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The FTC Reports on Follow-on Biologics and Authorized Generics: Applying Lessons from Hatch-Waxman to Promote Competition

BY ASIM VARMA, SON B. NGUYEN, AND JUSTIN P. HEDGE

AMIDST THE FLURRY OF LEGISLATIVE activity this past summer on health care reform, the Federal Trade Commission issued two reports that addressed competition in the pharmaceutical industry. The FTC's report, *Emerging Health Care Issues: Follow-on Biologics Drug Competition*, analyzed the potential competitive effects of establishing an abbreviated regulatory pathway for Food and Drug Administration approval of "follow-on" biologic drug products (FOBs)—competing biologic drug products that would rely upon the data supporting approval of an innovator biologic product while providing data to demonstrate that they are "biosimilar" and possibly interchangeable with the innovator product.[1] The same month as the FOB Report, the FTC issued *Authorized Generics: An Interim Report*, which presented the first set of results from its study of the effects of authorized generics (AGs) on pharmaceutical competition but also reiterated its support for legislation prohibiting "pay-for-delay" settlements, a top FTC priority.[2]

Both reports reflected the FTC's perception that the procompetitive benefits of Hatch-Waxman[3]—which sought to balance the competing policy objectives of encouraging brand companies to develop new, pioneer pharmaceuticals, while facilitating the introduction of cheaper generic versions of pioneer drugs—have been undermined by pharmaceutical companies "gaming" the system to secure profits for themselves without corresponding benefit to consumers.

In its FOB Report, the FTC concluded that because of scientific differences between biologic products and the small molecule drugs covered by Hatch-Waxman, competition from FOBs was more likely to resemble brand-to-brand competition than brand-to-generic competition of small molecule drugs.[4] The primary implication of this conclusion, in the FTC's view, was that patent protection and market-based pricing were sufficient incentives for manufacturers to continue to develop pioneer biologics and the trade secret protection currently afforded the pioneer's clinical data was unnecessary. The FOB Report also rejected the need for special procedures to resolve patent disputes between pioneer and FOB manufacturers before FDA approval. The FOB Report stated that this rejection was, in part, based on the FTC's opinion that the pre-approval process under Hatch-Waxman facilitated anticompetitive conduct aimed at reducing entry and thereby defeated the purpose of starting the patent litigation early.

In its AG Report, while the FTC concluded that consumers benefit when an AG competes during the 180-day exclusivity period awarded the first generic filer under Hatch-Waxman, it also highlighted that such competition "substantially" reduced the first generic firm's revenues.[5] The AG Report stated that the FTC had not yet drawn any conclusions about the long-term effects of the reduction in revenues on incentives for generic entry.[6] Moreover, the AG Report expressed concern over the increasing number of settlements that include provisions restricting the branded company's launch of an AG combined with an agreement with the first generic filer to delay entry. The AG Report's emphasis on the first generic filer's reduced revenues, and the resulting incentive to enter into patent settlements that precluded AGs, generated disagreement between Chairman Leibowitz and Commissioner Rosch about how the potential long-term effects of AGs on incentives for generic entry should be evaluated.[7]

The Hatch-Waxman Compromise

The process established by Hatch-Waxman pursuant to which generic drugs obtain FDA approval by relying on the clinical and testing data submitted by the brand name manufacturer is central to the FTC Reports. Before Hatch-Waxman, most drugs approved by the FDA after 1962 were in effect "new" drugs, each requiring a new drug application (NDA), including submission of clinical trials, and safety

Asim Varma is a partner and Son B. Nguyen and Justin P. Hedge are associates at Arnold & Porter LLP in Washington, DC. Arnold & Porter LLP regularly counsels research-oriented drug companies on competition, regulatory, and patent issues, including patent settlements.

and efficacy data.[8] The unpublished safety and efficacy data submitted with an NDA was considered trade secret information and therefore could not be relied on to approve generic versions of the drug.[9] With limited exceptions, manufacturers of generic drugs were required to prove independently that their drugs were safe and effective even if their products were chemically the same as drugs already approved. In addition, to the extent patents covered the pioneer drug, a generic manufacturer risked infringement liability not only if its drug were approved and marketed, but also for its use of the patented invention during development and clinical testing stages prior to FDA approval.[10] The generic manufacturers contended that the brand name companies received longer effective patent terms because development of generics was delayed by the risk of patent infringement and the requirement to repeat the pioneer's clinical trials.

For their part, brand name manufacturers complained that the lengthy drug approval process shortened the effective patent term covering pioneer drugs, making it more difficult for them to recoup their investments in research and development. Brand drug companies also faced the possibility that generic competitors could infringe the patent before expiration to obtain clinical data for FDA approval while injunctive relief or compensation for such infringement would be difficult to obtain because generic drug firms were judgment proof.

To address these issues, Hatch-Waxman created a regulatory pathway designed to facilitate generic entry while protecting brand name firms' proprietary interests. Hatch-Waxman introduced the Abbreviated New Drug Application (ANDA) whereby a generic drug could be approved by demonstrating that it was bioequivalent to a previously approved brand name product. Having made such a demonstration, the ANDA was entitled to rely on the FDA's approval of clinical data submitted by the brand name drug manufacturer to establish the safety and efficacy of the generic version. Concerned that permitting such "free riding" on pioneer drug development might reduce incentives for brand companies to continue to invest in research and development of new drugs, Hatch-Waxman gave the innovator a five-year "data exclusivity" period during which the FDA was not allowed to rely on the approval of the pioneer product, including the data contained in the NDA, and a three-year exclusivity period for certain supplemental submissions requiring new clinical investigations of a previously approved small molecule drug. In addition, to spur innovation by pioneer companies, Hatch-Waxman restored part of the patent life lost by innovator products as a result of the FDA review process.

