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Congress Considering Legislation Aimed at Increasing Competition in Pharmaceuticals

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In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act. Hatch-Waxman was designed to promote pharmaceutical competition by facilitating generic market entry, while at the same time maintaining adequate incentives for future innovation.[1] Although most would agree that Hatch-Waxman has by and large succeeded in its mission, some would argue that certain provisions of the Act, particularly those relating to patents, have been gamed by pharmaceutical companies in a manner that has frustrated the desire for generic competition. At a time the cost of drugs has taken center stage, it is not surprising that Congress is currently considering a large number of bills that would attempt to bring down drug prices, some aimed at reform of certain patent-related aspects of Hatch-Waxman and the Biologics Price Competition and Innovation Act of 2009 (BPCIA) (which can be thought of as Hatch-Waxman's analog for biological pharmaceutical products, most of which do not fall under the Hatch-Waxman regime).[2]

This article begins with a brief overview of some key provisions of Hatch-Waxman and the BPCIA that have been the target of current legislative reform efforts. It then turns to a discussion of some specific bills currently being considered by Congress that would seek to promote greater competition in the market for pharmaceuticals by amendments to the Food, Drug, and Cosmetics Act (FDCA) and Public Health Service Act (PHS Act), *i.e.*, the two statutes that were amended by Hatch-Waxman and the BPCIA, as well as aspects of the Patent Act relating to Hatch-Waxman. Also included in the discussion are bills that would seek to prevent pharmaceutical companies from settling patent litigation brought under Hatch-Waxman and/or the BPCIA through so-called "reverse payment settlements."

OVERVIEW OF HATCH-WAXMAN AND THE BPCIA

In order to market an innovative new drug in the U.S., the drug's sponsor must obtain FDA approval of a new drug application (NDA) containing data demonstrating, among other things, the safety and efficacy of the drug.[3] Hatch-Waxman created an abbreviated pathway for the approval of generic drugs by means of an Abbreviated New Drug Application (ANDA), which greatly reduces the cost of bringing a generic drug to market by permitting a generic company to essentially free ride on much of the costs incurred by the branded drug company in obtaining approval of the original NDA.[4] The ANDA process is one of two abbreviated pathways provided by Hatch-Waxman, the other being the increasingly relevant 505(b)(2) pathway, sometimes referred to as the "paper NDA."[5]

Under Hatch-Waxman, the holder of an approved NDA is required to list certain patents relating to the approved drug in the FDA's Orange Book (formally titled *Approved Drug Products with Therapeutic Equivalence Evaluations*), *i.e.*, all patents covering the drug's active ingredient, patents on specific

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[1]Public Law 98–417.
[2]Public Law 111–148.
[3]21 U.S.C. § 355(d).
[4]21 U.S.C. § 355(j)(2)(A)(iv).
[5]Food and Drug Administration (FDA) Guidance Document, *Applications Covered by Section 505(b)(2)* (Dec. 1999), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applications-covered-section-505b2 (last visited May 11, 2019).

formulations or compositions of the drug, and patents covering the methods of using the drug.[6]

Every ANDA must include a certification for each patent listed in the Orange Book with respect to the branded drug targeted for generic competition.[7] The certification for each listed patent must be one of four types, commonly referred to as the Paragraph I–IV certifications. In an ANDA containing only Paragraph I, II, and/or III certifications, the applicant effectively acknowledges the existence of any listed patents, and agrees not to enter the market until all of the patents have expired. Alternatively, a generic drug company can challenge a listed patent by making a Paragraph IV certification, whereby the ANDA applicant asserts that the patent is invalid or will not be infringed by the generic drug for which the ANDA applicant seeks approval. An ANDA filer that makes a Paragraph IV certification must provide a notice to the branded drug company with a detailed statement of the factual and legal basis for the ANDA filer's assertion that the patent is invalid or not infringed.[8]

Upon receiving notice of a Paragraph IV certification, the patent owner has two options. One option is to bring an immediate, pre-marketing infringement suit against the ANDA applicant. Under Hatch-Waxman, the mere filing of an ANDA with a Paragraph IV certification is an act of constructive infringement, permitting the patent owner to bring suit as soon as the certification is filed.[9] If the lawsuit is filed within 45 days of the patent holder receiving notice of the Paragraph IV certification, that filing will invoke an automatic stay of FDA approval of the ANDA, commonly referred to as the "30-month stay." The 30-month stay lasts until the earliest of one of the following occurrences: (1) the expiration of 30 months from the receipt of notice of the Paragraph IV certification; (2) a final determination of patent invalidity or noninfringement by a district court; or (3) expiration of the patent.

