Biosimilars Enter the Courts: How Will Patent Infringement Settlements Be Tested for Validity Under Antitrust Laws?

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In the 30 years since the advent of generic drugs under the Hatch-Waxman Act, certain patterns of litigation and settlements have developed. We are now entering a stage where the courts are starting to deal with the entry into the market of "biosimilars"—biologic drugs that are highly similar to or interchangeable with biologic drugs that have already been approved by the FDA ("biologic reference products"). This relationship bears a number of similarities to the one between generics and branded drugs. However, the statutory procedures for, and economics applicable to, the advent of biosimilar products suggest there will potentially be some differences in the antitrust analysis of settlements between biologics and biosimilars for validity, as compared to the settlements between branded and generic drugs.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) established an abbreviated pathway for the FDA to use in approving biosimilars. In our analysis we have concluded that the differences in the relationship between biologics and the BPCIA, as compared to that of generic drugs and the Hatch-Waxman Act, may lead to different considerations when settlements between biologics and biosimilars are analyzed under the antitrust laws to determine whether they are unlawful anticompetitive agreements. In particular:

1. We may observe more frequent "at-risk" launches of biosimilar products, and any anticompetitive impact of reverse payments involving biologics may be less and more difficult to calculate;
2. The threshold for considering whether a payment is "large" under Actavis will likely be higher for biologics. Thus, it may be more difficult to find a reverse payment to be "large" in biologics because it will need to surpass a higher threshold;
3. It may not be profitable for biologic companies to launch brand-authorized biosimilars. As a result, reverse payment settlements with a promise not to launch a brand-authorized biosimilar may be viewed as less anticompetitive than with small-molecule drugs; and
4. Reverse payment settlements involving biologics will likely have early entry provisions (allowing the biosimilar to enter the market before patent expiration), similar to what is observed in Hatch-Waxman cases.

Key Legal Procedures Under Hatch-Waxman

The Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, greatly simplified the process of obtaining FDA approval for a generic drug by allowing a generic company to file an Abbreviated New Drug Application (ANDA) to show that the generic drug is bioequivalent to the reference branded drug. This greatly reduced the costs of developing a generic, which have been estimated to be $2–$5 million.[1]

Biologics were excluded from the Hatch-Waxman Act—except for insulin and hGH, which are regulated as drugs—because, as late as 2004, the FDA was expressing uncertainty whether available science allowed a determination of sameness of the proposed biosimilar.[2] Moreover, it was known that biosimilars could not be shown to be structurally identical to their biologic reference products, so guidelines for demonstrating biosimilarity needed to be developed.[3]

Regulatory Procedures Under the BPCIA as Compared to Hatch-Waxman

Certain features of the BPCIA may call for a somewhat different analysis of the patterns of settlements between biosimilar and biologic companies, and of the reasonableness of such settlements. These features may be summarized as:

1. *Lack of interchangeability for biosimilars*: The BPCIA created a distinction between biosimilars and interchangeable products. The FDA has stated that it will issue draft guidelines on the requirements for interchangeability for biosimilars by the end of 2016,[4] but these requirements will likely be much higher than for biosimilarity alone.[5] As a consequence, it could be some time until interchangeable products enter the market.[6]
2. *Exclusivity period for biologics*: The reference biologic is provided a 12-year period of exclusivity[7] running from the date its product was first licensed,[8] and this period does not depend on the existence of any patent or trade secret.[9]
3. *Stay period for FDA approval of biosimilars*: There is no automatic 30-month stay or equivalent period for the FDA approval of biosimilars. However, this may not matter if the patent litigation is resolved before the end of the 12-year exclusivity period.
4. *Notice of intention to market biosimilars*: The Federal Circuit has held that "[t]he biosimilar applicant has to disclose its intention to market starting 180 days following the grant of approval by the FDA, regardless of whether the 'patent dance' is followed."[10] Following such a notice, the reference product sponsor may seek a preliminary injunction until a decision of patent validity, enforcement, and infringement is reached.[11]
5. *Wait period for biosimilars' applications*: The biosimilar application cannot be submitted until four years after the reference biologic was approved by the FDA.[12]
6. *Disclosure process of Subsections (l)(1)–(2)*: The biosimilar applicant may, should it choose, avail itself of the procedures of Subsections (l)(1)(B) and (l)(2). Although Subsection (l)(1)(B) states the applicant "shall" provide this information, the Federal Circuit in Amgen v. Sandoz ruled that this pathway is essentially optional for the biosimilar applicant.[13] Moreover, if the applicant chooses to follow this process, it can limit the immediate patent determination to a single patent (to be chosen by the reference sponsor).
7. *Lack of exclusivity period for first-approved biosimilars*: Unlike the 180-day exclusivity granted to first-approved generic drugs, there is no special preference accorded to the first approved noninterchangeable biosimilar. While the first *interchangeable* biological product receives a certain period of exclusivity,[14] because interchangeable products are not expected in the near term,[15] none of the biosimilars products that will launch in the short term will have a period of exclusivity.