Hatch-Waxman also established special procedures to promote early resolution of patent disputes. Under Hatch-Waxman, development activity performed for purposes of filing an ANDA was exempted from claims of patent infringement, but the actual filing of the ANDA was made a constructive act of infringement to allow the brand name manufacturer to enforce the patent prior to marketing of the generic.[11] The generic manufacturer was required to certify in the ANDA, with notice to the NDA/patent holder, that any patent claiming the branded drug was either expired, invalid, unenforceable, or would not be infringed. If the patentee chose to file an action for infringement, an automatic thirty-month stay was triggered preventing the FDA from approving the ANDA until the suit was resolved or the patent expired.[12] Hatch-Waxman also provided an incentive to the generic manufacturer to challenge or design around the patents on the pioneer drug by giving a 180-day exclusivity period to the first ANDA filer.

Follow-on Biologics

Hatch-Waxman does not apply to biologic products.[13] Today, to obtain FDA approval of a biologic, including one similar to an innovator product, a firm must independently generate its own supporting clinical data. As the number of biologic products and the amount spent on them have increased,[14] Congress has become more interested in encouraging entry and competition in the biologic segment of the pharmaceutical industry by creating an abbreviated regulatory pathway for approval of FOBs.[15] As the FOB Report noted, Hatch-Waxman is the "obvious model" for a regulatory framework for legislation designed to encourage FOBs.[16]

The scientific differences between biologics and small molecule drugs that are subject to Hatch-Waxman, however, have complicated efforts to create an approval process for FOB drugs. Generally, small molecule drugs have well-defined chemical structures and are chemically synthesized. Biologics are significantly larger and structurally complicated proteins. Deviations in a biologic protein's structure can have unexpected results on efficacy and safety. Accordingly, manufacturing a consistent biologic product presents significant difficulties.

In light of these difficulties, and under present analytical methods, it is the FDA's view that current technology does not permit the creation of exact copies of a biologic.[17] Of course, some biologics are less complex than others. Some scientists and the FDA are of the view that, at least for some biologics, the technology does exist to identify safe and effective biologics that are similar enough to well-characterized innovator biologics, without having to completely replicate all the clinical testing.[18] It is these "similar-enough" biologics that are referred to as FOBs.

Likely Market Impact of FOB Entry. The FOB Report concluded that because of the scientific differences with biologics, FOB competition would also be fundamentally different from generic competition in the small molecule context. The Report stated that competition would differ because present technology could not replicate a biologic with the precision likely to warrant automatic drug substitution, that is, interchangeability between the pioneer biologic and the FOB of the type that exists between branded and generic small molecule drugs. Moreover, due to manufacturing com-

plexity, even with an abbreviated approval path, costs of entry were expected to be higher and fewer companies expected to develop FOBs. In fact, the FOB Report anticipated that pioneer manufacturers in other biologic product markets were the most likely FOB entrants, with only two or three FOB manufacturers expected for any given pioneer biologic. The FOB Report concluded that the lack of automatic substitution and the attendant concerns about safety and efficacy of switching from brand to FOB would retard market share gains by the FOB. Further, the FOB Report stated that FOBs would have limited effect on innovator market share because reimbursement incentives to switch from brand to generic drugs may not apply to biologics, as they are typically delivered to patients by health care providers as part of medical treatments and not as pharmacy benefits.

For all these reasons, the FOB Report expected that prices charged by FOBs were unlikely to be discounted more than 10–30 percent from the pioneer drug's price, and FOBs would likely achieve only a 10–30 percent share, rather than the nearly 100 percent share achieved by small molecule generics. Accordingly, the FTC Report concluded that market share and revenues earned by the pioneer biologic were unlikely to fall off dramatically after FOB entry.[19]

Manufacturers of biologics, potential FOB manufacturers, and other stakeholders and commentators generally agreed that FOB competition would involve fewer entrants, be at a smaller price discount over pioneer biologics, and result in less market share erosion compared with generic small molecule drug competition.[20] They disagreed, however, with the FTC's conclusions regarding the implications of these differences for statutory incentives, specifically the FTC's conclusions that (i) a period of data exclusivity was not necessary to maintain incentives for pioneer biologic development and (ii) an early patent resolution process was not necessary to provide certainty and encourage FOB entry.

Data Exclusivity Period for Innovator Biologics. The first point of disagreement among stakeholders and the FOB Report was the length of the data exclusivity period for pioneer biologics. Pioneer biologic manufacturers have urged a twelve to fourteen-year data exclusivity period that would run concurrently with any patent coverage.[21] They argued that any abbreviated regulatory pathway for approving biologic products would fundamentally change the incentives for development of new biologics. By its very design, an abbreviated approval process would use the investments of the pioneer to facilitate approval and entry of a FOB. By allowing the FOB manufacturer to "free ride" at least in part on the clinical data of the innovator, the abbreviated pathway would help the FOB manufacturer bring its product to market faster, with less risk and uncertainty, and at a fraction of the innovator's costs.