Alternatively, if the patent owner fails to sue within 45 days, the benefit of the 30-month stay provision is forfeited, and the generic challenger is free to market the drug upon FDA approval of the ANDA. Upon generic market entry, the patent owner remains free to sue the generic company in a standard patent infringement action.

Analogous Paragraph IV certification provisions also apply to the 505(b)(2) "paper NDA" pathway. For simplicity, most of the discussion this article will focus on the more well-known ANDA pathway.

In order to incentivize patent challenges, Hatch-Waxman provides that the first generic applicant to file an ANDA containing a Paragraph IV certification is eligible for 180 days of marketing exclusivity, during which the FDA may not approve any subsequent ANDA corresponding to the same branded product. The requirements for receiving the 180 days of generic exclusivity ("180-day exclusivity") were originally quite straightforward: commencement of 180-day exclusivity was triggered by either the first commercial marketing of the generic drug by the first-filer, or by a court decision holding the patent invalid or not infringed.[10] However, if the first-filer reaches an agreement settling Paragraph IV litigation pursuant to which the first-filer agrees to delay or forgo market entry, it can create a bottleneck potentially precluding any other generic company from entering the market with a generic version of the drug until expiration of the challenged patent or patents. The potential for a single agreement between a generic company and the branded drug company to park 180-day exclusivity in a manner that precludes any other generic company from entering the market prior to patent expiration has long been a source of concern, particularly at the Federal Trade Commission (FTC),[11] and is the subject of some of the legislative proposals discussed below.

The BPCIA provides an abbreviated approval process for biological drugs that is analogous to, but in many respects substantially different from, the ANDA and 505(b)(2) abbreviated approval processes created by Hatch-Waxman and available for drugs regulated under the FDCA, which for the most part are traditional, small-molecule drugs. For one thing, there is no statutory requirement, under the BPCIA or otherwise, for an equivalent to the Orange Book for biological products regulated under the PHS Act. Instead of requiring patent owners to file a list of related patents for any approved biological pharmaceutical product, the BPCIA provides for a complex exchange of patent information, sometimes referred to as the "patent dance," which only becomes relevant if an application is filed for approval of a biosimilar or interchangeable version of the biological product under the abbreviated pathway provided under the BPCIA.[12] The patent dance

[6] 21 U.S.C. § 355(b)(1).
[7] 21 U.S.C. § 355(j)(2)(A)(vii).
[8] 21 U.S.C. § 355(j)(2)(B).
[9] 21 U.S.C. § 355(j)(5)(B)(iii).
[10] 21 U.S.C. § 355(j)(5)(B)(iv) (2000).
[11] Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489 (2007).
[12] Congressional Research Service (CRS) Report, *Drug Pricing and Intellectual Property Law: A Legal Overview for the 116th Congress* at 32–33 (Apr. 9, 2019). *See* 42 U.S.C. § 262(l).

begins when an applicant seeking approval of a biosimilar or interchangeable product under the abbreviated pathway provides the reference product sponsor, *i.e.*, the innovator, with a copy of the application, plus a description of the proposed manufacturing process. The reference product sponsor is then required to respond with a list of patents owned or exclusively licensed that could "reasonably be asserted" against a party manufacturing or marketing a biosimilar version of the innovative product. This list of patents is the closest the BPCIA comes to the Orange Book's patent list mandated under Hatch-Waxman.

On its own initiative, FDA began to publish a "Purple Book," which can be thought of as an analog of the Orange Book applicable to biological products. The official title of the Purple Book is "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations." Because the Purple Book is not mandated by statute, FDA has the discretion to provide any information it sees fit in the Purple Book, or to discontinue the Purple Book altogether.[13] FDA designed the Purple Book to help enable a user determine whether a particular biological product has been determined by FDA to be biosimilar to or interchangeable with a reference biological product.[14] The lists cross-reference the names of biological products licensed under section 351(a) of the PHS Act (the original, innovative biological product) with the names of biosimilar or interchangeable biological products licensed under section 351(k) (the statutory basis of the abbreviated approval process for biosimilar and interchangeable biological products). If FDA has determined that a biological product is protected by a period of reference product exclusivity under section 351(k)(7), the list will identify the date of first licensure and the date that reference product exclusivity (including any attached pediatric exclusivity) will expire.[15]

With this background in mind, let us turn to a consideration of some of the proposed legislation that would alter the dynamics of drug approval and patent exclusivity under the regimes created by Hatch-Waxman and the BPCIA.

