiry

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alleges that inventing around merely "redistribute[s] the reward from the original patentee to others." *Id.* at 1869.

114. *See generally* Schering Plough Corp. v. FTC, 402 F.3d 1056, 1058-61 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006); Valley Drug Co. v. Geneva Pharms. Inc., 344 F.3d 1294, 1298-1300 (11th Cir. 2003); La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896, 901-03 (6th Cir. 2003). "Invent around" patents allow the inventor "to enter in the market sooner without the risk of patent liability," for a similar invention. *See In re* Cardizem CD Antitrust Litig., 105 F. Supp. 2d 682, 703 (E.D. Mich. 2000), *aff'd sub nom.* La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc., 332 F.3d 896 (6th Cir. 2003).

115. Kaplow, *supra* note 93, at 1869-70.

116. *Id.* at 1868-69.

117. *Id.* at 1869.

118. *Id.*

119. *Id.* at 1868-69.

120. *Id.* at 1870.

121. *Id.* at 1873.

122. *Id.*

123. *Id.* at 1887.

involves the more complicated analysis of the ratio test.[124] When a practice, such as reverse payments, has multiple effects, only those practices that "exhibit a serious potential for substantial loss" should be prohibited.[125]

The Sixth Circuit's argument that reverse payments are subterfuges for anti-competitive activity is persuasive.[126] The reverse payment agreement in *In re Cardizem CD Antitrust Litigation* effectively prevented any of HMR's competitors from entering the United States market despite FDA approval to do so.[127] The court found that the practice was "a classic example of a *per se* illegal restraint of trade."[128] Even the Eleventh Circuit conceded that the anti-competitive effects of reverse payment agreements "cannot be seriously debated."[129]

However, even if the reverse payments were not subterfuges, the practice of using them as part of a settlement agreement still fails Kaplow's ratio test because the denominator is too large.[130] On average, a generic drug costs sixty dollars less per month than the equivalent brand name drug.[131] Furthermore, patients are estimated to need the brand name drug only 5% of the time, with the generic drug being suitable the other 95% of the time.[132] Pharmaceutical industry experts estimate that con-

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124. *Id.*

125. *See id.* at 1888. The loss referred to is a social loss at the hands of the monopoly. *See id.* at 1821; *supra* Part II.A.

126. La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896, 907-08 (6th Cir. 2003). The court found several undisputed facts dispositive including the fact that HMR paid "its only potential competitor at that time, Andrx" to "refrain from marketing its generic version of Cardizem CD even after it had obtained FDA approval, protecting HMR's exclusive access to the market for Cardizem CD throughout the United States." *Id.* at 907.

127. *Id.* at 907-08.

128. *Id.* at 908. The court reasoned that:

> There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade.

Id.

129. Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1312 n.27 (11th Cir. 2003). The Eleventh Circuit rejected both the per se rule and the traditional rule of reason because both are "aimed at assessing the anticompetitive effects of particular conduct; what is required here is . . . the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects." *Id.*

130. *See* Kaplow, *supra* note 93, at 1816.

131. *Generic Drugs Could Have Saved Us $20B*, USA TODAY ONLINE, Oct. 25, 2005, http://www.usatoday.com/news/health/2005-10-25-generic-drugs_x.htm?POE=click-refer. Express Scripts, Inc. conducted a study to determine the effects of consumer use of generic drugs, or lack thereof. *Id.* In addition to consumer savings, the study revealed that "doctors have no incentive to write generic drug prescriptions, especially when they receive samples and other perks from pharmaceutical companies." *Id.*

132. *Id.*

sumers will lose twenty-five billion dollars in savings this year alone, and that number only includes drugs for which a generic is available but not prescribed.[133] This is the type of loss to social welfare that Kaplow outlined in his application of the ratio test to settlements involving competing patents.[134]

The Eleventh Circuit's reasoning is also flawed under the patent-antitrust doctrine because the court granted antitrust immunity to patentees in spite of its identifiable problems, refusing to address the antitrust portion of the analysis.[135] Although the Supreme Court also granted such exemptions for patent holders, the practice has become unpopular.[136]

C. Traditional Theories of Statutory Interpretation Indicate that the HWA Favors the Per Se Rule.

Three dominant theories of statutory interpretation have developed in America: purposivism, intentionalism, and textualism.[137] Purposivism favors the interpretation that best accomplishes the purpose of the statute.[138] Intentionalism looks to the original intent of the statute's draft-

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133. *Id.* The estimate does not include the amount spent on brand name drugs for which a generic version is not even on the market because of a reverse payment agreement. *See id.*

134. Kaplow, *supra* note 93, at 1870. Kaplow argues that as long as "competition does not completely eliminate the incentive to invent around, there would be an additional social benefit because competition among patentees would lower prices and thus reduce the loss in social welfare." *Id.*

135. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1064 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006). The majority states that "[a]lthough we acknowledged in *Valley Drug* that an agreement to allocate markets is 'clearly anti-competitive,' resulting in reduced competition, increased prices, and a diminished output, we nonetheless reversed for a rather simple reason: one of the parties owned a patent." *Id.* (quoting Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1304 (11th Cir. 2003)).

136. Kaplow, *supra* note 93, at 1846 n.97. The courts have attempted to define categories of permissible activity but all assume some base level of patent exploitation that is undefined. *See id.* at 1846-48.