The Settlement Patterns and Challenges Under the BPCIA May Be Substantially Different than Under Hatch-Waxman

Settlement Patterns and Challenges Under Hatch-Waxman. In *Actavis*, the first reverse payment case to reach the U.S. Supreme Court, the Court ruled that reverse payment settlements would be tested for antitrust validity by a rule-of-reason analysis, examining the terms of the settlement and the professed justifications.[16] Although the Court expressly left it to the lower courts to structure the antitrust analysis, it called out several factors bearing on the analysis, including the reverse payment's size, scale in relation to the payor's anticipated litigation costs, independence from other services, and lack of any other justification for the payment.[17]

A number of reverse payment cases have reached district and appeals

courts after Actavis. These cases have addressed several issues, including whether parties could avoid rule-of-reason analysis if their settlements did not include cash payments.[18] Reversing the district court's dismissal of one action, the U.S. Court of Appeals for the Third Circuit ruled that "[w]e do not believe *Actavis's* holding can be limited to reverse payments of cash."[19]

Another issue faced by courts has been how to analyze complicated settlements, in which nonmonetary values flow in different directions.[20] Where a transaction has numerous components, with hard-to-value consideration flowing in the direction of the branded manufacturer, the courts are presented with a difficult challenge in determining whether the net of the values is a large payment in favor of the generic challenger. Faced with this issue, the parties' arguments have focused on who had the burden of proof on justification. Most or all plaintiffs have accepted, and at least one court has held, that plaintiffs had the burden to prove the payment was "large."[21]

Expected Competition Between Biosimilars and Biologics. As of today, the FDA has only approved four biosimilars[22] and only one of those, Zarxio,[23] is on the market. Thus, little is known yet about the actual levels of competition between biosimilars and reference biologics in the United States. However, given the characteristics of biologics products and the regulatory process established by the BPCIA, competition between biologics and biosimilars is expected to be substantially different than competition between small-molecule drugs and their AB-rated generics.

Some of the expected differences in competition result from the inherent differences between biosimilars and generic drugs. Generics will only be automatically substituted by pharmacies if they are found to be bioequivalent. Since no known state has allowed the substitution of a noninterchangeable biosimilar, biosimilars are expected to take a substantially lower share away from the reference biologic as compared to AB-rated generics, which take most sales away from the brand within a few months of generic entry. As such, biosimilar companies will likely need to promote their products both to physicians and to payors in order to incentivize biosimilar sales. That is, competition between biosimilars and biologics will likely be similar to brand-to-brand competition of branded small-molecule drugs.

Moreover, the costs of developing complex biologics could be over $100 million and take over five years.[24] These are considerably higher than the $2–$5 million of development costs and a time span of two to three years for generic drugs.[25] This—together with the lack of pharmacy substitution and with certain features of the BPCIA described below—will likely result in fewer biosimilar entrants for a given reference biologic.