LEGISLATION DIRECTED TOWARDS ORANGE BOOK LISTING REQUIREMENTS

The Orange Book Transparency Act, H.R. 1503, would amend the FDCA in a number of ways. For one, it would prohibit FDA from listing any patent in the Orange Book to the extent that such patent claims a device that is used for the delivery of the drug. This provision is no doubt prompted by the recent uproar over large increases in the price of the EpiPen product. The EpiPen dispenses epinephrine, a non-patented drug, and the patents associated with the EpiPen product are directed towards the device used to deliver the drug. By prohibiting Orange Book listing of patents on drug delivery devices, proponents of the bill presumably seek to prevent a branded drug company from securing a 30-month stay under Hatch-Waxman based on a drug-delivery device patent.

H.R. 1503 would also require listing in the Orange Book all non-patent exclusivity periods applicable to the approved drug, such as pediatric exclusivity under 505(A), orphan exclusivity, *etc.* The bill would also require the removal from the list of patents that have been found invalid in proceedings before the Patent Trial and Appeals Board (PTAB) or a final, nonappealable court decision. The bill specifies that the FDA shall not remove from the list any invalidated patent prior to the expiration of any 180-day exclusivity period based on a successful Paragraph IV challenge to that patent. It also requires the FDA to review the types of patent information that should be included in the Orange Book, and to report to Congress on the results of such review, including any recommendations about the types of patent information that should be included or removed from the Orange Book patent listing.

On May 8, 2019, the House passed H.R. 1503 and the bill has moved to the Senate for consideration.

The Reforming Evergreening and Manipulation that Extends Drug Years Act (the REMEDY Act,), S. 1209, would amend Hatch-Waxman such that the filing of a lawsuit would only result in a 30-month stay if the Orange Book-listed patent claims a drug substance, *i.e.*, a drug active ingredient. If the patent only claims a drug product, such as a drug formulation, or a method of using the drug, there will be no automatic 30-month stay to stand in the way of approval and marketing of the generic product. This distinction between drug substance patents,

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[13]FDA, *Background Information: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book)* (Mar. 5, 2015), available at https://www.fda.gov/drugs/biosimilars/background-information-lists-licensed-biological-products-reference-product-exclusivity-and (last visited May 11, 2019).

[14]*Id.*

[15]FDA, *Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act* (Aug. 2014), available at https://www.fda.gov/media/89049/download (last visited May 11, 2019).

often referred to as "primary" pharmaceutical patents, and drug product and method of use patents, often referred to as "secondary" pharmaceutical patents, reflects the often-espoused view that while primary patents are generally legitimate, secondary patents are used by drug companies to obtain unjustified extension of patent exclusivity, sometimes referred to as "evergreening."[16]

S. 1209 would require removal from the Orange Book of any listed patent that has had "any claim" relating to the drug or use of the drug canceled pursuant to a determination by the PTAB in an *inter partes* review (IPR) or post-grant review (PGR), so long as the cancellation (if appealed) has been upheld on appeal. This amendment is presumably intended to address situations in which patents with canceled claims have remained listed in the Orange Book and have arguably created an impediment to generic market entry. I would think that the bill's language calling for the striking from the Orange Book of any patent with respect to which "any claim" relating to the drug or use of the drug has been canceled should be interpreted as requiring the cancellation of "any and all claims" relating to the drug or use of the drug. If all that was required to strike a patent from the Orange Book was the cancellation of "any claim" relating to the drug or its use, then this proposed change to Hatch-Waxman would seem to require removal from the Orange Book of a patent containing claims that have survived review by the PTAB, and are thus still presumptively valid, and which would be infringed by a generic product.

S. 1209 would also amend Hatch-Waxman in a manner intended to ensure that the striking of a patent from the Orange Book based on cancellation of claims by the PTAB will have no effect on a first ANDA filer's 180-day exclusivity, provided that at the time the first applicant submitted an application containing a Paragraph IV certification, the patent that was the subject of such certification was listed in the Orange Book in connection with the subject drug.