137. WILLIAM N. ESKRIDGE, JR. & PHILIP P. FRICKEY, CASES AND MATERIALS ON LEGISLATION 514 (2d ed. 1995). Traditionally, American statutory interpretation has been conducted on a case-by-case basis, and has lacked any deductive guidelines. *Id.* Starting in the early 1900s, judges emphasized legislative intent, but in the 1930s the focus switched to statutory purpose. *Id.* at 515. Eventually purposivism was "criticized for slighting traditional rule-of-law values . . . and for engaging courts in policy analysis for which they are ill-equipped." *Id.* Finally, in the 1980s, new textualism emerged and sought "to return statutory interpretation to textual analysis." *Id.* However, the new textualist approach has been called "impractical and unrealistic" and will only be briefly addressed in this Comment. *Id.*

138. *Id.* at 514. The Supreme Court has often recognized the purpose of a statute as a staple of interpretation. *See, e.g.*, Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah, 508 U.S. 520, 533 (1993); Hunt v. Wash. State Apple Advert. Comm'n, 432 U.S. 333, 352-53 (1977); Washington v. Davis, 426 U.S. 229, 239 (1976). As recently as June 2005, the Court reiterated the importance of purposivism and recognized it as a "key ele-

ers.[139] Textualism relies only on the "plain meaning" of the statute's text.[140]

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ment of a good deal of constitutional doctrine." McCreary County v. ACLU, 125 S. Ct. 2722, 2734 (2005).

A purpose inquiry should examine "[t]he plain meaning of the statute's words, enlightened by their context and the contemporaneous legislative history." Edwards v. Aguillard, 482 U.S. 578, 594-95 (1987). When a remedial statute's purpose is stated in its text, it should be "liberally construed to achieve [its] remedial purpose." RONALD BENTON BROWN & SHARON JACOBS BROWN, STATUTORY INTERPRETATION: THE SEARCH FOR LEGISLATIVE INTENT § 4.12, at 59 (2002). This is especially so in the case of a remedial statute, like the HWA, which was enacted to correct a particular mischief. *Id.* Remedial statutes include those that "protect the public such as statutes of frauds; statutes of limitations; securities legislation; insurance regulation; social welfare programs; employee protection; civil rights; and environmental protection." *Id.* at 60; *see also infra* note 152.

139. ESKRIDGE & FRICKEY, *supra* note 137, at 514. The intentionalist theory of statutory interpretation first looks to the text of the statute to determine the intent of its drafters. McFarland v. Scott, 512 U.S. 849, 865 (1994) (Thomas, J., dissenting). When the intent is not obvious from the text itself or a proposed interpretation of the text yields an absurd result, courts use extrinsic tools like legislative history, surrounding statutes, and common law to determine what the legislature meant. *Cf.* ESKRIDGE & FRICKEY, *supra* note 137, at 633. With regard to legislative history, the Supreme Court has stated that official committee reports are the preferred form of extrinsic evidence. Holder v. Hall, 512 U.S. 874, 932 n.28 (1994) (Thomas, J., concurring). Intentionalism has been criticized for its use as a justification for judicially favored results. ABNER J. MIKVA & ERIC LANE, AN INTRODUCTION TO STATUTORY INTERPRETATION AND THE LEGISLATIVE PROCESS 7 (1997). Intentionalism was criticized early on. ESKRIDGE & FRICKEY, *supra* note 137, at 528-29. The primary criticism was that the meaning of the statute is often unclear. *See id.* at 529. Commentators argued that statutory interpreters should "consider the expectations of the legislators who wrote the statute." *Id.* (citing Frederick de Sloovére, *Textual Interpretation of Statutes*, 11 N.Y.U. L. REV. 538 (1934)). This criticism gave rise to purposivism, which is generally seen as a more objective way of determining what ambiguous statutory language means. MIKVA & LANE, *supra*, at 8. Unfortunately, the Supreme Court has often used "intent" and "purpose" interchangeably. *See, e.g.*, Liparota v. United States, 471 U.S. 419, 425-27 (1985).

140. ESKRIDGE & FRICKEY, *supra* note 137, at 514. There are two versions of textualism: traditional and new textualism. *See id.* at 514, 624. Textualism has become increasingly important because it is "now the central inquiry at the Supreme Court level." *Id.* at 625. This is primarily because of the presence of Justice Scalia and Justice Thomas, with the former actually closer to a new textualist. BROWN & BROWN, *supra* note 138, at 49; ESKRIDGE & FRICKEY, *supra* note 137, at 624. Textualists reject the use of legislative history altogether in favor of dictionaries as extrinsic sources. *See* BROWN & BROWN, *supra* note 138, at 48; ESKRIDGE & FRICKEY, *supra* note 137, at 625. The reasoning behind such a rejection is that the statute itself is the only law. BROWN & BROWN, *supra* note 138, at 49. Textualists argue that the legislative history of a statute is not the law and therefore irrelevant. *Id.* Textualists further argue that legislative history is really written by congressional staffers and therefore subject to manipulation. *Id.* They also contend that legislative history may not accurately reflect the drafters' intent once staffers finish manipulating it. *Id.* New textualists go even further by demanding the complete abandonment of even the mere reference to legislative history. *See* ESKRIDGE & FRICKEY, *supra* note 137, at 624. This differs from traditional textualism primarily because it shifts the focus away from the "actual expectations of the enacting Congress." *Id.* at 587.