Pioneer companies argued that patent rights, as they exist today, would not be sufficient to preserve the incentives for development of new biologic products. Because of technological limitations the FOB need not be the "same" as the innovator biologic in the proposed pathways. Therefore, contended pioneer companies, there would be significant questions about whether patents that cover an innovator's product or process will also cover a potential FOB. Thus, the possibility exists that a regulatory pathway would enable FOBs to achieve what generic small molecule competitors cannot, namely, the ability to avoid the innovator's patent rights but still get the benefit of the innovator's clinical data.

The twelve to fourteen-year period of data exclusivity urged by the biologics industry was based, in part, on the average time required to recoup the investment to develop and commercialize a typical biologic product.[22] Moreover, they noted that Hatch-Waxman provided, after patent extension, up to fourteen years of patent protection following marketing approval. As a result, new small molecule drugs have been, on average, marketed for 13.5 years before the entry of generic competition. Any FOB pathway, they contended, should at least guarantee the same degree of effective market protection as small molecules receive and, for the reasons noted above, that can best be achieved not by patent protection but by data exclusivity. According to the pioneer biologic manufacturers, any data exclusivity period substantially less than twelve to fourteen years would not preserve the incentives for development of new biologics.[23]

Certain potential FOB competitors argued that a five-year data exclusivity period was sufficient to address the concerns of pioneer companies. In their view, Hatch-Waxman struck an appropriate balance between competing incentives, and they contended that any differences in likely FOB competition did not support a longer data exclusivity period.[24] They also challenged the claim of innovators that patent protection for biologics is less robust than for small molecule drugs. In their view, biologics have more patents covering them than small molecule drugs and, because these patents are eligible for restoration of their term pursuant to Hatch-Waxman, there did not need to be any additional exclusivity beyond Hatch-Waxman.[25]

The FOB Report concluded that no data exclusivity period was needed because patents alone were sufficient to protect the investments of pioneer biologics manufacturers. According to the FTC, in a competitive landscape that resembled brand-to-brand competition and resulted in limited loss of market share upon FOB entry, the innovator biologic would continue to recoup costs after entry irrespective of patent protection. Addressing concerns about the inadequacy of patent protection where a pathway allows approval of similar rather than identical products, the FTC stated that little data suggested that biologics were not capable of being patented or that they may be designed around more easily than small molecule drugs.[26] The FTC acknowledged, however, that if pioneer biologics were not patentable then some data exclusivity period may be warranted.[27]

When the FOB Report was issued, there were a number of legislative proposals under consideration. All of them embraced a Hatch-Waxman model and provided for a data

exclusivity period for pioneer biologics. Two bills in the House this term proposed a twelve-year data exclusivity period,[28] Congressman Waxman's legislation in the House and its companion bill in the Senate proposed five years,[29] and another bill drafted by the Senate Committee on Health, Education, Labor and Pensions proposed twelve years.[30] Moreover, stakeholders and commentators other than the FTC have all endorsed a data exclusivity period.[31]

The White House immediately welcomed the FTC's report. In a letter to Representative Waxman shortly after the Report issued, the White House noted that the FTC has found that twelve to fourteen years of exclusivity "will harm patients by diminishing innovation and unnecessarily delaying access to affordable drugs" and, given the FTC's complete rejection of a data exclusivity period, called the seven-year period of exclusivity provided in the Administration's FY 2010 Budget as a "generous compromise" that struck "the appropriate balance between innovation and competition."[32]

Procedures to Resolve Patent Issues and Exclusivity for the First FOB. A second major difference between stakeholder positions and the FOB Report was the latter's departure from the Hatch-Waxman paradigm providing special procedures to promote early resolution of patent disputes. Both potential FOB competitors and innovators urged that a process for resolution of patent disputes before marketing be part of any FOB regulatory pathway.[33] The uncertainty about potential infringement liability, they contended, would discourage FOB entry.[34] Potential FOB competitors also argued that a period of marketing exclusivity for the first successful FOB entry was necessary to offset the cost of patent litigation to bring the FOB to market.[35]

The FOB Report, however, concluded that a special patent dispute process was not warranted because any challenges to patent validity could be adequately addressed after FDA approval, just as they are in brand-to-brand competitive situations. The Report noted that the special procedures for challenging patents in Hatch-Waxman were intended in 1984 to encourage the creation of a generic pharmaceutical industry.[36] Since filing an ANDA was relatively cheap, there were concerns at the time that generic manufacturers would be judgment proof—unable to pay the significant lost profits of the branded company due to irreversible price erosion and loss of market share if the generic firm lost the patent challenge. Because, in the Report's opinion, FOB entry was likely to be undertaken by the same companies that develop pioneer biologics, these companies were likely to have the expertise to determine whether to launch the FOB before the resolution of any patent litigation and the resources to pay any judgment should they launch despite an infringement risk and ultimately lose the patent dispute. Moreover, the FOB Report stated that special procedures were unlikely to be successful in providing certainty regarding patents because pioneer biologics were covered by more and varied patents than small molecule drugs, meaning that litigation would remain a lengthy process and an early start would be unlikely to avoid the need for FOBs to decide whether to launch at-risk.