LEGISLATION CREATING A STATUTORY BASIS FOR THE PURPLE BOOK

The Purple Book Continuity Act of 2019, H.R. 1520, would amend that the PHS Act to require the FDA to publish a Purple Book and make it electronically available to the public. Under the bill, the Purple Book would include a list of the official and proprietary names of each innovative biological product for which a biologics license under section 351(a) is in effect, the date it was licensed, and whether *in vitro* or *in vivo* bioequivalence studies, or both, are required for applications filed under section 351(k) for a biosimilar or interchangeable product that will refer to the innovative biological product. The FDA would be required to revise the list every 30 days to include any newly licensed biological products under 351(a) or (k).

H.R. 1520 includes a requirement that "[w]hen patent information has been provided by the reference product sponsor to the subsection (k) applicant respecting a biological product included on the list ... the Secretary shall ... include such information [on the list]." Thus, the Purple Book would not contain a listing of patents associated with the drug and its use unless the biological product serves as a reference product for a biosimilar or interchangeable product under the abbreviated 351(k) pathway. But if a 351(k) application is filed, and the parties engage in 351(k)'s "patent dance," then the list of patents provided by the reference product sponsor pursuant to the dance will be published in the Purple Book.

H.R. 1520 would also require the Secretary of Health and Human Services to complete a review of, and formulate recommendations on, the types of biological product patents that should be included in, or removed from, the list required under the Act, and report such recommendations to Congress.

On May 8, 2019, the House passed H.R. 1520 and the bill moved to the Senate for consideration.

In the Senate, the Biologic Patent Transparency Act, S. 659, would also amend the PHS Act to create a statutory requirement that FDA publish and maintain a single, searchable, publicly accessible list of approved biological products. The bill specifies that with respect to each listed biological product, the list provide the date of licensure and licensure status, marketing status, dosage form, route of administration, strength, and, if applicable, reference product, plus any period of reference product exclusivity, orphan exclusivity, and/or pediatric exclusivity, information regarding any determination related to biosimilarity or interchangeability, and information regarding approved indications for each such biological product.

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[16]Christopher M. Holman, *In Defense of Secondary Pharmaceutical Patents: A Response to the UN's Guidelines for Pharmaceutical Patent Examination*, 50 IND. L. REV. 759 (2017) (arguing that secondary pharmaceutical patent claims are necessary for incentivizing pharmaceutical innovation and neither inherently less legitimate and nor less worthy of protection than primary patents).

Like H.R. 1520, S. 659 requires a list of patents, but the listing requirement is quite different in the Senate bill, which requires the disclosure of any patent for which the holder of a biological product license

> believes a claim of patent infringement could reasonably be asserted by the holder, or by a patent owner that has granted an exclusive license to the holder with respect to the biological product that is the subject of such license, if a person not licensed by the holder engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of such license.

Giving teeth to this requirement, the bill would also amend section 271(e) of the Patent Statute such that the owner of a patent that "should have been included in the list" mandated by S. 659, "but was not timely included in such list, may not bring an action under this section for infringement of the patent." In other words, a failure to properly list a patent could result in a patent owner forfeiting its ability to enforce the patent under the Patent Act.[17]

LEGISLATION TARGETING REVERSE PAYMENT SETTLEMENTS

Some of the proposed legislation would seek to limit the ability of brand and generic companies to enter into so-called "reverse payment settlements" resolving patent litigation brought under Hatch-Waxman. The term "reverse payment" has been used as shorthand to characterize a variety of diverse agreements between patent owners and alleged infringers that involve a transfer of consideration from the patent owner to the alleged infringer.[18] The "payment" is "reverse" in the sense that one would normally expect any payment associated with settlement of a patent infringement lawsuit to flow from the accused infringer to the patent owner, not the other way around. In its most straightforward form, a reverse payment settlement involves a cash payment from the patent owner to the accused infringer, in exchange for which the which the accused infringer agrees to delay market entry, which has led some to label these agreements as "pay for delay," a pejorative term with clear antitrust implications. In many cases, however, the alleged payment comes not in the form of cash but in some other non-cash consideration, or as part of an ancillary agreement, and consideration often flows both ways.