There are also textual and grammatical canons,[141] rules of interpretation,[142] and extrinsic tools such as common law, legislative history, and surrounding statutes that work within these theories.[143]

During his tenure as a professor at Harvard Law School, Justice Frankfurter developed a three-step theory of statutory interpretation: "(1) [r]ead the statute; (2) read the statute; (3) read the statute."[144] A reading of the HWA's text shows that the statute favors the per se rule in two main ways. First, the HWA excludes reverse payments as a form of patent term extension by providing another specific procedure for obtaining such an extension.[145] Second, the HWA provides a precise remedy for

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There are three main justifications for new textualism: (1) that the law is only the text enacted by the legislature; (2) that attempts by Congress, or the courts, to control the interpretation of a statute via legislative history is in tension with Article I, Section 7 of the Constitution; and (3) that the Constitution embodies "liberal" principles that do not permit judges to fill a statutory vacuum. *Id.* at 587-88. Despite these justifications, new textualism is not a dominant position. *See id.* at 624. The Supreme Court, despite its modern textualist leanings, has not fully embraced new textualism. *Id.* For example, every Justice except Justice Scalia joined a footnote in *Wisconsin Public Intervenor v. Mortier* "explicitly rejecting Justice Scalia's insistence that legislative history is irrelevant to proper statutory interpretation." *Id.* (citing Wisc. Pub. Intervenor v. Mortier, 501 U.S. 597, 610 n.4 (1991)).

141. ESKRIDGE & FRICKEY, *supra* note 137, at 633-34, 640. The most common textual canons are the presumption of ordinary meaning over technical meaning, *noscitur a sociis* (a word will be interpreted in the context of surrounding words), *esjudem generic* (general words following particular words will be interpreted in light of the particular ones), and *expressio unius est exclusio alterius* (the express mention of things in a list excludes those things not mentioned). *Id.* at 637-38. The most common grammatical canons are punctuation, referential and qualifying words, conjunctive versus disjunctive connectors, and mandatory versus discretionary language. *Id.* at 640-42.

142. *See* MIKVA & LANE, *supra* note 139, at 6-8; *see also* ESKRIDGE & FRICKEY, *supra* note 137, at 516 (citing Heydon's Case, 76 Eng. Rep. 637 (Exch. 1584). The plain meaning rule requires that words in a statute be given their plain, ordinary meaning. MIKVA & LANE, *supra* note 139, at 10. If the plain meaning of the words would produce an absurd result, the second rule, the golden rule, states that courts should adopt an interpretation that avoids such a result. BROWN & BROWN, *supra* note 138, at 40-41.

143. ESKRIDGE & FRICKEY, *supra* note 137, at 633. There is arguably a third tool that gives deference to interpretations made by administrative agencies. *Id.* A thorough examination of the FTC's interpretation of the HWA is outside the scope of this Comment. In the United States, "[a]dministrative agencies routinely have first-line responsibility for interpreting the statutes they are charged with implementing." *Id.*

144. *Id.* at 513 (quoting HENRY FRIENDLY, *Mr. Justice Frankfurter and the Reading of Statutes*, *in* BENCHMARKS 202, 202 (1967)).

145. 35 U.S.C. § 156(a) (2000). There are five requirements for patent term extension under the HWA. *Id.* First, the patent extension application must be filed before the original patent term expires. *Id.* § 156(a)(1). Second, the term of the patent cannot have been previously extended. *Id.* § 156(a)(2). Third, the extension application must be submitted by the patent owner of record or its agent. *Id.* § 156(a)(3). Fourth, the patented product must have "been subject to a regulatory review period" prior to commercial marketing or use. *Id.* § 156(a)(4). Fifth, the patented product cannot have been commercially marketed or used prior to the regulatory review period. *Id.* § 156(a)(5).

patent holders that are damaged by erroneous FDA approval of a generic drug, making reverse payment remedies unnecessary.[146]

However, even Justice Frankfurter realized that sole reliance on the language does not necessarily lead to a complete understanding of the statute.[147] The legislative history of the HWA, in the form of official committee reports, also supports the text's preference for the per se rule.[148] The reports establish the remedial nature of the HWA by specifically articulating the mischief that the HWA was passed to correct.[149] Additionally, the reports explain the chosen remedial scheme and the reasoning behind it, while also identifying the need to include the HWA's damages provision.[150] These committee reports shed significant light on

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146. 35 U.S.C. § 271(e)(4)(B)-(C). The HWA states that for acts of infringement, courts may order:

> injunctive relief . . . against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and . . . .
>
> damages or other monetary relief . . . if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.

Id. Additionally, the HWA stipulates that these "are the only remedies which may be granted by a court for an act of infringement . . . except that a court may award attorney fees" in some circumstances. *Id.*

147. ESKRIDGE & FRICKEY, *supra* note 137, at 513. An example is given of an ordinance mandating that all pharmacies be closed at 10 p.m. every day. *Id.* The question then becomes whether "closed" means that all pharmacies must remain open until 10 p.m., or whether they can close sometime before that as long as they are closed *by* 10 p.m. *Id.* This type of ambiguous statutory language gives rise to a problem unique to America's constitutional system. *Id.* at 514. "On the one hand, it is generally assumed that 'any conflict between the legislative will and the judicial will must be resolved in favor of the former.'" *Id.* (quoting REED DICKERSON, THE INTERPRETATION AND APPLICATION OF STATUTES 8 (1975)). However, "statutory interpretation cannot be appropriately undertaken by a mechanical application of rules or 'unimaginative adherence to well-worn professional phrases.'" *Id.*

148. *See generally* H.R. REP. NO. 98-857, pt. 1, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648; H.R. REP. NO. 98-857, pt. 2, at 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688.

149. H.R. REP. NO. 98-857, pt. 2, at 4.

> The FDA rules on generic drug approval for drugs approved after 1962 have had serious anti-competitive effects. The net result of these rules has been the practical extension of the monopoly position of the patent holder beyond the expiration of the patent. This is so because of the inability of generics to obtain approval for these post-1962 drugs without enormous expenditures of money for duplicative tests.

