

Pharmaceutical Patent-Antitrust: Reverse Payment Settlements and Product Hopping

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Summary

Congressional attention has recently been directed towards two practices within the pharmaceutical industry. The first pertains to "reverse payment" or "pay-for-delay" settlements of patent litigation. Under this scenario, a generic firm agrees to neither challenge the brand-name company's patents nor sell a generic version of the patented drug for a period of time. In exchange, the brand-name drug company agrees to compensate the generic firm, sometimes with substantial monetary payments over a number of years. Because the payment flows counterintuitively, from the patent owner to the accused infringer, this compensation has been termed a "reverse" payment. Although the private settlement of disputes is usually encouraged, some observers believe that these arrangements are anticompetitive.

Another widely followed practice has been termed "product hopping." Most observers would agree that the introduction of new medicines lies in the public interest. However, some stakeholders have accused brand-name firms of releasing new, patent-protected versions of existing drugs—while simultaneously discontinuing an earlier drug that is near patent expiration—with the primary goal of delaying generic entry into the marketplace. Because the Hatch-Waxman Act presupposes the existence of a brand-name drug in order for a generic version to enter the market, product hopping can potentially delay generic competition.

Two notable judicial opinions have subjected these practices to antitrust scrutiny. In its 2013 decision in *Federal Trade Commission v. Actavis, Inc*., the U.S. Supreme Court held that the legality of reverse payment settlements should be evaluated under the "rule of reason" approach. Under this approach, courts consider whether conduct was reasonable by balancing the anticompetitive consequences of a challenged practice against its business justifications and potentially procompetitive impact. The 2015 decision of the U.S. Court of Appeals for the Second Circuit in *New York ex rel. Schneiderman v. Actavis PLC* applied the rule of reason to product hopping, concluding that this activity may indeed violate the antitrust laws.

Congress possesses a number of alternatives for addressing reverse payment settlements and product hopping. One possibility is to await further judicial developments. Another option is to stipulate antitrust standards that courts and antitrust enforcement agencies would follow in the future. Congress could also alter incentives for generic firms to settle with brand-name firms under the food and drug laws.

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Introduction

The increasing costs of health care have focused congressional attention upon both the development and public availability of prescription drugs. Congress has long recognized that the patent system has an important role to play in the pharmaceutical industry in each respect. The Drug Price Competition and Patent Term Restoration Act of 1984,[1] commonly known as the Hatch-Waxman Act, in part reformed both the patent and food and drug laws in order to balance incentives for innovation and competition within the pharmaceutical industry.[2]

Recently, congressional attention has been directed towards two practices within the pharmaceutical industry. The first pertains to "reverse payment" or "pay-for-delay" settlements of patent litigation. Under this scenario, a generic firm agrees to neither challenge the brand-name company's patents nor sell a generic version of the patented drug for a period of time. In exchange, the brand-name drug company agrees to compensate the generic firm, often with substantial monetary payments over a number of years. Because the payment flows counterintuitively, from the patent owner to the accused infringer, this compensation has been termed a "reverse" payment.[3]

Another widely followed practice has been termed "product hopping." The introduction of new medicines ordinarily serves the public interest. However, some stakeholders have accused brand-name firms of releasing new, patent-protected versions of existing drugs—while simultaneously discontinuing an earlier drug that is near patent expiration—with the primary goal of delaying generic entry into the marketplace. Because the Hatch-Waxman Act presupposes the existence of a brand-name drug in order for a generic version to enter the market, product hopping can potentially delay generic competition. Complaints over product hopping are often accompanied by suspicions over the therapeutic benefits of the newly released drug. But they may raise delicate questions over the competing values of public availability of marginally superior drugs versus lower cost medications.[4]

Two notable judicial opinions have subjected these practices to antitrust scrutiny. In its 2013 decision in *Federal Trade Commission v. Actavis, Inc.*,[5] the U.S. Supreme Court held that the legality of reverse payment settlements should be evaluated under the "rule of reason" approach. Under this approach, courts consider whether conduct was reasonable by balancing the anticompetitive consequences of a challenged practice against its business justifications and potentially procompetitive impact. The 2015 decision of the U.S. Court of Appeals for the Second Circuit in *New York ex rel. Schneiderman v. Actavis PLC*[6] applied the rule of reason to product hopping, concluding that this activity may indeed violate the antitrust laws.

In response to these recent judicial developments, this report introduces and analyzes innovation and competition policy issues associated with the pharmaceutical industry. It begins with a review of the Hatch-Waxman Act and its implications upon the availability of generic substitutes for

[1] P.L. 98-417, 98 Stat. 1585.

[2] CRS Report R41114, *The Hatch-Waxman Act: Over a Quarter Century Later*, by Wendy H. Schacht and John R. Thomas.

[3] See, e.g., Michael A. Carrier, "After Actavis: Seven Ways Forward," 67 *Rutgers University Law Review* 543 (2015).

[4] See, e.g, Lars Noah, "Product Hopping 2.0: Getting the FDA to Yank Your Original License Beats Stacking Patents," 19 *Marquette Intellectual Property Law Review* 161 (2015).

[5] 133 S. Ct. 2223 (2013).

[6] 787 F.3d 638 (2d Cir. 2015).

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brand-name medications. The report then turns to a basic review of the antitrust law. It then addresses judicial developments with respect to reverse payment settlements and product hopping. The report closes with a summary of congressional issues and possible alternatives.