Although in principle any parties to a patent infringement lawsuit could agree to a settlement involving a reverse payment, it is widely believed that reverse payment settlements are rare outside the context of brand-generic disputes. However, it must be noted that in general the terms of agreements settling patent litigation are confidential, so it is impossible to know how prevalent they might be outside the realm of pharmaceutical litigation. The law specifically requires pharmaceutical companies to disclose the terms of agreements to settle brand-generic disputes to the FTC, and based on these disclosures we know that such agreements do exist, and depending upon how one defines "reverse payment settlement," *i.e.*, to what extent non-cash consideration and ancillary agreements are assumed to be payments for delayed market entry, these agreements have at times been fairly common. As a practical matter, reverse payment settlements have only been seen as an issue in the context of brand-generic patent disputes, and for the remainder of this article the term "reverse payment settlement" will be used to denote an agreement settling a lawsuit between a branded drug company and would-be generic competitor under Hatch-Waxman.

The FTC has taken an active interest in reverse payment settlements since the 1990s, and has challenged a number of these agreements as anticompetitive and in violation of antitrust laws.[19] Early on, most courts rejected the assertion that the presence of a reverse payment constitutes a *per se* violation of antitrust laws, or even a presumption of antitrust violation. The judges that decided these cases often found that while the presence of a reverse payment might appear suspicious, in fact a reverse payment is a natural outcome of the unique dynamics created by Paragraph IV litigation. In lawsuits brought by branded drug companies under Hatch-Waxman, the allocation of risk is very different than in most other patent litigations, where the accused infringer typically risks substantial money damages if it loses, and thus it makes sense for the accused infringer to pay the patent owner settle the case. In

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[17]The patent owner would apparently not be barred from enforcing its patent under some other statute, such as through an International Trade Commission complaint brought under 19 U.S.C. § 1337.

[18]Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489 (2007).

[19]*Id.*

the context of Hatch-Waxman litigation, on the other hand, the defendant generic company is not at risk of having to pay damages; at most, the generic company is looking at an injunction that will delay market entry. The branded company, on the other hand, risks loss of market exclusivity and a resulting huge loss of revenue with the entry of generic competition. This substantial reallocation of risk between patent owner and accused infringer renders reverse payments entirely rational in brand-generic disputes, and courts generally have found that the flow of consideration from the patent owner to accused infringer does not, in and of itself, raise an inference that the settlement is anticompetitive.

Eventually, however, the FTC achieved a favorable ruling that resulted in a circuit split prompting the Supreme Court to weigh in on reverse payment settlements in 2013. In *FTC v. Actavis*,[20] a divided Supreme Court overruled a decision by the Eleventh Circuit Court of Appeals,[21] which had held that as long as the anticompetitive effects of a patent settlement fall within the scope of the patent's exclusionary potential, the settlement is immune from antitrust attack. The majority was unwilling, however, to go so far as to adopt the FTC's position that reverse payment settlements are presumptively unlawful. Instead, the Court charted a middle course, instructing courts to apply the "rule of reason" when reviewing such agreements for compliance with the antitrust laws. Under the "rule of reason," a court is to look at the agreement and the context in which it occurs, and to balance the anticompetitive harm of the agreement against any procompetitive benefits. The agreement should be found to violate the antitrust law only if it can be shown that the anticompetitive harm outweighs the procompetitive benefits.

Actavis left many unanswered questions with which the lower courts have just begun to grapple. For example, what is required in order for consideration passing from the patent owner to a generic company to be considered a "payment"? Some courts have found that the payment must be in the form of cash in order to come under *Actavis*, but others have held that the payment can be in the form of non-cash consideration, such as a no-authorized generic (no-AG) agreement, a co-promotion agreement, or a licensing and distribution agreement between the parties, and this broader interpretation of payment appears to be an emerging consensus. Another ongoing question is under what circumstances the size of a reverse payment can serve as a surrogate for the weakness of the patent owner's case.

The Competitive DRUGS Act of 2019, H.R. 1344, would effectively overturn *Actavis* by creating a strong legal presumption that a reverse payment settlement violates the antitrust laws unless it can be demonstrated by clear and convincing evidence that either the payment is not given in return for delayed market entry by a generic competitor, but is instead compensation solely for other goods or services, or that procompetitive benefits of the agreement outweigh anticompetitive effect. In effect, the legislation would overturn the Supreme Court and codify the position advanced by the FTC in *Actavis*.