Id.; *see also* Hatch-Waxman Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered section of 15, 21, 35 & 42 U.S.C.). The Act's stated purpose is "[t]o amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications, to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes." *Id.*

150. *See* H.R. REP. NO. 98-857, pt. 2, at 10.

> [A] requirement that [the] FDA defer generic approval until after a court decision of patent invalidity would substantially delay FDA approvals. Of course, in the event

the purpose of the HWA's text and lend clear support to the two textual arguments in favor of the per se rule.[151]

1. The Hatch-Waxman Act's Text and Legislative History Exclude Reverse Payment Agreements as Options for Patent Term Extension.

Since the HWA was passed to solve a problem, it can be characterized as a remedial statute.[152] Therefore, the purposivist theory should be used to determine legislative intent because "[t]he traditional canon is that remedial statutes are to be liberally construed to achieve their remedial purpose."[153]

A major purpose of the HWA can be found in the statute's preamble, which states that the HWA is intended "[t]o amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications . . . to authorize the extension of the patents for certain regulated

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that the FDA approves a generic because of the expiration of 18 months without a court decision, and it is later determined that the patent is valid, the patent owner may still recover damages from the generic. Therefore, in most cases the bill affords greater protection for patent holders than current law.

Id. (footnote omitted).

151. *See supra* notes 148-50 and accompanying text.

152. BROWN & BROWN, *supra* note 138, at 59-60. The HWA is a remedial statute as opposed to "for example, a taxing or revenue raising statute." *Id.* at 60. Additionally, the HWA serves to protect the public by making more low cost generic drugs available. H.R. REP. NO. 98-857, pt. 1, at 14. Public protection is another characteristic of a remedial statute. BROWN & BROWN, *supra* note 138, at 60.

153. BROWN & BROWN, *supra* note 138, at 59. The official committee reports of the HWA plainly indicate the drafters' intent to rectify problems associated with the old FDA procedures for generic drug approval. *See* H.R. REP. NO. 98-857, pt. 1, at 14-15; H.R. REP. NO. 98-857, pt. 2, at 4. The House Committee on the Judiciary recognized the anti-competitive effects of the generic drug approval process present prior to the enactment of the HWA. H.R. REP. NO. 98-857, pt. 2, at 3-4. The drafters intended to decrease the anti-competitive characteristics of the arduous approval process through the creation of the ANDA. *Id.* at 5. Reverse payment agreements have anti-competitive effects that seem counter to the drafters' intent to encourage an environment where generic drugs are more easily approved for market. *See* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006); Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1300 (11th Cir. 2003); La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896, 911 (6th Cir. 2003). The courts found that reverse payment agreements had anti-competitive effects. *Schering-Plough*, 402 F.3d at 1076; *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 911.

Likewise, textualism favors the per se rule: even though the HWA does not specifically state that reverse payment remedies are unavailable, it does list what remedies are available for parties to a patent infringement suit. Hatch-Waxman Act of 1984 § 202, 35 U.S.C. § 271(e)(3)-(4) (2000). Even without consulting a single piece of legislative history, the textual canon of *expressio unius est exclusio alterius* demands that things absent from a list, like the availability of reverse payments, be excluded from that list. ESKRIDGE & FRICKEY, *supra* note 137, at 638; James Veltrop & Michael Keeley, *'Schering' Overruled: Risk of Settling Patent Disputes Reduced?*, N.Y. L.J., Apr. 7, 2005, *available at* http://www.avhlaw.com/assets/attachments/19.pdf.

products, and for other purposes."[154] Inasmuch as reverse payments extend the patent term by extending a pioneer manufacturer's exclusive market share,[155] they appear to fall within the literal meaning of one of the stated purposes of the HWA. However, a reading of the HWA's section on patent term extension immediately raises problems with that conclusion.[156]

Patent term extension under the HWA is limited to the period during which a drug is subjected to FDA review.[157] Even if a patent is eligible, the extension awarded has specific limitations.[158] This limited set of listed circumstances invites the application of the textual canon of *expressio unius est exclusio alterius*.[159] "When the legislature provide[s] a specific term or a list of specific terms, the implication is that the legislature intended to exclude others."[160] Because the HWA limits patent extension to the period of FDA review, under the canon of *expressio unius est exclusio alterius*, it excludes other methods of patent term extension includ-

154. Hatch-Waxman Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

155. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d at 907.

156. *See* 35 U.S.C. § 156 (2000 & Supp. III 2003). Section 156 outlines several instances for which patent term extension is appropriate and the requirements for obtaining an extension. *Id.* § 156(a)(1)-(5). Additionally, § 156 limits the extension to a time not longer than the regulatory review period to which the patented drug was subject. *Id.* § 156(c). It is this section that seems to eliminate the possibility for patent term extension via reverse payment agreements. If the HWA permits an extension only as compensation for the portion of the patent term lost to regulatory review, it is unlikely that an extension for some other reason would fall within the meaning of the statute.

157. *Id.* § 156(c) (2000).

158. *Id.* § 156(g)(1)(A) (2000). The patent term is generally extended for the same length as the regulatory approval period. *Id.* § 156(c). This can never exceed five years for patents issued after the enactment of the HWA in 1984. *Id.* § 156(g)(6)(A).