The Hatch-Waxman Act

Patent Fundamentals

Inventors must prepare and submit applications to the U.S. Patent and Trademark Office (USPTO) if they wish to obtain patent protection.[7] USPTO officials, known as examiners, then assess whether the application merits the award of a patent.[8] A patent application must include a specification that so completely describes the invention that skilled artisans are able to practice it without undue experimentation. Applicants must also draft at least one claim that particularly points out and distinctly claims the subject matter that they regard as their invention.[9]

While reviewing a submitted application, the examiner will determine whether the claimed invention fulfills certain substantive standards set by the patent statute. Two of the most important patentability criteria are novelty and nonobviousness. To be judged novel, the claimed invention must not be fully anticipated by a prior patent, publication, or other knowledge within the public domain.[10] The sum of these earlier materials, which document state-of-the-art knowledge that is accessible to the public, is termed the "prior art." To meet the standard of nonobviousness, an invention must not have been readily within the ordinary skills of a competent artisan based upon the teachings of the prior art.[11]

If the USPTO allows the application to issue as a granted patent, the owner or owners of the patent obtain the right to exclude others from making, using, selling, offering to sell, or importing into the United States the claimed invention.[12] The term of the patent is ordinarily set at 20 years from the date the patent application was filed.[13] Patent title therefore provides inventors with limited periods of exclusivity in which they may practice their inventions, or license others to do so. The grant of a patent permits inventors to receive a return on the expenditure of resources leading to the discovery, often by charging a higher price than would prevail in a competitive market. In the pharmaceutical industry, for example, the introduction of generic competition often results in the availability of lower-cost substitutes for the innovative product.

A patent proprietor bears responsibility for monitoring its competitors to determine whether they are using the patented invention. Patent owners who wish to compel others to observe their intellectual property rights must often commence litigation in the federal district courts.

[7] 35 U.S.C. §111.

[8] 35 U.S.C. §131.

[9] 35 U.S.C. §112.

[10] 35 U.S.C. §101.

[11] 35 U.S.C. §103.

[12] 35 U.S.C. §271.

[13] 35 U.S.C. §154(a)(2).

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FDA Approval Procedures

Although the award of a patent claiming a pharmaceutical provides its owner with a proprietary interest in that product, it does not actually allow the owner to distribute that product to the public. Permission from the Food and Drug Administration (FDA) must first be obtained.[14] In order to obtain FDA marketing approval, the developer of a new drug must demonstrate that the product is safe and effective. This showing typically requires the drug's sponsor to conduct both preclinical and clinical investigations. In deciding whether to issue marketing approval or not, the FDA evaluates the test data that the sponsor submits in a so-called New Drug Application (NDA).[15]

Prior to the enactment of the Hatch-Waxman Act, the federal food and drug law contained no separate provisions addressing marketing approval for independent generic versions of drugs that had previously been approved by the FDA. The result was that a would-be generic drug manufacturer had to file its own NDA in order to sell its product. Some generic manufacturers could rely on published scientific literature demonstrating the safety and efficacy of the drug by submitting a so-called paper NDA. Because these sorts of studies were not available for all drugs, however, not all generic firms could file a paper NDA. Further, at times the FDA requested additional studies to address safety and efficacy questions that arose from experience with the drug following its initial approval. The result was that some generic manufacturers were forced to prove once more that a particular drug was safe and effective, even though their products were chemically identical to those of previously approved pharmaceuticals.[16]

Some commentators believed that the approval of a generic drug was a needlessly costly, duplicative, and time-consuming process. These observers noted that although patents on important drugs had expired, manufacturers were not moving to introduce generic equivalents for these products due to the level of resource expenditure required to obtain FDA marketing approval.[17]

In response to these concerns, Congress enacted the Hatch-Waxman Act, a complex statute that sought compromise between brand-name and generic pharmaceutical companies.[18] Its provisions included the creation of an expedited marketing approval pathway for generic drugs termed an Abbreviated New Drug Application, or ANDA. An ANDA allows an independent generic applicant to obtain marketing approval by demonstrating that the proposed product is bioequivalent to an approved pioneer drug, without providing evidence of safety and effectiveness from clinical data or from the scientific literature. The availability of ANDAs often allows a generic manufacturer to avoid the costs and delays associated with filing a full-fledged NDA. They may also allow an independent generic manufacturer, in many cases, to place its FDA-approved bioequivalent drug on the market as soon as any relevant patents expire.[19]

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[14] CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by Susan Thaul.

[15] See FDA, "Drugs: Development and Approval Process (Drugs): How Drugs Are Developed and Approved," April 23, 2010 (available at http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/default.htm).

[16] See Colleen Kelly, "The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond," 66 *Food and Drug Law Journal* (2011), 417.

[17] See Matthew Avery, "Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments," 60 *Hastings Law Journal* (2008), 171.

[18] See Timothy A. Cook, "Pharmaceutical Patent Litigation Settlements: Balancing Patent and Antitrust Policy Through Institutional Choice," 17 *Michigan Telecommunications and Technology Law Review* (2011), 417.

[19] See Michael R. Herman, "The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution (continued...)

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As part of the balance struck between brand-name and generic firms, Congress also provided patent proprietors with a means for restoring a portion of the patent term that had been lost while awaiting FDA approval. The maximum extension period is capped at five years, or a total effective patent term after the extension of not more than 14 years. The scope of rights during the period of extension is generally limited to the use approved for the product that subjected it to regulatory delay. This period of patent term extension is intended to compensate brand-name firms for the generic drug industry's reliance upon the proprietary pre-clinical and clinical data they have generated, most often at considerable expense to themselves.[20]

Resolution of Patent Disputes

During its development of accelerated marketing approval procedures for generic drugs, Congress recognized that the brand-name pharmaceutical firm may be the proprietor of one or more patents directed towards that drug product. These patents might be infringed by a product described by a generic firm's ANDA or in the event that product is approved by the FDA and sold in the marketplace. The Hatch-Waxman Act therefore established special procedures for resolving patent disputes in connection with applications for marketing generic drugs.[21]