Some of the expected differences in competition result from certain novel features of the BPCIA that limit the rewards for biosimilar entry. For example, because the reference biologic has 12 years of exclusivity, by the time the biosimilar is launched, improved follow-on versions of the reference biologic may be available with prescriptions switched to the follow-on product.[26] Additionally, the lack of exclusivity period for the first noninterchangeable biosimilar potentially limits the incentives for early biosimilar entry. Finally, the reimbursement rules for biologics and biosimilars under Medicare Part B as established by the BPCIA do not encourage biosimilar use.[27]

The lack of interchangeability and pharmacy substitution, higher biosimilar development costs, the 12 years of exclusivity for the branded biologic, the lack of biosimilar exclusivity, and the reimbursement rules for biosimilars will likely result in fewer entrants into the market and smaller price discounts for biosimilars, compared to those observed for generic drugs. Therefore, the potential price benefit to consumers from biosimilar entry is likely smaller, such that any anticompetitive impact of reverse payment settlements will likely be lesser for biosimilars than for generics.

Reverse Payments May Be Less Likely Under the BPCIA. There are reasons to believe that reverse payment settlements between biologic and biosimilar companies will be less common than with brand and generic companies.

First, it will likely be more difficult for biosimilar and biologic companies to agree to the terms of a reverse payment settlement. As long as a biosimilar is noninterchangeable and not automatically substituted at the pharmacy, the branded biologic will generally not lose as much share to the biosimilar as a branded product loses to their generic equivalents. At the same time, because the biosimilar price is closer to the biologic price, the joint profits of the biologic and the biosimilar will be relatively close to the profits that the biologic company would earn on its own. This means that there is a narrower range of reverse payment settlement amounts that would be acceptable to both parties.

Second, it is possible that the reference biologic's patents will have expired by the end of the 12-year exclusivity period, in which case a patent settlement may not be necessary. This possible reduction of patent disputes may, however, be offset to some degree by the fact that a greater number of patents may be asserted against biosimilars, for reasons discussed below. Additionally there is substantially more time between the start of the patent litigation (assuming biosimilars choose to enter into the "patent dance") and the end of the 12-year exclusivity period. Thus, it is possible that patent litigation is resolved through a trial by the time 12-year period is over, which may reduce the likelihood of a reverse payment settlement.

Third, because there is no exclusivity for the first noninterchangeable biosimilar, the incentives for patent challenges and therefore patent litigation may be less common with biologics than with small-molecule drugs. This would also reduce the likelihood of reverse payment settlements.

The Statutory Differences Between BPCIA and Hatch-Waxman May Lead to Different Considerations When Analyzing Settlements Between Biologics and Biosimilar Companies Under the Antitrust Laws. There are a number of reasons why patent settlements between biologic and biosimilar companies will be different than for small-molecule drugs[28] and, therefore, why the antitrust considerations may also be different. The issue posed in *King v. Cephalon*—"A reasonable jury could find that a reverse payment to a generic manufacturer that comes close to or exceeds the expected profits to be earned by prevailing in the patent litigation could induce a generic manufacturer to forfeit its claim"[29]—would involve different analyses in the world of biosimilars.

One reason why antitrust considerations may be different for biosimilars is that—to the extent that patent litigation is still pending after the 12-year exclusivity period for the reference biologic—biosimilar companies are more likely to launch "at-risk" than small-molecule generic manufacturers. This is because the difference between the biologic and the biosimilar prices is relatively smaller than for small-molecule drugs, meaning that an eventual payment of damages by the biosimilar company will be closer to what it made as profits. As such, the risk of paying damages due to an "at-risk" launch will be smaller for biosimilar companies than for small-molecule generics. "At-risk" entry will likely be more common in the next few years, as biologic products are past their 12-year exclusivity period, but, because of the recency of the BPCIA, patent litigation did not begin with that 12-year period.

A consequence of an increase in "at-risk" launches is that, in the event of a settlement, a feasible payment from the biologic to the biosimilar is the forgiveness of damages. And assuming that *Actavis* applies to biologic settlements, an important question will be whether such forgiveness of damages constitutes a payment. On this point, two observations should be made. First, we have found only one court ruling that, under *Actavis*, forgiveness of damages may be considered a reverse payment.[30] Accordingly, although the Court in *Actavis* noted that the courts reviewing settlement for antitrust compliance might not need to assess the strength of the underlying patents, it is hard to see how a court could avoid that exercise if it needed to determine whether there was a "large" forgiveness of damages.