H.R. 1344 provides that any agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product, shall be an unfair method of competition in violation of Section 5 of the Federal Trade Commission Act, if pursuant to the agreement (1) an ANDA filer receives anything of value, including an exclusive or nonexclusive license, an agreement regarding the marketing the product, or any other commercial opportunity or benefit; and (2) the ANDA filer agrees to limit or forgo research, development, manufacturing, marketing, or sales of the ANDA product for any period of time. The bill would not prohibit a settlement in which the consideration granted to the ANDA filer as part of the settlement includes one or more of the following and nothing else: (1) the right to market the ANDA product in the U.S. prior to the expiration of any patent that is the basis for the patent infringement claim, or any patent right or other statutory exclusivity that would prevent the marketing of such drug; (2) a payment, not to exceed $7,500,000, if based on reasonable litigation expenses; or (3) a covenant not to sue on any claim that the ANDA product infringes a U.S. patent.

H.R. 1344 provides for enforcement by the FTC, with judicial review in the U.S. courts of appeal. It also provides for a civil penalty sufficient to deter such violations, up to three times the value received by the party that is reasonably attributable to such violation, which will accrue to the government of the United States. The bill also provides a variety of other penalties, including amending the Internal Revenue Code to impose a tax of 50% on receipt of pay-for-delay payments and denial of a tax deduction for pay-for-delay payments, as well as clawback of research and development tax benefits from manufacturers found to have entered into an illegal reverse payment settlement. Consent decrees

[20] 570 U.S. 136 (2013).

[21] *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298 (11th Cir. 2012).

entered into with FTC would be deemed violations for purposes of triggering the clawback provision.

Another bill that has also been introduced in the House, the Protecting Consumer Access to Generic Drugs Act of 2019, H.R. 1499, largely tracks H.R. 1344, albeit with some notable differences. H.R. 1344 only applies to reverse payment settlements entered into by an ANDA filer, and thus is limited to drugs regulated under the FDCA, which are generally traditional small-molecule drugs. To date, this has been where most of the branded-generic litigation has occurred, and has been the focus of reverse payment settlement enforcement. H.R. 1344 would not addresses settlements of litigation brought under the BPCIA, wherein the branded product is a biological product and the patent challenger seeks to bring a biosimilar or interchangeable product to market. This limitation is addressed in H.R. 1499, which explicitly encompasses reverse payment settlements involving both ANDA filers and firms applying for approval of a biosimilar or interchangeable biological product.

Perhaps the most significant difference between the two bills is that H.R. 1499 does not include H.R.1344's exception for any agreement which the parties can demonstrate by clear and convincing evidence provides procompetitive benefits outweighing its anticompetitive effects. H.R. 1499 would also amend the FDCA such that a generic company found to have violated the law by entering into a reverse payment settlement will be required to forfeit any 180-day exclusivity period it would have otherwise enjoyed, particularly as a first Paragraph IV filer. On April 3, 2019, H.R. 1499 was reported out of committee and sent to the full House.

The Preserve Access to Affordable Generics and Biosimilars Act, H.R. 2375, is the most recent reverse payment bill to be introduced in the House, and represents something of a hybrid between H.R. 1344 and H.R. 1499. H.R. 2375 largely tracks the language of H.R. 1499, applying to both generics and biosimilars, but reintroduces the exception for any agreement which the parties can demonstrate by clear and convincing evidence provides procompetitive benefits outweighing its anticompetitive effects. On April 30, 2019, H.R. 2375 was reported out of committee and sent to the full House.

LEGISLATION TO CURB "GAMING" OF 180-DAY EXCLUSIVITY

As discussed above, some reverse payment settlements have resulted in the "parking" of a first-filer's 180-day exclusivity in a manner that blocks other generic competitors from entering the market, which has understandably created competition concerns. In fact, it was this parking of the 180-day exclusivity that initially caused the FTC to have concerns with reverse payment settlements.[22]

In 2003, Congress sought to address the 180-day exclusivity parking problem through provisions in the Medicare Modernization Act (MMA) amending Hatch-Waxman. These amendments provide that a first-filer will forfeit its 180-day exclusivity if a "forfeiture event," as defined by the amendments, occurs with respect to that first-filer. "Forfeiture events" include failure to market the generic drug in a timely manner, *e.g.*, within 75 days of approval of the ANDA application or 30 months after submission of the ANDA application, withdrawal of the application, amendment or withdrawal of the Paragraph IV certification, failure to obtain tentative approval, or entry into an agreement with another drug company that is found to be in violation of the antitrust laws by the FTC or a court, *e.g.*, a reverse payment settlement.[23]

Although the forfeiture provisions introduced by the 2003 amendments were intended to prevent parking of 180-day exclusivity, they were not entirely successful, and the potential for the creation of a bottleneck continues to some extent.[24] The challenge comes in trying to amend the 180-day exclusivity provisions of Hatch-Waxman to eliminate the potential for parking 180-day exclusivity without, at the same time, creating situations where a first-filer loses its 180-day exclusivity in the absence of any reverse payment or other improper collusion with a patent owner. Members of Congress continue to propose legislation to amend the 180-day exclusivity provisions of Hatch-Waxman in a manner intended to prevent gaming of 180-day exclusivity to the detriment of generic competition.