The FOB Report concluded that an exclusive marketing period for the first FOB filer was unnecessary to foster FOB entry and patent challenges. The Report posited that FOBs were likely to earn substantial profits for an extended period of time after entry and thus have a sufficient financial incentive to enter without a guaranteed period of FOB exclusivity. The FOB Report asserted that the Hatch-Waxman model encouraged excessive litigation over patents. Instead, the FOB Report hypothesized that if patent challenges were resolved after marketing approval, pioneer companies would only assert their strongest patents, significantly simplifying litigation.[37]

Underlying the FOB's Report's rejection of a Hatch-Waxman model for patent dispute resolution was the perception that such a model facilitates anticompetitive conduct, ultimately defeating the purpose of starting patent litigation early. In the FTC's words: "It is likely that a pre-approval patent resolution in the FOB context could facilitate collusive agreements and/or provide the pioneer drug manufacturer with competitively sensitive information about a significant potential competitor to which it would otherwise not have access."[38] The FTC has strongly opposed what it sees as collusive, anticompetitive settlements of Hatch-Waxman patent infringement litigation, specifically what it calls pay-for-delay settlements where it argues pioneer companies reach agreements with the first ANDA filer to anticompetitively extend brand drug patent terms.[39]

Authorized Generics

The FTC's perceptions about the abuses of Hatch-Waxman also played a prominent role in the AG Report. While presenting its preliminary analysis of the effects of AG competition on generic drug prices, the FTC devoted a significant portion of the AG Report to discussion of patent settlements that include provisions related to AG entry. The release of an "interim" report on AGs appears to have been motivated, in part, by pending legislation prohibiting marketing of AGs during the 180-day exclusivity period as well as pending legislation prohibiting "pay-for-delay" brand-generic settlements.[40]

AGs are approved by the FDA as brand name drugs that the manufacturer chooses to market concurrently as a generic. Since AGs are manufactured under the brand name drug's NDA, and not an ANDA, brand name companies are allowed to market AGs during what would otherwise be the first ANDA filer's 180-day exclusivity period under Hatch-Waxman.[41] Proponents of AGs have argued that AGs benefit consumers through increased generic competition and lower prices. Critics of AGs, however, have contended that AGs reduce the value of the 180-day exclusivity period, diminishing the long-run incentives for generic entry and undermining the Hatch-Waxman compromise.

In 2006, at the request of several members of Congress, the FTC initiated a study to examine the short and long-term

effects of AGs on generic drug competition. The AG Report presented preliminary results of the FTC's study and addressed only the short-term effects of AGs on competition during the 180-day exclusivity period. A final report with econometric analyses and an examination of the long-term effects of AGs is forthcoming, although the date for its release has not been announced.

AG's Effect on Prices During Exclusivity Period. The AG Report first addressed the effect of AG competition during the 180-day exclusivity period awarded the first generic filer under Hatch-Waxman. The AG Report's conclusions showed that consumers benefit from AG competition during the 180-day period. The AG Report found that, on average, retail prices were 4.2 percent lower and wholesale prices were 6.5 percent lower when an AG and the first filer generic competed during the 180-day exclusivity period than when an AG did not enter. When weighted for sales, the FTC's results showed that the price differential between worlds with and without AG competition was 8.1 percent.[42] Thus, the results showed that consumers tend to receive deeper discounts when an AG is launched for a drug with high sales volume.[43] The AG Report noted that the FTC used the same basic methodology as two prior studies, one done in 2006 by IMS, which was commissioned by the Pharmaceutical Research and Manufacturers of America (PhRMA). The IMS Study found that relative to the price of the brand drug, wholesale generic drug prices were 16 percent lower when the first generic faced AG competition.[44] A second study by Hollis and Lang, sponsored by the Generic Pharmaceutical Association (GPhA), analyzed the same set of drugs as the IMS Study but examined retail rather than wholesale prices.[45] This study found retail prices 5 percent lower with AG competition, but when the results were weighted by sales, the average generic discount off the pre-entry brand price with and without AGs was about the same, i.e., for the drugs and time period examined AG competition did not benefit consumers overall. While neither the retail nor wholesale price data set reflects all sales, as the AG Report noted, wholesale price data contains information about purchases by more outlets; in particular, it captures sales to HMOs and hospitals.

The prior two studies and the AG Report compared prices of groups of drugs, distinguished by whether an AG was marketed, to estimate the effect of the AG entry.[46] The AG Report cautioned that because the decision whether to market an AG was a choice made by the branded drug manufacturer, it was not appropriate to assume that drugs are randomly assigned to a group with an AG or a group without an AG. In other words, because market characteristics determined whether a branded company will launch an AG, one could not assume that the non-AG group of drugs was a "control group" and conclude from the results that the lower prices in the AG group were caused by the presence of the AG. The FTC's final econometric analysis will attempt to control for factors that predict the likelihood of AG entry.

The AG Report also noted that the study, which covered 2002 through 2008, included more than twice as many drugs as were included in the prior industry sponsored studies. The AG Report, however, did not address whether a change in the law governing the computation of "best price" for purposes of Medicaid and Medicare rebates may have reduced the level of AG discounting. After January 2007, all drugs sold under the same NDA must be considered for purposes of calculating best price and Average Manufacturer Price for the brand name drug.[47] The effect of including the lower priced AG in this calculation was to reduce the brand drug's effective price under Medicaid and Medicare. As these government programs cover significant percentages of prescriptions, the inclusion of AGs has the potential to reduce the branded firm's incentive to launch and discount an AG.