In particular, the Hatch-Waxman Act states that each NDA applicant "shall file" a list of patents that the applicant believes would be infringed if a generic drug were marketed prior to the expiration of these patents.[22] The FDA then lists these patents in a publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is more commonly known as the "Orange Book."[23] Would-be manufacturers of generic drugs must then engage in a specialized certification procedure with respect to Orange Book-listed patents. An ANDA applicant must state its views with respect to each Orange Book-listed patent associated with the drug it seeks to market. Four possibilities exist:

> (1) that the brand-name firm has not filed any patent information with respect to that drug;
>
> (2) that the patent has already expired;
>
> (3) that the generic company agrees not to market until the date on which the patent will expire; or
>
> (4) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the ANDA is submitted.[24]

These certifications are respectively termed paragraph I, II, III, and IV certifications. An ANDA certified under paragraphs I or II is approved immediately after meeting all applicable regulatory and scientific requirements. An independent generic firm that files an ANDA including a

(...continued)

of Pharmaceutical Patent Litigation," 111 *Columbia Law Review* (2011), 1788.

[20] See Ann Kotze, "Reining in Patent Term Extensions for Related Pharmaceutical Products Post-*Photocure* and *Ortho-McNeil*," 106 *Northwestern University Law Review* (2012), 1419.

[21] See Linda P. Nussbaum and John D. Radice, "Where Do We Go Now? The Hatch-Waxman Act Twenty-Five Years Later: Successes, Failures, and Prescriptions for the Future," 41 *Rutgers Law Journal* (2009), 229.

[22] 21 U.S.C. §355(b)(1).

[23] See Ian Hastings, "Dynamic Innovation Inefficiency in Pharmaceutical Patent Settlements," 13 *North Carolina Journal of Law and Technology* (2011), 31.

[24] 21 U.S.C. §355(j)(2)(A)(vii).

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paragraph III certification must, even after meeting pertinent regulatory and scientific requirements, wait for approval until the drug's listed patent expires.[25]

The filing of an ANDA with a paragraph IV certification constitutes a "somewhat artificial" act of patent infringement under the Hatch-Waxman Act.[26] The act requires the independent generic applicant to notify the proprietor of the patents that are the subject of a paragraph IV certification. The patent owner may then commence patent infringement litigation against that applicant.[27]

In order to encourage challenges of pharmaceutical patents, the Hatch-Waxman Act provides prospective manufacturers of generic pharmaceuticals with a potential reward. That reward consists of a 180-day exclusivity period awarded to the first ANDA applicant to file a paragraph IV certification.[28] Once a first ANDA with a paragraph IV certification has been filed, the FDA cannot issue marketing approval to a subsequent ANDA with a paragraph IV certification on the same drug product for 180 days. Because market prices could drop considerably following the entry of additional generic competition, the first paragraph IV ANDA applicant may potentially obtain more handsome profits than subsequent market entrants—thereby stimulating patent challenges in the first instance.[29]

Antitrust Fundamentals

The primary legal mechanism for addressing conduct alleged to be anti-competitive—including reverse payment settlements and product hopping—consists of the antitrust laws. The antitrust laws consist of the Sherman Act, the Clayton Act, the Federal Trade Commission Act, and other federal and state statutes that prohibit certain kinds of anticompetitive economic conduct. Although a complete review of the antitrust laws exceeds the scope of this report, other sources provide more information for the interested reader.[30]

Section 1 of the Sherman Act declares "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade ... to be illegal." The courts have long interpreted this language as applying only to unreasonable restraints of trade. The determination of whether particular conduct amounts to an unreasonable restraint of trade is commonly conducted under the "rule of reason." Under this approach, "the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect."[31] The rule of reason essentially calls upon courts to reach a judgment of reasonableness by balancing the anticompetitive consequences of a challenged practice against its business justifications and potentially procompetitive impact.[32]

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[25] See Emily Michiko Morris, "The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act," 22 *Fordham Intellectual Property Media and Entertainment Law Journal* (2012), 245.

[26] Eli Lilly & Co. v. Medtronic, 496 U.S. 1047 (1990).

[27] See Morris, *supra*.

[28] 21 U.S.C. §355(j)(5)(B)(iv).

[29] See Scott Hemphill and Mark A. Lemley, "Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act," 77 *Antitrust Law Review* (2011), 947.

[30] See, e.g., Federal Trade Commission, *FTC Guide to the Antitrust Laws* (available at http://www.ftc.gov/bc/antitrust/).

[31] State Oil Co. v. Khan, 522 U.S. 3, 10 (1997).

[32] See Meredith Bateman, "*In re K-Dur Antitrust Litigation*—Reverse Payments: Against Prices, Purchasers, and Policy," 15 *Tulane Journal of Technology and Intellectual Property* (2012), 293.