Second, because competition between biologics and biosimilars is similar to brand-to-brand competition, estimating the branded sales lost due to the biosimilar entry may be difficult because the market definition could be broader than simply the biologic and the biosimilar drugs together. Specifically, because there is no automatic substitution with the reference biologic, and because the biosimilar company will likely promote its drug to some extent, sales of the biosimilar will likely come from (a) sales of the reference biologic; (b) sales of the follow-on reference biologic, if available; (c) sales of other non-reference biologics; and (d) patients who were not taking a biologic drug.[31] Importantly, because sales of the biosimilars will not be directly tied to sales of the reference biologic (in contrast to many situations involving small-molecule drugs), estimating damages to the reference biologic is likely going to be a complex exercise, especially in therapeutic categories with more significant competition.

Another reason why antitrust considerations may be different is related to a critical question in *Actavis*, namely whether the reverse payment is "large." This question will likely remain in any reverse payment case involving biologics. However, the determination of whether the payment is "large" and the kinds of payments are likely to be seen will be different for biologics. First, in *Actavis*, "large" is often compared to the amount of

litigation costs, which according to the American Intellectual Property Law Association (AIPLA) are approximately $5 million for disputes involving more than $25 million at risk.[32] For biologics, however, litigation costs are likely much larger because biologic disputes are expected to involve more patents, and more complex patents, as well as trade secret issues.[33] Thus, the threshold for considering whether a payment is "large" under *Actavis* will likely be higher for biologics.

Second, certain noncash payments are less likely to be seen in settlements between biologics and biosimilar companies. For example, in reverse payment cases between small-molecule brands and generics, one kind of payment that has been reviewed is a promise by the brand not to launch an authorized generic.[34] Brand-authorized generics are drugs that are sold by the branded company as a generic, but at a lower price than the brand. The brand-authorized generic typically competes with other generics on price. In the case of biologics, the incentives of the biologic company to launch a brand-authorized biosimilar will be different. Specifically, because a brand-authorized biosimilar would be interchangeable with the biologic, but would be priced lower than the biologic, it would take sales away from both the biosimilar (as brand-authorized generics take sales away from generics) and the biologic. Thus, when deciding whether to launch a brand-authorized biosimilar, the biologic company would need to consider the gain from obtaining some sales from the biosimilar versus the loss from cannibalizing biologic sales.[35] Whether this is viewed as anticompetitive will depend (among other factors) on the level of sales that the biosimilar would obtain. The higher the level of biosimilar sales, the more profitable it should be to launch a brand-authorized biosimilar. Taken together, this means that brand-authorized biosimilars should be less common than brand-authorized generics. As a result, reverse payment settlements with a promise not to launch a brand-authorized biosimilar may be less likely to be viewed as anticompetitive because such brand-authorized biosimilars would not have launched in the first place.

Moreover, the value of not having a brand-authorized biosimilar will be lower to biosimilar companies than to generic companies because there is no 180-day exclusivity for non-interchangeable biosimilars. This 180-day period is when generic companies obtain the vast majority of their profits and is a reason why no-brand-authorized generic clauses have raised antitrust concerns in reverse payment cases involving generic drugs. Such considerations will be different in reverse payment cases involving biologics.

Also important, as in Hatch-Waxman, is the fact that settlements often include early entry provisions that let the generic drug launch before the patent expires without liability. These provisions may be net procompetitive, as has been noted in defense of Hatch-Waxman reverse payment settlements.[36] Such provisions are likely expected as well under BPCIA because a biosimilar would not have an incentive to enter into a settlement without such early entry provisions. Moreover, like in Hatch-Waxman, early entry provisions can lead to more biosimilar competition, and not less, and thus be procompetitive.

Endnotes

1 Henry G. Grabowski, Rahul Guha & Maria Salgado, *Regulatory and Cost Barriers Are Likely to Limit Biosimilar Development and Expected Savings in the Near Future*, 33 HEALTH AFF. 1048, 1050 (2014).