159. *See* MIKVA & LANE, *supra* note 139, at 24. There are some objections to the application of textual canons in the first place. These objections generally take three forms: (1) "[t]he canons are no help"; (2) the canons "do not reflect ordinary use of language"; and (3) the canons "conflict with each other." KENT GREENAWALT, STATUTORY INTERPRETATION: 20 QUESTIONS 203 (1999). However, these criticisms have proven to be "overstated" and "misconceive the proper role of the canons." *Id.* The Latin phrase *expressio unius est exclusio alterius* means that the "expression of one thing is the exclusion of another." Hickman v. Workman, 450 A.2d 388, 391 (Del. 1982).

160. BROWN & BROWN, *supra* note 138, at 81 (citing Gotkin v. Miller, 379 F. Supp. 859 (E.D.N.Y. 1974); Moonlit Waters Apartments v. Cauley, 666 So. 2d 898, 900 (Fla. 1996)). The authors state that if the legislature had intended to include other options, "it would have included a general term at the end of the list." *Id.* For example:

> Consider a statute that applies to apples, peaches, and oranges. Does the statute also apply to plums? There is no general term at the end of this list in which plums might be included. By not specifically including the specific term "plums" or a general term in which plums might be included, it appears that the legislature intended not to include plums. That is the negative implication.

Id. at 81-82.

ing reverse payment agreements.[161] This, however, raises a question: If the patent owner negotiates a reverse payment agreement that lasts only as long as the regulatory review period, would that not fall within the listed patent extension provision? Extrinsic tools such as the legislative history of the HWA can help discern the answer.[162]

First, because the HWA was passed, in part, to amend Title 35 of the United States Code, there is a closely related statute that may aid in determining the purpose behind the patent term extension provisions of the HWA.[163] Title 35 codifies the patent term extension section from the provisions of the HWA as discussed above.[164] Prior to the HWA amendments, Title 35 had no patent term extension provisions at all.[165]

Second, the HWA contains legislative history that sheds light on the purpose of the patent extension provisions.[166] Both the House Commit-

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161. *See* ESKRIDGE & FRICKEY, *supra* note 137, at 638. The doctrine of *expressio unius est exclusio alterius*, while consistently part of the statutory interpretation landscape, is enjoying increased application by the Supreme Court. *See id.* at 639; *see also* Key Tronic Corp. v. United States, 511 U.S. 809, 818-19 (1994) (refusing to find attorney fee award where not listed in statute); United States v. Smith, 499 U.S. 160, 167 (1991) (stating that the express creation of two causes of action by Congress implicitly limits finding a third); Miss. Band of Choctaw Indians v. Holyfield, 490 U.S. 30, 43 (1989) (stating that absent plain indication, a federal statute is not dependent on state law). However, courts will not apply the doctrine "when they believe it would lead to an improper result." ESKRIDGE & FRICKEY, *supra* note 137, at 638.

162. *See* CHRISTIAN E. MAMMEN, USING LEGISLATIVE HISTORY IN AMERICAN STATUTORY INTERPRETATION 40 (2002). There are thresholds that must be met before the legislative history of a statute can be used for interpretation purposes. *Id.* For cases such as this one, where a statute is passed to amend another statute, courts will not upset the surrounding statute unless there is clear evidence in the legislative history of a legislative intent to do so. *Id.* The HWA does much to upset the status quo of the federal laws it amends by creating several entirely new procedures for both the approval of generic drugs and the award of damages for victims of patent infringement. *See generally* Hatch-Waxman Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, (codified as amended in scattered sections of 15, 21, 35 & 42 U.S.C.).

163. *See generally* 35 U.S.C. (2000). Title 35 of the United States Code deals with patents generally. *See generally id.* Part I establishes the U.S. Patent and Trademark Office and outlines its functions, officers, and employees, while Part II outlines patentability of inventions and the grant of patents. *See generally id.* Part III describes patent rights. *See generally id.* Part IV codifies the Patent Cooperation Treaty. *See generally id.*

164. *See* 35 U.S.C. § 155 (2000 & Supp. III 2003). Section 155 deals specifically with patent term extension and reflects amendments brought about by the passage of the HWA. *Id.* The section provides that the term of a patent shall be extended if its subject has gone through the FDA review process, and limits the length of the extension to not longer than the period of such review. *Id.* The extension, once granted, is then considered part of the original patent. *Id.*

165. *See* S. REP. NO. 98-547, at 2 (1984).

166. *See id.* at 1; H.R. REP. NO. 98-857, pt. 1, *reprinted in* 1984 U.S.C.C.A.N. 2642; H.R. REP. NO. 98-857, pt. 2, *reprinted in* 1984 U.S.C.C.A.N. 2686. "[O]fficial committee reports are preferred to other forms of legislative history." MAMMEN, *supra* note 162, at 26. This preference is likely because "a committee report presents more reasoned analysis and

tee on the Judiciary and the House Committee on Energy and Commerce were concerned about the FDA's procedure for the approval of generic drugs, and passed the HWA in response to deficiencies in those procedures.[167] The House Committee on the Judiciary noted that the FDA rules for approval of generic drugs prior to the HWA "had serious anticompetitive effects."[168] Both committees reasoned that the FDA's requirement of repeat testing of generic drugs effectively extended the pioneer manufacturer's patent term by making the new drug application too costly for the generic manufacturer.[169] This line of reasoning demonstrates the mischief the statute seeks to rectify, namely the extension of patent terms beyond their expiration date through the cumbersome requirements imposed on generic drug approval.[170]

The HWA remedy balances the interests of the pioneer manufacturer, the generic manufacturer, and the public by implementing a patent term extension equal to the regulatory review period.[171] The extension com-

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bears a stronger imprimatur of official consensus than do floor statements, which may represent more partisan posturing." *Id.*

167. *See* H.R. REP. NO. 98-857, pt. 1, at 14-15; H.R. REP. NO. 98-857, pt. 2, at 4. After the Food and Drug Amendments of 1962, the FDA required extensive and duplicative tests for generic drugs. H.R. REP. NO. 98-857, pt. 2, at 4.