AG's Effect on ANDA Revenues During Exclusivity Period. Although the AG Report concluded that AG competition benefited consumers in the short term, it found that such competition reduced the first generic firm's revenues, which "is likely to change the calculus of business decision-making in some circumstances for both generic and branded firms."[48] Specifically, the AG Report found that the first ANDA-filer's revenues (used as a proxy for profits) dropped with the entry of an AG, with estimates of the average decline ranging from 47–51 percent. The decline in revenue was attributable to both a decline in prices and a decline in sales resulting from the additional generic competition. The FTC concluded that "[t]he revenue effect for generics is so much larger than the price effect for consumers primarily because the AG represents a very close substitute for the independent generic and therefore typically obtains significant market share at the expense of the independent generic."[49] The FTC stated that prior studies suggested that AGs are "most likely to have a consequential impact on [patent] challenges for drugs with relatively low sales volume."[50] The AG Report, however, did "not analyze[] whether AG entry deters generic entry prior to patent expiration that otherwise would take place."[51]

The AG Report's focus on the generic firm's revenues during the 180-day exclusivity period prompted a vigorous disagreement between Chairman Leibowitz and Commissioner Rosch.[52] Commissioner Rosch stated in his concurring statement that "the [AG] Report analyzes whether AG competition will reduce *ANDA generics' revenues* during the 180-day period." In so doing, stated Commissioner Rosch, "the [AG] Report improperly treat[ed] ANDA generics as though they were a separate market from AGs." He concluded that "no one has ever condemned price competition on the ground that it will reduce another competitor's revenue." Since the AG Report's findings did not support a conclusion that AG competition affected the total output of the particular generic drug, Commissioner Rosch believed the first filer's revenues should not raise any antitrust concerns. Thus, for Commissioner Rosch, it was inappropriate to "highlight[] these effects on competitors (i.e., ANDA generics) notwithstanding the

fact that these effects tell us nothing about whether AG competition adversely impacts *consumers or the economy*."

Chairman Leibowitz disagreed, noting that "Congress did not ask [the FTC] for an antitrust analysis."[53] Rather, in asking for this study, Congress asked "how much do authorized generics benefit consumers?" and "how much do they undermine the incentive for generics to seek entry prior to patent expiration?" In Chairman Leibowitz's view, the AG report preliminarily answered the two questions: the effect of AG competition in lowering prices was "modest" but the effect on the first generic filer's revenue was "substantial."

The disagreement between Chairman Leibowitz and Commissioner Rosch presages a potential lack of consensus on how the FTC will evaluate the likely effects of AG pharmaceutical competition. Commissioner Rosch emphasized the need for an "antitrust analysis," and, as far as he was concerned, the FTC's analysis showing that AGs reduce prices should be the end of the matter. Chairman Leibowitz, however, suggested that, at least from a policy perspective, it was appropriate to weigh the consumer benefits from AG price competition against the effect on incentives for generic entry.

Use of AGs in Patent Settlements. While discussing the benefit of AG competition during the 180-day exclusivity period, the FTC used the AG Report primarily to express concerns about the increasing number of settlements that include provisions restricting the branded drug company's launch of an AG combined with an agreement by the first-ANDA to delay entry. According to the AG Report, the "substantial" loss of revenue by the first generic provided an incentive for the generic to delay its entry in return for a brand's agreement not to launch an AG. The Report found that between 2004 and 2008, branded manufacturers reached seventy-six patent settlement agreements with first filer generics. Twenty of these settlement agreements contained an explicit agreement by the brand not to launch an AG combined with an agreement by the first filer to delay entry by an average of approximately thirty-five months from the settlement date.

The AG Report concluded that such agreements could harm consumers in two ways. First, such agreements delayed generic entry, significantly increasing consumer drugs costs during the period. Second, consumers lost the benefit of competition between the AG and ANDA generic during the 180-day market exclusivity period. The AG Report then addressed at length the problem of anticompetitive brand-generic patent settlements, including the different possible uses of provisions relating to AGs to forestall generic entry. The AG Report, however, declined to address whether limitations on AG entry during the 180-day exclusivity period would reduce the incidence of such settlements.

Nevertheless, Chairman Leibowitz concluded that because the impact on the first filer's revenue was so substantial, the branded firm's promise not to launch an AG was "a huge bargaining chip" and a "relatively low-cost way for a brand to preserve its monopoly and its high profits along with it."[54] Commissioner Rosch responded that the AG Report overstated the concern regarding such settlements and "conflate[d] the debate about the merits of an agreement that an AG will not compete with the debate about the merits of pay-for-delay settlements."[55] He wrote: "To the extent that pay-for-delay settlements cause consumers harm, the [AG] Report does not (because it cannot) show that AG competition is the cause of that harm." Commissioner Rosch noted that to the extent settlements that implicate AGs were a problem, the remedy was not to preclude AGs but to provide that a brand's promises not to launch an AG would be presumptively illegal, absent proof by the parties to justify such an agreement.

Thus, despite their disagreement on the implications of AGs as a bargaining chip in settlements between branded and generic firms, both Chairman Leibowitz and Commissioner Rosch agreed that pay-for-delay settlements cause consumers harm and should be restricted. On this point, both Chairman Leibowitz's and Commissioner Rosch's statements, as well as other public statements by the FTC, reflect that eliminating such settlements is one of the FTC's top priorities. ■

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1 Fed. Trade Comm'n, *Emerging Health Care Issues: Follow-on Biologics Drug Competition* (June 2009) [hereinafter *FOB Report*], *available at* http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf.