2 For a small-molecule drug covered by a composition-of-matter patent, the chemical composition of the drug was, by definition, disclosed in the patent, and a proposed generic could be compared directly to the branded product. Biologics, however, were not necessarily comparable in this way. It was noted that the characteristics of a biologic pharmaceutical product were not always determinable from the finished product and that instead "the manufacturing process is unique to each biologic and is not generally disclosed as part of the published patent." 155 CONG. REC. E688 (daily ed. Mar. 17, 2009) (remarks of Rep. Eshoo). Or, as some in the industry have put it, "the process is the product." Accordingly, the intellectual property protection could involve a combination of narrowly drawn product composition disclosed in a patent with confidential trade secrets relating to the manufacturing process. *See also The Law of Biologic Medicine: Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 9–10 (2004) (statement of Lester Crawford, Acting Commissioner, Food and Drug Administration).

3 Henry G. Grabowski, *Genia Long & Richard Mortimer, Implementation of the Biosimilar Pathway: Economic and Policy Issues*, 41 SETON HALL L. REV. 511, 512–13 (2011).

4 *FDA to Issue Draft Guidance on Interchangeability by End of Year*, BIG MOLECULE WATCH (Oct. 26, 2016), http://www.bigmolecule watch.com/2016/10/26/ fda-to-issue-draft-guidance-on-interchangeability-by-end-of-year/.

5 Steven Kozlowski et al., *Developing the Nation's Biosimilars Program*, 365 NEW ENG. J. MED. 385, 385–88 (2011).

6 Grabowski, Guha & Salgado, *supra* note 1, at 1048.

7 Regarding the reference product manufacturer's trade secrets concerning data provided to the FDA, the legislative history leading to the BPCIA sometimes references this as "a 12-year period of [data] exclusivity," as compensation for "allow[ing] competitors access to their data and a shortcut into the market." *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 9 (2009) (testimony of Rep. Eshoo). This is an allusion to the fact that the 12-year period was said to be related to the 11-and-a-half-year period that was the "average length of time that drugs are marketed under patent." *Id.* at 8. But in the BPCIA the 12-year period applies regardless of patents, and patents still come into play following the 12-year period.

8 42 U.S.C. § 262(k)(7)(A). Unless otherwise specified, all subsection references herein are to subsections of 42 U.S.C. § 262. The statutory phrase "first licensed" does not refer to a particular indication.

9 Many of the blockbuster biologics are nearing or past those dates. Remicade was approved in 1998, Humira in 2002, Enbrel in 2000, Lantus in 2000, Neulasta in 2002, and Neupogen in 1998.

10 Amgen Inc. v. Apotex Inc., 827 F.3d 1052 (Fed. Cir. 2016), *petition for cert. filed* (U.S. Sept. 14, 2016) (No. 16-332). Apotex has petitioned the Supreme Court for certiorari on this issue. *See* Jeff Overley, *Apotex Takes Biosimilar Case to Supreme Court*, LAW360, Sept. 16, 2016. "Patent dance" is a name often given to the schedule by which the biosimilar applicant and the reference product sponsor exchange information regarding the patents that may be the subject of litigation.

11 42 U.S.C. § 262(l)(8)(B).

12 42 U.S.C. § 262(m)(2)(A).

13 794 F.3d 1347, 1355–56 (Fed. Cir. 2015), *petition for cert. filed* (U.S. Mar. 23, 2016) (No. 15-1195).

14 42 U.S.C. § 262(k)(6).

15 Substantial obstacles are being argued in opposition to findings of interchangeability. *See, e.g.*, Citizen Petition from AbbVie Inc. to the FDA (Dec. 16, 2015), http://www.bigmoleculewatch.com/wp-content/uploads/2016/01/Citizen_Petition_from_AbbVie_Inc_.pdf.

16 FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237–38 (2013). In *Actavis*, Solvay Pharmaceuticals had obtained approval to market a branded drug called AndroGel in 2000. *Id.* at 2229. When two companies—Actavis Inc. and Paddock Laboratories—filed an ANDA to market a generic drug modeled after AndroGel, Solvay initiated Paragraph IV patent litigation to establish that Solvay's patent barred their entry into the market until expiration of the patent in January 2021. That litigation then settled in 2006. *Id.* One term of the settlement was that Actavis would not bring its generic to market until August 31, 2015, unless someone else marketed a generic sooner; other terms included the payment for an estimated $19–$30 million per year to Actavis during those nine years. *Id.* The FTC sued the settling parties, claiming that the settlement violated Section 5 of the Federal Trade Commission Act of 1914, alleging that the payments to the proposed generic manufacturers were unlawful as agreements not to compete, and that competition would have substantially reduced the costs of the drug to consumers. *Id.* at 2229–30.