168. H.R. REP. NO. 98-857, pt. 2, at 4. The committee found that:

> The net result of these rules has been the practical extension of the monopoly position of the patent holder beyond the expiration of the patent. This is so because of the inability of generics to obtain approval for these post-1962 drugs without enormous expenditures of money for duplicative tests.

Id.

169. *See* H.R. REP. NO. 98-857, pt. 1 at 16-17; H.R. REP. NO. 98-857, pt. 2, at 4.

170. H.R. REP. NO. 98-857, pt. 2, at 4. The mischief rule directs the interpreter to consider what mischief the statute seeks to resolve. *See* ESKRIDGE & FRICKEY, *supra* note 137, at 516. Some critics of the mischief rule state that it presumes that the mischief is discoverable. BROWN & BROWN, *supra* note 138, at 43-44. In this case, the mischief is clearly outlined in the committee reports: patent terms were being extended only because the FDA's 1962 rules made it too expensive for generics to routinely reach the market. H.R. REP. NO. 98-857, pt. 2, at 4.

When applying the mischief rule to discern the purpose of a statute, *Heydon's Case* requires the consideration of four factors: (1) the state of the common law prior to the legislation; (2) the problem "for which the common law did not provide"; (3) the remedy the legislation proposes; and (4) the reason for the remedy. ESKRIDGE & FRICKEY, *supra* note 137, at 516 (citing Heydon's Case, 76 Eng. Rep. 637 (Exch. 1584)). In *Church of the Holy Trinity v. United States*, the Supreme Court applied the mischief rule considering additional factors such as "contemporaneous events, the situation as it existed, and as it was pressed upon the attention of the legislative body." Church of the Holy Trinity v. United States, 143 U.S. 457, 463 (1892).

In this case, the common law is irrelevant since the FDA approval process for generic drugs is governed exclusively by statute. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (2000); 21 U.S.C. § 355 (2000 & Supp. III 2003).

171. 35 U.S.C. § 156(a), (c) (2000). Another stated purpose of the HWA is to "create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval." H.R. REP. NO. 98-857, pt. 1, at 15.

pensates the pioneer manufacturer for the portion of its patent term consumed by the FDA approval process, while allowing the generic manufacturer to get its product on the market as soon after the expiration of the pioneer patent as possible.[172] The generic manufacturer can then generate profits more quickly and provide a cheaper, bio-equivalent drug to the public.[173] Since compensation for loss of monopoly rights due to regulatory review is the only patent term extension provision discussed in the official committee reports, the purpose of the patent term extension must be to accomplish those goals.[174] Therefore, the HWA provides a specific remedy that does not include reverse payment agreements.

2. The Hatch Waxman Act's Text and Legislative History Preclude the Use of Reverse Payment Agreements as Remedies for Patent Infringement.

A stated purpose of the HWA is to amend Title 35 of the United States Code.[175] However, the surrounding text of Title 35 does not provide adequate interpretative context because prior to the passage of the HWA, there was no such thing as an ANDA.[176] Therefore, there was no need for a remedy to make the patent owner whole upon a premature approval of an ANDA application.[177] By creating the ANDA, the drafters of the HWA created a situation in which the patent holder could be harmed.[178]

The Title II patent term extension provision was added in response to expert testimony given before the committee by representatives of pharmaceutical firms who testified "that the average effective patent term of drugs ha[d] declined," and further testified that "a continuation of the decline would result in decreased expenditures for research and development and, eventually, in a decline in the introduction of new drugs." *Id.* at 17.

172. H.R. REP. NO. 98-857, pt. 2, at 5-6. The committee included an exception that an ANDA applicant's use of a patented drug to conduct bioequivalency tests to comply with the FDA pre-market approval procedures does not constitute patent infringement. *Id.* at 5.

173. *See id.* at 8-9. The House Committee on the Judiciary agreed with the House Committee on Energy and Commerce's public policy arguments, stating:

> [W]ithout [s]ection 202 generic manufacturers would be required to engage in these bioequivalency tests after the expiration of the patent. This would result in delays of about two years after the expiration of the patent before a generic could go on the market. Thus, the Committee on Energy and Commerce reasoned that section 202 of the bill was essential to implement the policy objective of getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent.

Id. (footnote omitted).

174. *See generally* H.R. REP. NO. 98-857, pt. 1; H.R. REP. NO. 98-857, pt. 2.

175. Hatch-Waxman Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 35 & 42 U.S.C.).

176. *See id.* § 101.

177. *See id.*

178. *See* H.R. REP. NO. 98-857, pt. 2, at 9-10. The committee identified a situation in which the generic drug could be approved before a final judgment of patent validity. *Id.* at 10. This meant that there would be a period of time where the generic drug would be on

The drafters attempted to solve this problem by adding subsection (e) to 35 U.S.C. § 271.[179] The amended section describes activity that constitutes infringement under the new generic drug approval procedure and sets out remedies for such activity.[180] The specific list of available remedies—injunctive relief and monetary damages[181]—again prompts the application of the textual canon of *expressio unius est exclusio alterius*.[182]

There are three avenues of relief specifically listed in the HWA. First, a court may order the FDA approval date of the generic drug to occur no earlier than the expiration of the valid and infringed patent.[183] Second, a court can enjoin the infringer from further making, using, or selling the generic drug.[184] Third, a court may order the infringer to pay money damages if the patent holder can show that the generic manufacturer commercially manufactured, used, or sold the generic drug.[185] The HWA further states that the three remedies listed "are the only remedies" that may be granted for an act of infringement.[186] Under the canon of *expressio unius est exclusio alterius*, this list must be interpreted as exhaustive.[187]

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the market in infringement of a valid patent. *See id.* To fix this problem, Congress inserted a damages provision into the HWA. *Id.* at 10 & n.14.