2 Fed. Trade Comm'n, *Authorized Generics: An Interim Report* (June 2009) [hereinafter *AG Report*], *available at* http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf; Jon Leibowitz, Chairman, Fed. Trade Comm'n, "Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution), Remarks Prepared for Center for American Progress (June 23, 2009), *available at* http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf.

3 Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984). Letter from C. Landis Plummer, Acting Sec'y, by direction of the FTC, to Frank Pallone, Jr., Chairman, Subcomm. on Health, Comm. on Energy and Commerce, U.S. House of Representatives at 2 (May 2, 2008), *available at* http://energycommerce.house.gov/Press_110/110-ltr.050208.respto040308.FTC.pdf. For a summary of Hatch-Waxman, see generally Appendix B to the FOB Report. *FOB Report*, *supra* note 1, at 55–59.

4 "A small molecule drug, such as a statin (e.g., Lipitor, Mevacor), is small (only 400 Daltons) and simple in contrast to a biologic drug. A biologic drug is significantly larger (5,000–300,000 Daltons) and has a complex structure . . . ." *FOB Report*, *supra* note 1, at 8.

5 *AG Report*, *supra* note 2, Exec. Summary at 3.

6 *Id.* Exec. Summary at 2.

7 While the vote to issue the AG Report was 3–0 (with Commissioner Pamela Jones Harbour recusing herself), FTC Chairman Jon Leibowitz and Commissioner J. Thomas Rosch issued separate statements. Statement of Chair-man Jon Leibowitz on the Release of the Commission's Interim Report on Authorized Generics [hereinafter Leibowitz Statement], *available at* http://www.ftc.gov/os/2009/06/P062105authgenstatementLeibowitz.pdf; Concurring Statement of Comm'r J. Thomas Rosch on the Release of the Commission's Interim Report on Authorized Generics [hereinafter Rosch Statement], *available at* http://www.ftc.gov/os/2009/06/P062105authgenconcurringrosch.pdf.

8 *See* H.R. Rep. 98-857(I), at 16. An applicant could submit a "paper NDAs" that relied on published scientific or medical literature. *See* 21 U.S.C. § 355(b) (2006).

9 *See* 37 Fed. Reg. 9128, 9130–31 (May 5, 1972).

[10] *See* Roche Prods., Inc. v. Bolar Pharm. Co., Inc., 733 F.2d 858 (Fed. Cir. 1984).

[11] 35 U.S.C. § 271(e)(1) (2006) (codifying the *Bolar* Amendment, which provides that use of a patent for uses reasonably related to development and submission of information to the FDA is not an act of infringement); 35 U.S.C. § 271(e)(2) (2006) (filing of ANDA constitutes an act of infringement); *see also* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990) (filing of ANDA deemed constructive act of infringement to give the brand name drug companies a legal basis for their infringement action).

[12] Hatch-Waxman Act § 101 (codified as amended at 21 U.S.C. § 355(j) (2006)). An ANDA can be filed four years after the data exclusivity period where the ANDA filer asserts that any patents are covering the NDA drug are not infringed or valid. The thirty-month stay must then be extended (by up to twelve months) to provide a total exclusivity period of seven and a half years after NDA approval. 21 U.S.C. § 355(c)(3)(E)(ii).

[13] Hatch-Waxman applies to drugs regulated only under the Federal Food Drug and Cosmetic Act (FD&C Act), which it amended. Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585; *FOB Report*, *supra* note 1, at 3. The FDA approves most biologic products under the Public Health Service Act., 58 Stat. 702 (codified as amended at 42 U.S.C. § 262 (1944)); *FOB Report*, *supra* note 1, at 3; *see Assessing The Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the Subcomm on Health of the H. Comm. on Energy and Commerce*, 110th Cong. 4 (2007) (Statement of Janet Woodcock, Deputy Comm'r, Chief Medical Officer, FDA) [hereinafter Woodcock Statement] (noting that historically some biologic proteins have been regulated under the FD&C Act), *available at* http://energycommerce.house.gov/images/stories/Documents/Hearings/PDF/110-he-hrg.050207.Woodcock-testimony.pdf.

[14] *FOB Report*, *supra* note 1, at 3 (In 2007, $40.3 billion or approximately 14 percent of prescription drug expenditures was spent on biologics). An annual course of treatment on a biologic can cost a patient anywhere from $20,000 to more than $200,000 depending on their particular disease. Andrew Pollack, *Costly Drugs Known as Biologics Prompt Exclusivity Debate*, N.Y. Times, July 21, 2009, *available at* http://www.nytimes.com/2009/07/22/business/22biogenerics.html?_.

[15] H.R. 1427, 111th Cong. (2009); H.R. 1548, 111th Cong. (2009); S. 726, 111th Cong. (2009).

[16] *FOB Report*, *supra* note 1, at i.

[17] *FDA Generic Biologics Policy May Change Under McClellan*, Pink Sheet Oct. 14, 2002, at 7 ("As a scientific matter, it is true that certain biological products, due to their inherent structural complexity, heterogeneity, and manufacturing process, do not currently lend themselves to being copied generically."); Woodcock Statement, *supra* note 13, at 8 ("Because of the variability and complexity of protein molecules, current limitations of analytical methods, and the difficulties in manufacturing consistent product, it is unlikely that, for most proteins, a manufacturer of a follow-on product could demonstrate that its product is identical to an already approved product.").