The Fair and Immediate Release of Generic Drugs Act, or "FAIR Generics Act," H.R. 1506, and its Senate counterpart, the Expanding Access to Low-Cost Generic Drugs Act, S. 2476, are the latest efforts in this direction. These bills are quite similar to bills that were introduced in 2009 as the Drug Price Competition Act of 2009 (S.1315) and in 2011 and 2015 as the Fair and Immediate Release of Generic Drugs Act, or the "FAIR GENERICS Act" (S. 1882 and S. 131, respectively). The language of the amendments created by these bills is very complex and

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[22] *Id.*

[23] 21 U.S.C. § 355(j)(5)(D).

[24] Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489 (2007).

difficult to parse, a natural consequence of how difficult it is to define the requirements for 180-day exclusivity in a manner that precludes gaming but retains the intended incentive for generic companies to challenge Orange Book-listed patents.

H.R. 1506 would substantially change the definition of a "first applicant" under 21 U.S.C § 355(j)(5)(B)(iv)(II). Under Hatch-Waxman, 180-day exclusivity goes to "first applicants." The Act currently defines a "first applicant" as any applicant that, "on the first day on which a substantially complete application containing a [Paragraph IV certification] is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a [Paragraph IV certification] for the drug." Under this definition, there can be more than one first applicant if more than one generic company files a "substantially complete" application containing a Paragraph IV certification on the same day and "lawfully maintains" that certification. As discussed above, the MMA introduced a number of "forfeiture events" that will result in a first applicant forfeiting the 180-day exclusivity period.[25]

H.R. 1506 would expand the definition of "first applicant" to include a new category of first applicants, *i.e.*, there would be two categories of "first applicants." The first category, designated "(v)(I) applicants," would retain the identical definition that currently applies to first applicants. In other words, a generic filer that meets the current requirements to qualify as a first applicant would qualify under the proposed amendment as a "(v)(I) applicant." But H.R. 1506 would create a second category of "(v)(II) applicants," and here is where things get complicated. To my mind there is some ambiguity in the language of the bill defining the requirements for (v)(II) applicants, so I will discuss two possible interpretations of the language. First, here is the language I considered to be ambiguous verbatim:

> The applicant described in clause (v)(II) submitted and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) or a statement described in paragraph (2)(A)(viii) for each unexpired patent for which a first applicant described in clause (v)(I) had submitted a certification described in paragraph (2)(A)(vii)(IV) *on the first day on which a substantially complete application containing such a certification was submitted.*[26]

The ambiguity I see is the meaning of the last part of the definition, italicized above. I think the most plausible interpretation would be that the phrase, "on the first day on which a substantially complete application containing such a certification was submitted," refers to a "first applicant described in clause (v)(I) had submitted a certification described in paragraph (2)(A)(vii)(IV)." If that is the case, the language is entirely redundant, because by definition a (v)(I) applicant has submitted a Paragraph IV certification "on the first day on which a substantially complete application containing such a certification was submitted." But assuming this is the correct interpretation, the bill creates a new category of (v)(II) applicants that can qualify for first applicant status by submitting and lawfully maintaining a Paragraph IV certification or a Paragraph VIII certification at any point in time, *i.e.*, a (v)(II) applicant could qualify for first applicant status without filing a substantially complete application containing a Paragraph IV certification on the first day on which such application was filed.

The other interpretation I can see as plausible would be to interpret the phrase, "on the first day on which a substantially complete application containing such a certification was submitted," as referring to the (v)(II) applicant. Under this interpretation, the bill would expand the definition of *first applicant* by allowing a party to qualify merely by submitting and lawfully maintaining a Paragraph IV certification, even if that certification is not part of the submission of a "substantially complete application." It would also expand the definition to encompass a generic company that files a Paragraph VIII carve-out certification[27] rather than a Paragraph VI certification. But the certification would have to be filed "on the first day on which a substantially complete application containing such a certification was submitted."