17 *Id.* at 2237.

18 King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388 (3d Cir. 2015), *cert. denied*, 84 U.S.L.W. 3482 (U.S. Nov. 7, 2016) (No. 15-1055). Note that the first generic is guaranteed a 180-day period of exclusivity as to generic competition except for such competition as the branded manufacturer might authorize. FTC studies in this area have suggested that in the Hatch-Waxman context the first generic version of a drug is priced on average nearly 15 percent lower than the brand name drug. FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT (2011), http://www.ftc.ov/os/2011/08/2011genericdrugreport.pdf. But as more generics become available, the price may fall further: after additional generic competitors enter, generic prices ultimately end up 85 percent lower on average than the brand-name manufacturers' original prices. FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAYOFFS COST CONSUMERS BILLIONS (2010), https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billionsfederal-trade-commission-staff. The brand-name drug ultimately loses on average about 90 percent of its market share by unit sales. *Id.*

19 *Smithkline*, 791 F.3d at 403. At least one former FTC Commissioner has described that question as "not even a close one." Joshua D. Wright, Commissioner, Fed. Trade Comm'n, Remarks at the Antitrust Masters Course VII: Antitrust Analysis of Reverse Payment Settlements after *Actavis*: Three Questions and Proposed Answers 5 (Oct. 10, 2014), https://www.ftc.gov/system/files/documents/public_statements/ 591131/141010actavisspeech.pdf. FTC Chairwoman Edith Ramirez went further earlier this year, stating that the FTC is committed to "stopping pay-for-delay agreements that inflate the prices of prescription drugs and harm competition, *regardless of the form they take*." Press Release, Fed. Trade Comm'n, FTC Sues Endo Pharmaceuticals Inc. and Others for Illegally Blocking Lower-Cost Generic Versions of the Branded Drugs Opana ER and Lidoderm (Mar. 31, 2016) (emphasis added), https://www.ftc.gov/news-events/press-releases/2016/03/ftcsues-endo-pharmaceuticals-inc-others-illegally-blocking-lower.

20 King Drug Co. of Florence, Inc. v. Cephalon, Inc., 88 F. Supp. 3d 402 (E.D. Pa. 2015).

21 *Id.* at 414. As to how one proves "large," the court agreed with the plaintiffs "that a reverse payment is sufficiently large if it exceeds saved litigation costs and a reasonable jury could find that the payment was significant enough to induce a generic challenger to abandon its patent claim." *Id.* at 417. Later discussion clarified "large" as an amount "that comes close to or exceeds the expected profits to be earned by prevailing in the patent litigation." Id. That said, at least one former FTC Commissioner has made statements that suggest that the analysis should include procompetitive benefits to the settlement agreement considered as a whole, even if those benefits were connected only by the settlement agreement itself. Wright, *supra* note 19, at 16–20.

22 *See* John T. Aquino, *Second U.S. Biosimilar Approval Shows FDA's Confidence*, BLOOMBERG BNA (Apr. 6, 2016), http://www.bna.com/second-us-biosimilar-n57982069574/; Press Release, FDA, FDA Approves Erelzi, A Biosimilar to Enbrel (Aug. 30, 2016), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518639.htm; Ezequiel Minaya, *FDA Approves Amgen's Biosimilar Version of Humira*, WALL ST. J., Sept. 23, 2016.

23 Ben Hirschler & Michael Shields, *Novartis Launches First U.S. "Biosimilar" Drug at 15 Percent Discount*, REUTERS (Sept. 3, 2015), http://www.reuters.com/article/us-novartis-drug-idUSKCN0R30C220150903. *See also* Press Release, Novartis, Sandoz Launches Zarxio™ (figrastim-sndz), the First Biosimilar in the United States (Sept. 3, 2015), https://www.novartis.com/news/media-releases/sandoz-launcheszarxiotm-filgrastim-sndz-first-biosimilar-united-states.