179. 35 U.S.C. § 271(e) (2000 & Supp. III 2003). Section 271(e) states that an infringing generic product cannot be approved by the FDA prior to the expiration of the infringed patent, that injunctive relief is available against an infringer, and that victims of infringement may seek monetary damages if the infringing product has been marketed and sold commercially in the United States. *Id.* § 271(e)(4). More importantly, the HWA specifically states that the above rememdies "are the *only* remedies which may be granted by a court for an act of infringement . . . except that a court may award attorney fees." *Id.* (emphasis added).

180. *Id.* § 271(e). Infringement does not include making, using, or selling a patented invention solely for the purpose of developing and submitting information to the FDA. *Id.* § 271(e)(1). Infringement does include filing a sham ANDA in order to gain early market entry. *See id.* § 271(e)(2). Injunctive relief cannot be granted if it prohibits the making, using, or selling of a patented invention, but it can be granted against the infringer. *Id.* § 271(e)(3)-(4). Additionally, damages and other monetary relief (including attorney fees) can be awarded against the infringer, but only if there has been a showing of actual infringement. *See id.* § 271(e)(4). These are the only available remedies. *See id.* § 271(e)(1)-(4).

181. *Id.* § 271(e)(4).

182. *See* ESKRIDGE & FRICKEY, *supra* note 137, at 638-39. For example, assume that the worst happens from the patent owner's point of view. During a court proceeding to determine the patent's validity, the thirty-month stay expires and the FDA approves the generic drug. The generic manufacturer then proceeds to make, use, and sell its bioequivalent product even though the pioneer patent is arguably still valid. At some point later, the court declares the patent valid and infringed. Meanwhile, the generic drug has drastically and negatively affected the pioneer's market share. Consequently, the patent holder is harmed. *See supra* Part I.B.

183. 35 U.S.C. § 271(e)(4)(A) (2000).

184. *Id.* § 271(e)(4)(B).

185. *Id.* § 271(e)(4)(C).

186. *Id.* § 271(e)(4).

187. *See supra* note 160 and accompanying text.

Since reverse payment agreements provide an additional remedy for the patent holder, without a final judicial determination about the patent's validity, the agreements authorize the patent holder to circumvent the only statutorily available remedies.[188] Reverse payment agreements allow the patent holder to delay market entry of the generic drug through an admission that its patent is invalid or not infringed.[189] Such an agreement counteracts the explicit purpose of the HWA because there can be no infringement of an invalid patent.[190] Yet, even though the patent is admittedly invalid or not infringed, the generic drug does not make it into the marketplace as early as it could have absent the agreement, and the pioneer manufacturer gets an extension of a patent term to which it is not entitled.[191]

Even though the intrinsic evidence is already compelling, the extrinsic evidence found in the legislative history is even more so. The House Committee on Energy and Commerce anticipated that some generic drugs would be ready for market before the pioneer patent expired.[192] This situation created a new potential mischief—that the generic drug manufacturer would infringe the pioneer patent as soon as it got its FDA approval and entered the marketplace.[193] The House proposed a solution to this problem that was later incorporated into the final HWA.[194] The committee reasoned that "[i]f the applicant certified that one or more of the product or controlling use patents were invalid or not infringed, then approval of the ANDA . . . may not be made effective" until thirty

188. *See* 35 U.S.C. § 271(e)(4).

189. *Cf.* Valley Drug Co. v. Geneva Pharms. Inc., 344 F.3d 1294, 1300-01 (11th Cir. 2003); La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896, 902-03 (6th Cir. 2003).

190. *See* Hatch-Waxman Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, 35 & 42 U.S.C.) (noting Congress' intent to "amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications, to amend title 35, United States Code, to authorize the extension of the *patents* for certain regulated products, and for other purposes." (emphasis added)).

191. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d at 911. The court rejected the defendant's argument that "Andrx would not have entered the market even if there had been no Agreement and payment because of its fear of damages in the patent infringement litigation," arguing instead that the payment of eighty-nine million dollars "renders incredible" the claim that Andrx would have stayed out of the market absent the reverse payment agreement. *Id.*

192. H.R. REP. NO. 98-857, pt. 1, at 27 (1984), *reprinted in* U.S.C.C.A.N. 2647, 2660 ("The Committee recognizes that some ANDA's [sic] will be submitted and ready for approval before the patent on the listed drug has expired. To deal with this situation and to assure that the FDA concerns itself solely with the safety and effectiveness of the generic drug . . . the FDA [is permitted to] approve an ANDA but make the approval effective at some later date when appropriate.").