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Other sorts of restraints are deemed unlawful *per se*. *Per se* illegality is appropriate "[o]nce experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it." The Supreme Court has explained that "there are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use."[33] Among the practices that have been judged per se violations include price fixing, group boycotts, and market division.[34]

In some circumstances, courts apply an antitrust standard that falls between the *per se* illegality standard and the rule of reason. The so-called "quick look" or "truncated rule of reason" approach applies when the plaintiff demonstrates that the defendant has engaged in practices similar to those previously held to be subject to *per se* treatment. In these circumstances, the defendant must then demonstrate that the practice has pro-competitive justifications in order to avoid liability for an antitrust violation.[35]

Reverse Payment Settlements

As discussed previously, a generic firm's filing of a paragraph IV ANDA may result in a patent infringement suit brought by a brand-name drug company. In such litigation, if the NDA holder demonstrates that the independent generic firm's proposed product would violate its patents, then the court will ordinarily issue an injunction that prevents the generic drug company from marketing that product. That injunction will expire on the same date as the NDA holder's patents. Independent generic drug companies commonly amend their ANDAs in this event, replacing their paragraph IV certifications with paragraph III certifications.[36]

On the other hand, the courts may decide in favor of the independent generic firm. The court may conclude that the generic firm's proposed product does not infringe the asserted patents, or that the asserted patents are invalid or unenforceable. In this circumstance, the independent generic firm may launch its product once the FDA has finally approved its ANDA.[37]

In addition to the issuance of final judgment in favor of either the brand-name drug company or generic firm, another resolution of pharmaceutical patent litigation is possible. This legal situation led to a number of cases with varying details, but a common core fact pattern. Upon filing a paragraph IV ANDA, a generic firm would be sued for patent infringement as provided by the Hatch-Waxman Act. The NDA holder and generic applicant would then settle their dispute. The settlement would call for the generic firm to neither challenge the patent nor produce a generic version of the patented drug, for a period of time up to the remaining term of the patent. In exchange, the NDA holder would agree to compensate the ANDA applicant, often with substantial monetary payments over a number of years.[38] This compensation has been termed an

[33] Northern Pacific Railroad Co. v. United States, 356 U.S. 1, 5 (1957).

[34] See Leegin Creative Leather Products, Inc. v. PSKS, Inc., 551 U.S. 877 (2007).

[35] See California Dental Association v. FTC, 526 U.S. 756 (1999).

[36] 21 C.F.R. §314.94(a)(12)(viii)(A).

[37] 21 U.S.C. §355(j)(5)(B)(iii).

[38] See C. Scott Hemphill, "Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem," 81 *New York University Law Review* (2006), 1560.

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"exclusion"[39] or "exit"[40] payment or, because the payment flows counterintuitively, from the patent proprietor to the accused infringer, a "reverse" payment.[41]

Notice of Payment Settlements

Congress initially addressed reverse payment settlements in 2003 with the Medicare Prescription Drug, Improvement, and Modernization Act (MMA).[42] That legislation mandated that the Department of Justice (DOJ) and Federal Trade Commission (FTC) receive copies of certain patent- or exclusivity-based settlement agreements in the pharmaceutical field. Section 1112 of the MMA sets out two sorts of agreements that are subject to this notice requirement: Section 1112(a) agreements between a brand-name drug company and a paragraph IV ANDA applicant, and Section 1112(b) agreements between two paragraph IV ANDA applicants.

Section 1112(a) agreements must occur between an ANDA applicant, on one hand, and either the NDA holder or an owner of an Orange Book-listed patent, on the other.[43] Such agreements are subject to the MMA's notification requirement if their subject matter relates to one of three topics:

> (1) The manufacture, marketing, or sale of the brand-name drug that is listed in the ANDA;
>
> (2) The manufacture, marketing, or sale of the generic drug for which the ANDA was submitted; or
>
> (3) The 180-day generic exclusivity period[44] as it applies to that ANDA, or to another ANDA filed with respect to the same brand-name drug.[45]

In turn, Section 1112(b) requires that agreements between two paragraph IV ANDA applicants relating to the 180-day generic exclusivity provision be submitted to the DOJ and FTC.[46]

The MMA stipulates that certain agreements are not subject to this filing requirement. In particular, agreements that solely consist of purchase orders for raw materials, equipment and facility contracts, employment or consulting contracts, or packaging and labeling contracts need not be submitted to the DOJ or FTC.[47] Failure to file in keeping with MMA requirements exposes a contracting party to a civil penalty, compliance order, and other equitable relief.[48]

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[39] See Herbert Hovenkamp et al., "Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments," 88 *Minnesota Law Review* 712 (2004).

[40] Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1309 (11th Cir. 2003).

[41] See David W. Operbeck, "Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation," 98 *Georgetown Law Journal* 1303 (2010); Thomas F. Cotter, "Refining the 'Presumptive Illegality' Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Honvekamp, Janis and Lemley," 87 *Minnesota Law Review* 1789 (2003).

[42] P.L. 108-173, 117 Stat. 2066.

[43] Ibid., §1112(a)(1).

[44] Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act provides for a 180-day period of "generic exclusivity" to the first ANDA applicant in certain situations.

[45] MMA §1112(a)(1).

[46] Ibid. §1112(a)(2).

[47] Ibid. §1112(c)(1).

[48] Ibid. §1115.

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FTC v. Actavis

Although the MMA required pharmaceutical firms to inform the government concerning reverse payment settlements, that legislation did not impose substantive standards concerning antitrust oversight of these arrangements.[49] The courts were left to develop the appropriate level of antitrust oversight of these settlements. Facing somewhat different facts, they developed varying approaches to the issue.[50] However, these distinctions were laid to rest by the 2013 Supreme Court opinion in *Federal Trade Commission v. Actavis, Inc.*[51]

In *Actavis*, the Supreme Court held that the legality of reverse payment settlements should be evaluated under the "rule of reason" approach.[52] However, the Court declined to hold that such settlements should be presumptively illegal under a "quick look" analysis.[53] The *Actavis* opinion resolves a longstanding split among the lower courts regarding the approach that should be taken toward settlement of pharmaceutical patent cases under the antitrust laws. The lower courts now face the potentially complex task of applying the rule of reason to reverse payment settlements going forward.[54]

The patent proprietor in the *Actavis* litigation was Solvay Pharmaceuticals, the NDA holder of the testosterone-replacement drug AndroGel. When generic firms Actavis and Paddock Laboratories filed paragraph IV ANDAs, Solvay brought charges of patent infringement in keeping with the Hatch-Waxman Act. The parties ultimately settled the case, with the generic firms receiving cash payments in exchange for the promise not to market their products until August 31, 2015, 65 months before Solvay's patent expired.[55]