[18] Woodcock Statement, *supra* note 13, at 11; Comments of Generic Pharm. Ass'n (GPhA), Scientific Considerations Related to Developing Alternative Brand and Generic Biopharmaceuticals, FDA Docket No. 2004N-0355 (Mar. 16, 2005), *available at* http://www.gphaonline.org/resources/2005/03/15/comments-fda-generic-biopharmaceuticals; *Safe and Affordable Biotech Drugs—The Need for a Generic Pathway: Hearing Before the H. Comm. on Oversight and Government Reform*, 110th Cong. at 2 (Mar. 26, 2007) (statement of Ganesh Venkataraman, Momenta Pharms., Inc.), *available at* http://oversight.house.gov/documents/20070326121658-50108.pdf.

[19] *FOB Report*, *supra* note 1, at 8–19, 23–26.

[20] *See, e.g.*, Comments of the Biotechnology Industry Organization (BIO), Emerging Health Care Competition and Consumer Issues, FTC Project No. P08390 at 2 (Sept. 30, 2008); Comments of the Pharm. Research and Mfrs. of Am. (PhRMA), Emerging Health Care Competition and Consumer Issues, FTC Project No. P08390 at 5 (Sept 30, 2008); Comments of Amgen, Inc., Emerging Health Care Competition and Consumer Issues, FTC Project No. P08390 at 5 (Sept. 30, 2008); Comments of Mylan, Inc. to the FTC at 2 (Jan. 5, 2009); Comments of Momenta Pharm., Inc., Emerging Health Care Competition and Consumer Issues, FTC Project No. P08390 at 6 (Dec. 22, 2008); Comments of Barr Pharm., Inc., Emerging Health Care Competition and Consumer Issues, FTC Project No. P08390 at 6 (Sept. 30, 2008). All comments submitted to the FTC in connection with its FOB workshop and considered in its ultimate report can be found at http://www.ftc.gov/os/comments/healthcarecompissues/index.shtm.

[21] *See, e.g.*, Comments of Novartis Corp., Emerging Health Care Competition and Consumer Issues, FTC Project No. P08390 at 15 (Sept. 30, 2008); Amgen Comments, *supra* note 20, at 3; Comments of Eli Lilly & Co., Emerging Health Care Competition and Consumer Issues, FTC Project No. P08390 at 3 (Dec. 19, 2008); Comments of Wyeth Pharm., Emerging Health Care Competition and Consumer Issues, FTC Project No. P08390 at 5 (Sept. 30, 2008); PhRMA Comments, *supra* note 20, at 10; BIO Comments, *supra* note 20, at 9.

[22] Henry C. Grabowski, *Follow-on Biologics: Data Exclusivity and the Balance Between Innovation and Competition*, 7 Nature Reviews Discovery 479, 483 (2008); BIO Comments, *supra* note 20, at 9; PhRMA Comments, *supra* note 20, at 10–13; *FOB Report*, *supra* note 1, at vii (stating that the Grabowski model on which innovator's rely for twelve to fourteen year exclusivity "contains numerous methodological and conceptual weaknesses that render its results too imprecise and non-robust to inform discussions about the ideal length of any branded exclusivity period").

[23] Comments of BIO, Emerging Health Care Competition and Consumer Issues, FTC Project No. P08390 at 5–6 (Dec. 22, 2008); *Biologics and Biosimilars: Balancing Incentives with Innovation: Hearing Before the Subcomm. on Courts of the H. Comm. on Judiciary*, 111th Cong. 3–4 (July 14, 2009) (Statement of Jeffrey P. Kushan, Biotech. Industry Org.) [hereinafter BIO Statement], *available at* http://bio.org/healthcare/followonbkg/BIO_FOB_Testimony_Final.pdf; BIO Comments, *supra* note 20, at 8–9; PhRMA Comments, *supra* note 20, at 10–13.

[24] Comments of Teva Pharm. USA, Emerging Health Care Competition and Consumer Issues, FTC Project No. P08390 at 4 (Oct. 8, 2008); Comments of GPhA, Emerging Health Care Competition and Consumer Issues, FTC Project No. P08390 at 4 (Sept. 30, 2008); Barr Comments, *supra* note 20, at 7.

[25] GPhA Comments, *supra* note 24, at 4.

[26] *FOB Report*, *supra* note 1, at iv, 26, 36.

[27] *Id.* at 45. The *Bolar* Amendment, which exempts from infringement liability use of a patented invention solely for purposes related to development and submission of an FDA application, has been broadly construed and would preclude an innovator from suing FOB manufacturers where the pre-approval use of patents is reasonably related to securing FDA approval. *See* Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005); BIO Statement, *supra* note 23, at 17; PhRMA Comments, *supra* note 20, at 15.

[28] H.R. 1548, 111th Cong. (2009); H.R. 3200, 111th Cong. (as amended and reported by the H. Comm. on Energy and Commerce) (2009).

[29] H.R. 1427, 111th Cong. (2009); S. 726, 111th Cong. (2009).

[30] Affordable Health Choices Act (Draft), S. 1679, 111th Cong. (2009), *available at* http://help.senate.gov/BAI09A84_xml.pdf.

[31] *See, e.g.*, Letter from Frank M. Torti, Principal Deputy Comm'r and Chief Scientist, FDA, to Frank Pallone, Jr., Chairman, Subcomm. on Health, H. Comm. on Energy and Commerce at 11 (Sept. 18, 2008) (supporting significant period of exclusivity independent of patent protection to ensure continued innovation), *available at* http://energycommerce.house.gov/Press_110/fdabiosimilarresponse20080918.pdf; GPhA Comments, *supra* note 24, at 4 (five-year data exclusivity sufficient).