193. *See id.*

194. 35 U.S.C. § 271(e)(4)(A)-(C) (2000) (permitting the patent owner to sue for injunctive relief or damages).

months after a challenge by the patent holder.[195] The thirty-month stay allowed the patent infringement suit to be adjudicated to a final verdict without completely precluding the possibility of approval for the generic drug.[196]

Congress added the remedies provision to the HWA recognizing that sometimes the thirty-month stay would expire before disposition of the infringement suit.[197] Even if it did, the remedies provided by the statute would correct any harm done to the patent holder upon a finding that the patent was valid and infringed, while still serving the declared purposes of the statute.[198]

The remedies provision in the HWA effectively supersedes the purpose of reverse payment agreements.[199] Because the statute provides both injunctive and monetary relief to the victim of infringement, the remaining motivation behind reverse payment agreements is to enforce and extend a patent that is probably invalid or not infringed.[200] That motivation cannot be consistent with the purpose of the statute—to facilitate the commercial availability of lower cost pharmaceuticals.[201]

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195. H.R. REP. NO. 98-857, pt. 1, at 27. The first waiting period was eighteen months, but it was later changed to thirty months upon the recommendation of pharmaceutical industry participants. *See supra* note 36 and accompanying text.

196. *See* H.R. REP. NO. 98-857, pt. 2, at 9-10 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2693-94; *see also* H.R. REP. NO. 98-857, pt. 1, at 27 (discussing the ability of courts to shorten the waiting period if a judicial decision is reached prior to its expiration).

197. *See supra* notes 36-37 and accompanying text. The House Committee on the Judiciary examined figures from the Judicial Conference of the United States and the Annual Report of the Director of the Administrative Office of the United States Courts to determine whether or not to accept an amendment proposed by Representative Tom Sawyer. H.R. REP. NO. 98-857, pt. 2, at 9-10. The Sawyer Amendment would have required that the FDA refrain from approving generic drugs for the entire life of a valid patent. *Id.* at 9. The committee rejected the amendment because the average time of disposition for a patent case was thirty-six months, with about 10% of those taking longer than seventy-seven months, and therefore adoption of the amendment would significantly delay the approval of generic drugs. *Id.* at 9-10.

198. *See* H.R. REP. NO. 98-857, pt. 2, at 10. The committee reasoned that, in most cases, the new HWA amendments would afford the patent holder more protection than the patent laws without the amendments. *Id.*

199. *See* 35 U.S.C. § 271(e)(4) (2000); *see also* 35 U.S.C. § 155 (2000 & Supp. III 2003) (listing the specific procedures for patent term extension). The Director of the United States Patent and Trademark Office will make a determination about the grant of an extension based on the patentee's application. *Id.* Once an extension is granted under seal, it remains on file with the Patent and Trademark Office and is considered part of the original patent. *Id.*; *see also supra* note 164.

200. *See* 35 U.S.C. § 271(e)(4)(B)-(C).

201. H.R. REP. NO. 98-857, pt. 1, at 14 (stating that "[t]he purpose . . . is to make available more low cost generic drugs by establishing a generic drug approval procedure").

III. COURTS SHOULD APPLY THE PER SE RULE IN REVERSE PAYMENT CASES

Reverse payments thwart at least two of the purposes of the HWA. First, when a pioneer manufacturer pays a generic manufacturer to delay market entry, the public is unable to obtain access to lower-cost pharmaceuticals.[202] Additionally, even though the generic manufacturer is able to make money via the payments, the pioneer manufacturer effectively extends its monopoly over and above the regulatory review extension provided by the HWA.[203]

Application of the per se rule in reverse payment cases would solve both problems. If reverse payments were not available, pioneer patent holders would have to resort to the patent term extension provided in the statute, and generic drug manufacturers would be able to gain market entry as soon as the patent expired, providing cheaper drugs to the public at an earlier time.[204]

The Eleventh Circuit rejected the per se rule citing policy concerns.[205] The court argued that the use of such a rule would cause increases in litigation costs and docket crowding, while causing a decrease in beneficial settlements.[206] However, these policy concerns are not resolved through the use of the patent rule of reason. The Eleventh Circuit reasoned that the use of the per se rule would force courts to determine the presence or absence of anti-competitive conduct in every reverse payment case.[207] On the other hand, if the parties were free to craft a settlement, the agreements would never reach the court.

However, the validity of a reverse payment agreement can be challenged by the government, not just the parties to the settlement, making it hard to predict the number of cases that would actually reach the courts.[208] Under the patent rule of reason, each case that did reach the courts would be subjected to an extensive factual inquiry.[209] Such a case-

202. *See id.*

203. *See* H.R. REP. NO. 98-857, pt. 2, at 4. The bioequivalency tests required by the HWA take about two years. *Id.* at 8. The House Committee on the Judiciary agreed with the House Committee on Energy and Commerce that allowing the generic manufacturer to conduct bioequivalency tests prior to the expiration of the pioneer patent "was essential to implement the policy objective of getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent." *Id.* at 8-9.

204. *See id.*

205. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

206. *Id.* The court stated that it "fear[ed] and reject[ed] a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic's entry date, and, in an ancillary transaction, pays for other products licensed by the generic." *Id.*

207. *See id.* at 1065-66, 1076.

208. *See, e.g., id.* at 1061.

209. *See supra* note 72 and accompanying text.

by-case inquiry would be less likely to provide guidance for future cases and would often be substantially more complicated, time-consuming, and costly than a simpler per se analysis.[210] Moreover, the per se rule would encourage future settlements by providing a clearer definition of what would constitute an impermissible reverse payment.[211]

IV. CONCLUSION

Reverse payment agreements are in opposition to the prevailing analysis under the patent-antitrust doctrine. The agreements cause such a loss to society that the ratio test produces a value that is much too small to indicate a permissible activity. Additionally, reverse payments are outside the stated purpose of the HWA as demonstrated by the text itself and the statute's official legislative history. As a result, future courts should adopt the per se rule when evaluating the validity of patent settlements containing reverse payment agreements until the HWA is amended to provide for them.

210. *See supra* note 72 and accompanying text.
211. *See supra* note 20 and accompanying text.