The FTC subsequently charged the settling parties with a violation of section 5 of the Federal Trade Commission Act,[56] in that they unlawfully agreed "to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years."[57] The District Court for the Northern District of Georgia rejected the FTC's claims,[58] and on appeal the Eleventh Circuit affirmed. Applying the "scope of the patent" standard that had been developed in earlier cases, the Court of Appeals explained that

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[49] See, e.g, Christopher O. Estwick, "Reverse Payment Settlements: How Actavis Activated the Rule of Reason," 39 *Journal of Corporate Law* 859 (2014); Susan Schipper, "Bed Medicine: FTC v. Actavis, Inc. and the Missed Opportunity to Resolve the Pay-for-Delay Problem," 73 *Maryland Law Review.* 1240 (2014); Zhenghui Wang, "Reanalyzing Reverse-Payment Settlements: A Solution to the Patentee's Dilemma," 99 *Cornell Law Review* 1227 (2014).

[50] See, e.g, In re K-Dur Antitrust Litigation, 686 F.3d 197 (3d Cir. 2012); Arkansas Carpenters Health and Welfare Fund v. Bayer AG, 604 F.3d 98, 94 USPQ2d 1908 (2d Cir. 2010); In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323, 88 USPQ2d 1801 (Fed. Cir. 2008); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 74 USPQ2d 1001 (11th Cir. 2005); In re Cardizem CD Antitrust Litigation, 332 F.3d 896 (6th Cir. 2003).

[51] 133 S. Ct. 2223 (2013).

[52] Ibid. at 2237.

[53] Ibid.

[54] See Aaron Edlin et al., "The Actavis Inference: Theory and Practice," 67 *Rutgers University Law Review.* 585 (2015); Audra J. Passinault, "A Prescription for the Future: Reverse-Payment Settlements in the Wake of FTC v. Actavis Pharmaceuticals," 29 *Notre Dame Journal of Law, Ethics and Public Policy* 549 (2015); Allison A. Schmitt, "Competition Ahead? The Legal Landscape for Reverse Payment Settlements After Federal Trade Commission v. Actavis, Inc.," 29 *Berkeley Technology Law Journal* 493 (2014).

[55] 133 S. Ct. at 2229.

[56] 15 U.S.C. §45.

[57] 133 S. Ct. at 2229–30.

[58] In re Androgel Antitrust Litig., 687 F. Supp. 2d 1371 (N.D. Ga. 2010).

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"absent sham litigation or fraud in obtaining a patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the exclusionary potential of the patent."[59]

The Supreme Court subsequently agreed to hear the case. In a 5-3 ruling, the Supreme Court reversed the judgment of the Eleventh Circuit and remanded. Writing for the majority, Justice Breyer accepted that the anticompetitive effects of the agreement between Solvay and the generic firms fell with the scope of its patent. However, this fact by itself did not immunize the agreement from antitrust scrutiny. The majority explained that while the holder of a valid patent may be exempt from antitrust liability when enforcing the exclusionary right, litigation under the Hatch-Waxman Act involves assertions of patent invalidity or noninfringement. If the generic firm successfully makes either case, the patent proprietor would not enjoy the right to exclude the proposed generic product from the marketplace. As a result, such agreements may have significant adverse effects on competition.

Justice Breyer therefore reasoned that "it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well."[60] Observing that its precedent had held that certain patent-related settlements can violate the antitrust laws, the Court summarized its patent-antitrust case law as follows:

> [R]ather than measure the length or amount of a restriction solely against the length of the patent's term or its earning potential, as the Court of Appeals apparently did here, this Court answered the antitrust question by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents.[61]

The Court also concluded that the structure of the Hatch-Waxman Act—including its patent challenge provisions, requirement of notification of settlements to the antitrust authorities, and its "general procompetitive thrust"—was consistent with subjecting reverse payment settlements to antitrust scrutiny.[62]

Justice Breyer acknowledged that the strong judicial policy favoring the settlement of disputes supported the holding of the Eleventh Circuit. But he cited five considerations in support of a contrary result:

> [A] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments. In our view, these considerations, taken together, outweigh the single strong consideration—the desirability of settlements—that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements.[63]

Finally, Justice Breyer declined to adopt the Commission's suggestion that reverse payment settlements should be presumptively unlawful and subject to a "quick-look approach." According

[59] FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012).

[60] 133 S. Ct. at 2231.

[61] Ibid.

[62] Ibid. at 2225–26.

[63] Ibid. at 2237.

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to the majority, this approach was appropriate only where "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets."[64] This treatment was inappropriate in this case because the likelihood of a reverse payment bringing about anticompetitive effects depends upon a number of factors, including the size of the payment, its scale in relation to the payor's anticipated litigation costs, its independence from other consideration within the settlement, and the lack of any other convincing justification. Instead, the Court concluded that the FTC must establish antitrust liability using the traditional rule of reason analysis.[65]

Chief Justice Roberts contributed a dissent that was joined by Justices Scalia and Thomas. The dissenters would have held that a reverse payment settlement violates antitrust law only when it exceeds the scope of the patent, the patents were obtained by fraud, or the patentee engages in sham litigation.[66] The dissenters feared that the majority holding would dissuade generic firms from challenging patents in the first place,[67] discourage settlement of patent litigation,[68] and weaken the protection afforded to innovators by patents.[69]

Commentators have viewed the ruling in *Actavis* as making a significant change to patent-antitrust practice. Although the Supreme Court's opinion does not eliminate the ability of pharmaceutical firms to settle litigation under the Hatch-Waxman Act, the contracting parties will have to structure and explain their agreements with greater care. Parties may also be more willing to litigate their pharmaceutical patent cases to a final conclusion. With respect to existing agreements, the lower courts have been assigned the potentially complex task of giving substance to the rule of reason in Hatch-Waxman cases.