[32] Letter from Nancy-Ann DeParle, Dir., Office of Health Reform & Peter Orszag, Dir., OMB, to Rep. Henry Waxman (June 24, 2009), *available at* http://energycommerce.house.gov/Press_111/20090625/biologicsresponse.pdf.

[33] BIO Comments, *supra* note 20, at 19–21 (discussing the potentially irreversible loss of market share and price erosion from improper, premature marketing by an FOB); GPhA Comments, *supra* note 24, at 6 (advocating for a system allowing only the FOB sponsor to initiate suits, not the branded manufacturers).

[34] *See* Barr Comments, *supra* note 20, at 8.

[35] *Id.* Biologic pioneers, on the other hand, cautioned against creating a marketing exclusivity period that would encourage patent challenges. *See* BIO Comments, *supra* note 20, at 24–25. Their concern here was twofold: first,

there would be less advantage to encouraging patent challenges because resolution was less likely to be used by other FOBs since no two biologics are identical and second, the higher cost of developing a FOB relative to a small molecule generic might increase the temptation to bring meritless challenges to protect that increased sunk cost.

[36] *FOB Report*, *supra* note 1, at 47–48.

[37] *See id.* at 54–55, 69–70.

[38] *Id.* at viii–ix.

[39] Concurring Statement of Comm'r Jon Leibowitz in FTC v. Watson Pharm., FTC File No. 071 0060 at 1 (Feb. 2, 2009) *available at* http://ftc.gov/os/caselist/0710060/090202androgeleibowitzstmt.pdf ("Eliminating these pay-for-delay settlements is one of the most important objectives for antitrust enforcement in America today."). The FTC has challenged "pay for delay" settlements as anticompetitive, alleging that they thwart the goal of Hatch-Waxman. *See, e.g.*, *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1336 (Fed. Cir. 2008); *In re* Tamoxifen Citrate Antitrust Litig., 429 F.3d 370 (2d Cir. 2005), amended by 466 F.3d 187 (2d Cir. 2006); Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005).

[40] Leibowitz Statement, *supra* note 7, at 1–2; Rosch Statement, *supra* note 7, at 1–3; H.R. 573, 111th Cong. (2009) (prohibiting marketing of AGs during 180-day exclusivity period).

[41] The FDA and two federal courts of appeals have rejected challenges to AGs under Hatch-Waxman. *See* Teva Pharm. Indus. v. Crawford, 410 F.3d 51, 55 (D.C. Cir. 2005) (affirming FDA's rejection of Teva's petition that marketing and distribution of AG during the 180-day exclusivity period be prohibited and that Pfizer be required to submit a pre-approval supplemental new drug application before marketing AG); Mylan Pharms., Inc. v. FDA, 454 F.3d 270, 272 (4th Cir. 2006) (holding Mylan was not prohibited under Hatch-Waxman from marketing an AG through third-party license during the 180-day exclusivity period afforded first generic manufacturer).

[42] The executive summary of the AG Report and the FTC's press release omit the finding that the weighted wholesale average price difference between AG and no-AG competition was 8.1 percent. *AG Report*, *supra* note 2, ch. 1 at 11, tbl. 1-D; Rosch Statement, *supra* note 7, at 2.

[43] The FTC split the data sample into "high sales" drugs and "low sales" drugs. The line dividing these drug categories was determined by whether the brand sales for the three months preceding generic entry were above or below the median of all drugs that first faced generic competition in the FTC's time window and for which at least one generic firm was granted exclusivity by the FDA. The median drug in the retail data had pre-entry brand annual sales of $130 million. AGs entered for only 16 of the 49 low sales drugs (or 33 percent), implying that AG entry was much more common for products with high sales, where AG entry occurred for 37 out of 46 drugs in the FTC's sample (80 percent). *AG Report*, *supra* note 2, ch. 1 at 7.

[44] *See IMS Consulting, IMS Health, Assessment of Authorized Generics in the U.S.* (2006) [hereinafter *IMS Study*], *available at* http://www.phrma.org/files/IMS Authorized Generics Report_6-22-06.pdf.

[45] *See* Aiden Hollis & Bryan A. Liang, An Assessment of the Effect of Authorized Generics on Consumer Prices (2006), *available at* http://www.gphaonline.org/sites/default/files/GPhA_AG_Study.pdf.

[46] *AG Report*, *supra* note 2, ch. 1 at 2. Despite the comparable methodologies, however, there is only one drug that is included in the PhRMA/GPhA studies' AG grouping and the FTC's AG grouping. Compare *AG Report*, *supra* note 2, tbl. A6 and *IMS Study*, *supra* note 44, at 6.

[47] *See* Section 6003 of the Deficit Reduction Act of 2005, Pub. L. No. 109-171, 120 Stat. 4 (2006).

[48] *AG Report*, *supra* note 2, Exec. Summary at 2.

[49] *Id.* ch. 1 at 1.

[50] *Id.* ch. 1 at 4 n.6; *see also supra* note 43.

[51] *AG Report*, *supra* note 2, Exec. Summary at 2.

[52] Rosch Statement, *supra* note 7, at 1; Leibowitz Statement, *supra* note 7, at 1–2.

[53] Leibowitz Statement, *supra* note 7, at 2.

[54] *Id.* at 1.

[55] Rosch Statement, *supra* note 7, at 3.