24 *See* FED. TRADE COMM'N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION 14 (2009), https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commissionreport/p083901biologicsreport.pdf.

25 Grabowski, Guha & Salgado, *supra* note 1, at 1050.

26 *See* 42 U.S.C. § 262 (k)(7)(A). For further discussion of how the 12-year exclusivity period could affect competition, see Sara Champion, Rahul Guha & Maria Salgado,

Emerging Competition Issues in Biologics, 26 ANTITRUST HEALTH CARE CHRON. (ABA Section of Antitrust Law Newsl.), July 2013, at 9, 10–11.

27 Specifically, under the BPCIA, biologics are reimbursed at 106 percent of the biologic's average sales price (ASP), while the biosimilar is reimbursed at 100 percent of the biosimilar's ASP plus 6 percent of the reference biologic's ASP. Patient Protection and Affordable Care Act § 3139, 42 U.S.C. § 1395w-3a (2012). Thus, the reimbursement beyond the ASP is the same whether the biosimilar or the biologic is used, which does not encourage providers to use biosimilars.

28 Section 1112 of the Medicare Modernization Act of 2003 (MMA) requires that agreements between brand name companies and generic companies regarding the manufacture or sale of a generic be filed with the Assistant Attorney General and the FTC for review within ten days after the agreements are executed. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 § 1112, 21 U.S.C. § 355 (2012). No such reporting is required for the BPCIA. *See Biosimilars*, HEALTH AFFAIRS: HEALTH POLICY BRIEFS (Oct. 10, 2013), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=100.

29 *Cephalon*, 88 F. Supp. 3d at 417.

30 In *In re Nexium (Esomeprazole) Antitrust Litigation*, 42 F. Supp. 3d 231, 285–86 (D. Mass. 2014), the generic manufacturer paid $9 million to settle the case, but the plaintiffs contended that this was over $20 million less than the actual damages. The court denied summary judgment, ruling that the plaintiffs "sufficiently demonstrate[d] a significant forgiveness of debt [from a separate patent litigation] to support a reasonable inference that Teva received a reverse payment to delay its generic Nexium launch." *Id.* at 286.

31 Category (d) includes people who were potentially taking a non-biologic drug, or they were not being treated with drugs at all. *See generally* SHASHANK UPADHYE, GENERIC PHARMACEUTICAL PATENT AND FDA LAW § 16 (2016) (discussing various factors in damages analysis for pharmaceutical patent infringement in a non-two-supplier market scenario).

32 Am. Intellectual Prop. Law Ass'n (AIPLA), *2015 Report of the Economic Survey* 37 (2015), http://files.ctctcdn.com/e79ee274201/b6ce d6c3-d1ee-4ee7-9873-352dbe08d8fd.pdf.

33 It is not clear how the fact that more patents may ultimately come into play for the reference product manufacturer will affect the analysis. On the one hand, one may expect that the inclusion of process patents may put additional arrows in the patentee's quiver; but, on the other hand, the fears expressed in the legislative history (as discussed above) that the composition-of-matter patents may not be as easy to enforce as to biosimilars suggest a countervailing weakness of the patentee's protection. Consistent with this suggestion, the patent whose potential infringement led to the settlement challenged by the FTC in Actavis was a composition-of-matter and a method-of-treatment patent, whereas the patent asserted in *Amgen v. Sandoz* was a method-of-treatment and "pharmaceutical kit" patent.

34 Press Release, Fed. Trade Comm'n, FTC Submits Proposed Amicus Brief Concerning "No-Authorized-Generic" Commitments in Drug Companies' Patent Settlements (Aug. 15, 2013), https://www.ftc.gov/news-events/press-releases/2013/08/ftc-submits-proposed-amicusbrief-concerning-%E2%80%9Cno-authorized.

35 This is different than small-molecule drugs because with small-molecule drugs a brand-authorized generic mainly takes sales away fromother generics but does not take additional sales from the brand.

36 Diane E. Bieri, *Implications of* FTC v. Actavis: *A Reasonable Approach to Evaluating Reverse Payment Settlements*, 15 MINN. J.L. SCI. & TECH. 135, 145–46 (2014).

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