Post-*Actavis* Developments

Although commentators initially expected that reverse payment settlements would be subject to more severe antitrust scrutiny in the future, [70] several district court opinions issued shortly after *Actavis* continued to uphold the settlements as lawful.[71] However, as suggested by the 2015 decision of the U.S. Court of Appeals for the Third Circuit in *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*,[72] lower court response to *Actavis* continues to evolve. *King Drug v. Smithkline Beecham* addressed two important issues: (1) whether the *Actavis* holding was limited to cash payments, as compared to other forms of contractual consideration; and (2) whether *Actavis* dictated the substantive terms of the rule of reason analysis the lower courts were meant to apply.

As to the first issue, reverse payment settlements have often involved a cash payment made by the brand-name firm to the generic firm. However, the facts of litigated cases reveal that many such settlements have involved non-cash consideration instead. Possible non-cash consideration

[64] Ibid.

[65] Ibid.

[66] Ibid. at 2239 (Roberts, C.J., dissenting).

[67] Ibid. at 2247 (Roberts, C.J., dissenting).

[68] Ibid. at 2238 (Roberts, C.J., dissenting).

[69] Ibid. at 2247 (Roberts, C.J., dissenting).

[70] See, e.g., Joshua P. Davis and Ryan J. McEwan, "Deactivating Actavis: The Clash Between the Supreme Court and (Some) Lower Courts," 67 *Rutgers University Law Review* 557 (2015).

[71] See Michael A. Carrier, "How Not to Apply Actavis," 109 *Northwestern University Law Review Online* 113 (2014).

[72] 2015 WL 3967112 (3d Cir. June 26, 2015).

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includes payment for unrelated generic services, such as backup manufacturing capacity or the promise to supply a raw material used to make the pharmaceutical.[73]

Shortly after the Supreme Court issued *Actavis*, at least two district courts held that its ruling was limited to settlements where the brand-name firm paid cash to the generic firm.[74] These courts observed that the *Actavis* opinion frequently focused upon the form of consideration that was relevant to that case, namely, cash. They further concluded that the rule of reason analysis compelled by *Actavis* could reasonably be accomplished with respect to a cash payment. However, non-cash consideration was deemed to be difficult to quantify numerically. As a result, these courts limited *Actavis* to its specific facts and upheld settlements that did not involve the transfer of cash.

However, the U.S. Court of Appeals for the Third Circuit rejected this analysis in *King Drug v. Smithkline Beecham*.[75] Writing for the Court of Appeals, Judge Scirica concluded that non-cash agreements potentially transferred considerable wealth from the brand-name firm to the generic firm.[76] Judge Scirica also explained that simply because the patent laws generally allow patent proprietors to license their patents does not immunize a particular license with anticompetitive effects from antitrust scrutiny.[77] Rejecting the argument that the Supreme Court intended to draw a formal line between cash and non-cash consideration in *Actavis*, the Third Circuit held that an unusual, unexplained transfer of value from the patent proprietor to the alleged infringer is subject to the rule of reason.[78]

Judge Scirica's reasoning in *King Drug* potentially applies to any transfer of value between parties settling a patent case. Because brand-name firms are typically uninterested in obtaining the services of generic firms outside the context of a patent settlement, *King Drug v. Smithkline Beecham* considerably buttresses the *Actavis* ruling and extends its logic to a wide swath of commercial arrangements. Whether the other courts of appeal will adopt the logic of the Third Circuit remains to be seen.

Some disagreement among commentators has also arisen about the substantive scope of the rule of reason analysis. A staple of antitrust law, the rule of reason analysis requires courts to consider whether the parties to the reverse payment settlement had market power and exercised it, whether the restraint had anti-competitive consequences, and whether these consequences are otherwise justified.[79] In an attempt to apply these basic principles within the context of reverse payments settlements, certain lower courts made considerable use of the "five sets of considerations" on which Justice Breyer relied to overcome the strong judicial preference for private settlement of disputes. In particular, Justice Breyer explained that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess

[73] See Michael Carrier, "Eight Reasons Why 'No-Authorized-Generic' Promises Constitute Payment," 67 *Rutgers University Law Review* 697 (2015); Michael A. Carrier, "Payment After Actavis," 100 *Iowa Law Review*. 7 (2014).

[74] See In re Loestrin 24 FE Antitrust Litigation, 45 F.Supp.3d 180 (D.R.I. 2015); In re Lamictal Direct Purchaser Antitrust Litigation, 18 F. Supp.3d 560 (D.N.J.), vacated and remanded sub nom. King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 2015 WL 3967112 (3d Cir. June 26, 2015).

[75] 2015 WL 3967112 (3d Cir. June 26, 2015).

[76] Ibid. at *11.

[77] Ibid. at *12.

[78] Ibid. at *14.

[79] See Benjamin M. Miller, "Antitrust Analysis After Actavis: Applying the Rule of Reason to Reverse Payments," 15 *Wake Forest Journal of Business and Intellectual Property Law* 382 (2015).

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market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments."[80]

Most readers of the *Actavis* opinion viewed these five factors as expressing the Supreme Court's rationales for adopting a rule of reason approach for analyzing the antitrust implications of reverse payment settlements. However, some district courts instead believed these factors were intended "to guide district courts in applying the rule of reason in this context.... "[81] Put differently, factors that the Supreme Court seemingly provided as a justification for its holding were viewed as defining standards for conducting the rule of reason analysis itself. Under this approach, the lower courts would essentially analyze whether a particular reverse payment settlement should be governed by the rule of reason on a case-by-case basis. However, the Supreme Court already concluded that they should, and therefore this sort of analysis is unnecessary.

The U.S. Court of Appeals for the Third Circuit recognized this problem and attempted to restore order to the rule of reason analysis in *King Drug v. Smithkline Beecham*.[82] The Third Circuit there explained that district courts should not view the five justifications that the Supreme Court offered in *Actavis* as an expression of the rule of reason itself. Rather, the district courts should proceed immediately to the rule of reason analysis when reviewing reverse payment settlements. This reading of *Actavis* will prevent courts from imposing a more difficult burden upon antitrust plaintiffs in reverse payment settlement cases than in other categories of litigation.

Product Hopping

Congress intended both the patent laws, on one hand, and the food and drug laws, on the other, to promote the development of new drugs. FDA approval of a new medication would therefore appear to promote the public interest. Antitrust enforcers have become increasingly concerned, however, that new drugs may be developed and marketed for the principal purpose of delaying generic entry. In particular, some stakeholders have accused brand-name drug companies of introducing new, patented drugs while contemporaneously removing off-patent drugs from the marketplace. This practice has been termed "product hopping," at least by its detractors.[83]

The reasons that product hopping deters generic competition are more subtle than may first appear.[84] Merely because a brand-name firm withdraws its products from the market,

[80] 133 S.Ct. at 2237, 106 USPQ2d at 1964.

[81] In re Lamictal Direct Purchaser Antitrust Litigation, 18 F. Supp.3d 560 (D.N.J.), vacated and remanded sub nom. King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 2015 WL 3967112 (3d Cir. June 26, 2015). See also In re Loestrin 24 FE Antitrust Litigation, 45 F.Supp.3d 180 (D.R.I. 2015).

[82] 2015 WL 3967112 (3d Cir. June 26, 2015).

[83] See Vikram Iyengar, "Mylan v. Warner Chilcott: A Study in Pharmaceutical Product Hopping," 19 *Marquette Intellectual Property Law Review* 245 (2015); Michael A. Carrier, "A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping," 62 *Florida Law Review* 1009 (2010); Mark Metzke, "Targeting Enantiomer Product Hopping with a New 'Obviousness' Standard," 14 *UCLA Journal of Law and Technology* 1 (2010); Jessie Cheng, "An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry," 108 *Columbia Law Review* 1471 (2008). See also Michelle L. Ethier, "Permissible Product Hopping: Why a Per Se Legal Rule Barring Antitrust Liability Is Necessary to Protect Future Innovation in the Pharmaceutical Industry," 3 *Akron Intellectual Property Journal* 323 (2009).

[84] See Lars Noah, "Product Hopping 2.0: Getting the FDA to Yank Your Original License Beats Stacking Patents," 19 *Marquette Intellectual Property Law Review* 161 (2015).

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accompanied by removal of the drug from the Orange Book, would not prevent a generic firm from filing an ANDA rather than an NDA. The FDA has expressly concluded that an ANDA "that refers to ... a listed drug that has been voluntarily withdrawn from sale in the United States must be accompanied by a petition seeking a determination whether the listed drug was withdrawn for safety or effectiveness reasons."[85] Put differently, an ANDA applicant need only demonstrate that a withdrawn reference product was not removed from the market for safety or effectiveness reasons in order to obtain marketing approval.

The principal reason that product hopping is a potentially effective generic exclusion strategy has more to do with state drug substitution laws. Under the laws of all 50 states and the District of Columbia, pharmacists are either permitted or required to dispense a therapeutically equivalent generic drug in place of a brand-name drug unless the prescribing physician has stipulated otherwise. Most states and the District of Columbia have adopted the FDA's definition of "therapeutically equivalent"—namely, a generic drug must be designated as "AB"-rated within the Orange Book to be deemed therapeutically equivalent to a brand-name drug.[86] Generic drug companies commonly compete with brand-name firms through state drug substitution laws. As a result of this situation, when a brand-name firm "product hops" by withdrawing an off-patent drug and introducing a new, patented medication, generic firms may not be deemed therapeutically equivalent to the new drug under state law and therefore will not be substituted for brand-name prescriptions.[87]

Until 2015, judicial precedent addressing product hopping was sparse and limited to decisions of the federal district courts.[88] The watershed decision of the U.S. Court of Appeals for the Second Circuit in *New York ex rel. Schneiderman v. Actavis PLC*[89] considerably altered the judicial landscape, providing that product hopping may indeed violate the antitrust laws. For sake of clarity, this report will refer to the Second Circuit's effort as the *Namenda* decision. Issued two years after the Supreme Court groundbreaking decision in *Actavis*, the *Namenda* opinion will likely embolden both government enforcers and the private plaintiffs' bar to pursue additional product hopping cases.

Namenda involved two versions of the Alzheimer's drug, Namenda IR and Namenda XR. Namenda IR is a twice-daily drug that neared the end of patent protection during July 2015. As a result, Actavis introduced a new, once-daily extended release version called Namenda XR. According to the Attorney General of New York, Actavis initially embarked upon a "soft switch" strategy by continuing to market both drugs but actively promoting Namenda XR. By early 2014, Actavis shifted to a "hard switch" approach by notifying the FDA it would discontinue Namenda IR, with one limited exception. Actavis also requested that the Centers for Medicare and Medicaid Services remove Namenda IR from their formularies, with the result that Medicare health plans would not cover it.[90]

The New York Attorney General responded by bringing an antitrust suit against Actavis, asserting that it had violated state and federal antitrust laws. The U.S. District Court for the Southern District of New York issued a preliminary injunction requiring that Actavis continue to market

[85] 21 C.F.R. §314.122(a).

[86] See Jaymes V. Fairfax-Colombo and David DeMatteo, "Are Bioequivalents Really Equal? Generic Substitution in the Context of Mental Illness," 12 *Indiana Health Law Review* 281 (2015).

[87] See Noah, *supra*.

[88] See M. Sean Royall et al., Antitrust Scrutiny of Pharmaceutical "Product Hopping," 28 *Antitrust* 71 (Fall 2013).

[89] 787 F.3d 638 (2d Cir. 2015).

[90] Ibid. at 648.

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Namenda IR until 30 days after July 11, 2015, the date of generic entry.[91] Actavis then appealed to the Second Circuit, which affirmed the grant of the injunction.

Writing for a three-judge panel, Judge Walker acknowledged that innovation generally benefits consumers.[92] However, he concluded that the Namenda product hop was both anticompetitive and exclusionary. In particular, the Second Circuit found that Actavis had crossed the line from permissible "soft switch" persuasion to impermissible "hard switch" coercion. The Court of Appeals also believed that the removal of Namenda IR would substantially reduce competition. Judge Walker found that withdrawal of Namenda IR would necessarily convert patients to Namenda XR with little probability of their switching back to Namenda IR once a generic version became available.[93]

Judge Walker also found little evidence of procompetitive justifications for withdrawing Namenda IR from the market. He cited evidence that Actavis intended to delay generic competition and further found no evidence that antitrust scrutiny would meaningfully deter innovation.[94] The Second Circuit concluded "that the combination of withdrawing a successful drug [IR] from the market and introducing a reformulated version of that drug [XR], which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification, violates §2 of the Sherman Act."[95]

The *Namenda* decision leaves open a number of issues that future litigation might resolve. First, the Second Circuit seems to imply that a "soft switch" approach of aggressive marketing, but maintaining the older product on the market, would not run afoul of the antitrust laws. The sorts of activities that, in the words of the Court of Appeals, "crosses the line" to impermissible conduct remains to be seen. Second, many critics of product hopping have suggested that newly introduced products do not provide much of an improvement over the old. In circumstances where the new medicine is superior to its predecessor, perhaps the courts will prove more sympathetic to product hopping. Finally, the extent to which brand-name firms must actively support their generic competitors by keeping older products on the market may prove a divisive issue.

Issues and Observations

In the absence of explicit congressional guidance, the federal courts have applied general principles of antitrust law to address reverse payment settlements and product hopping. Several options are available for Congress. One possibility is to await further judicial developments in view of the *Actavis* and *Namenda* decisions.

Another option is to regulate the settlement of pharmaceutical patent litigation in some manner. In the 114th Congress, the Fair and Immediate Release of Generics Act (S. 131), introduced by Senator Bingaman, would make a number of changes to the Hatch-Waxman Act in order to discourage reverse payments settlements. In particular, S. 131 would grant any generic firm the right to share the 180-day regulatory exclusivity if it wins a patent challenge in the district court or is not sued for patent infringement by the brand company.[96] The legislation would also oblige

[91] Ibid. at 649.

[92] Ibid. at 652.

[93] Ibid. at 654-56.

[94] Ibid. at 658.

[95] Ibid. at 659.

[96] S. 131 at §2.

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generic firms to abide by any deferred entry date agreed to in their settlements with brand-name firms, even if relevant patents were struck down previously.[97] Finally, brand-name firms would be required to make a decision to enforce their patents within 45 days of being notified of a patent challenge by a generic firm under the Hatch-Waxman Act.[98]

In addition, the Preserve Access to Affordable Generics Act (S. 2019), introduced by Senator Klobuchar, would declare that certain reverse payment settlements constitute acts of unfair competition. In particular, that bill would amend the Federal Trade Commission Act to provide that an agreement "shall be presumed to have anticompetitive effects and be unlawful if—(i) an ANDA filer receives anything of value; and (ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time." Certain exceptions apply—for example, the payment of reasonable litigation expenses not exceeding $7.5 million is not unlawful. That "quick look" presumption would not apply if the parties to the agreement demonstrated by clear and convincing evidence that the procompetitive benefits of the agreement outweighed the anticompetitive effects of the agreement. S. 2019 includes a list of factors to be weighed by the courts in such circumstances.[99]

A third bill, S. 2023, the Prescription Drug Affordability Act of 2015, was introduced by Senator Sanders. Title IV of this legislation would act similarly to S. 2019. It would also create a presumption that reverse payment settlements violated the Federal Trade Commission Act, subject to certain exceptions. However, unlike S. 2019, the parties to the agreement cannot overcome this presumption by showing that its procompetitive benefits outweighed the anticompetitive harms.

Congress has yet to consider legislation with respect to product hopping. If the current situation is deemed satisfactory, then no action need be taken. Another alternative is to encourage more active antitrust enforcement in this area in view of the *Namenda* decision. And although the rules governing generic substitution are currently a matter of state law, federal oversight of these principles could also discourage product hopping.

The interaction between brand-name and generic firms forms an important component of the public health system of the United States. The U.S. patient population relies upon brand-name drug companies to develop new medicines, but it also relies upon generic firms to increase access to such medications once they have been developed. The Hatch-Waxman Act provides for patent litigation between these two traditional rivals, as well as generic substitution, as the mechanisms through which these competing demands are mediated. When concluded in a manner that comports with antitrust principles, these practices may further the public policy goals of encouraging the labors that lead to medical innovation, but also distributing the fruits of those labors to consumers.

[97] Ibid. at §3(a).

[98] Ibid. at §3(b).

[99] S. 214 at §3.

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