The first interpretation appears to be closer to the expressed intent of the bill's sponsor, which is to "allow[] a third competing product to enter the market."[28] Along similar lines, a press release by

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[25]21 U.S.C. § 355(j)(5)(D).

[26]21 U.S.C. § 355 (j)(5)(B)(vi)(I) as amended under H.R. 1506 (emphasis added).

[27]The Paragraph VIII carve-out certification is based on 21 U.S.C. § 355(j)(2)(A)(viii), which provides that "An abbreviated application for a new drug shall contain[,] if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use."

[28]Press Release, *Rep. Barragán Introduces Legislation to Lower Prescription Drug Prices* (Mar. 19, 2019), available at https://barragan.house.gov/rep-barragan-introduces-legislation-to-lower-prescription-drug-prices/ (last visited May 11, 2019).

Congressman Frank Pallone, Jr., Chairman of the Energy and Commerce Committee, states that H.R. 1506 would "allow[] any generic filer who wins a patent challenge in court or is not sued for patent infringement by the brand company to share in the 180-day exclusivity period of a first applicant."[29]

H.R. 1506 would impose additional requirements on (v)(II) applicants that would not be applicable to (v)(I) applicants. In particular, with regard to each unexpired patent for which the (v)(II) applicant has submitted a Paragraph IV certification, either: (1) no action for patent infringement was brought within the 45-day period provided under the Hatch-Waxman Act; (2) or if an action was brought within that time period, the action was withdrawn or dismissed by a court without a decision that the patent was invalid and infringed; or (3) if an action was brought and not dismissed or withdrawn, the applicant has obtained a court decision that the patent is invalid or not infringed. Furthermore, if a (v)(I) applicant has begun commercial marketing of the generic drug, the (v)(II) applicant may not begin commercial marketing of the drug until 30 days after a (v)(I) applicant began marketing the drug.

H.R. 1506 would also create a variety of escalating consequences for an ANDA applicant that enters into an agreement with the holder of the application for the listed drug (or an owner of a patent as to which any applicant submitted a certification qualifying such applicant for the 180-day exclusivity period) whereby that applicant agrees either (1) not to seek an approval of its application that is made effective on the earliest possible date, or (2) not to begin the commercial marketing of its drug on the earliest possible date after its application is approved. In particular, the bill creates an FDA notification requirement, pursuant to which an ANDA holder is required to submit to the Secretary of Health and Human Services the text of any such agreement to defer approval or commercial marketing, or, if such an agreement has not been reduced to text, a written detailed description of such agreement that is sufficient to disclose all the terms and conditions of the agreement. The ANDA holder is also required to submit the text (or written detailed description) of any other agreements that are contingent upon, provide a contingent condition for, or are otherwise related to an agreement to defer approval or commercial marketing. The bill specifies that any information or documentary materials submitted may not be made public, except as may be relevant to any administrative or judicial action or proceeding, or if disclosure is required by Congress.

H.R. 1506 would also limit the ability of ANDA applicants to enter into agreements containing an acceleration feature. In particular, if an agreement to defer approval or commercial marketing, as defined above, includes more than one possible date when an ANDA applicant may seek approval of its application or begin commercial marketing the drug, then the bill specifies that the applicant may only seek approval of its application or begin commercial marketing of its drug on the date that is the earlier of (1) the latest date set forth in the agreement on which that applicant can receive an approval or begin commercial marketing, without regard to any other provision of such agreement pursuant to which the commercial marketing could begin on an earlier date; or (2) 180 days after another first applicant begins commercial marketing of such drug. This provision is presumably intended to discourage ANDA applicants from entering into agreements with acceleration clauses that allow for an earlier date of market entry in the event another company brings a generic drug to market. These acceleration clauses are seen by some as anticompetitive, since they create a situation in which other generic companies might be dissuaded from entering the market by the fact that one or more other generic companies have entered into an agreement that allows that company to immediately enter the market to compete with the first generic market entrant.

H.R. 1506 also defines a category of "disqualifying agreement" that will result in forfeiture of first applicant status (and hence forfeiture of 180-day exclusivity) by any ANDA applicant that enters into such an agreement. A "disqualifying agreement" is defined as an agreement between an ANDA applicant and the holder of the application for the listed drug (or an owner of one or more of the patent as to which any applicant submitted a certification qualifying such applicant for the 180-day exclusivity period) whereby that applicant agrees, directly or indirectly, not to seek an approval of its application or not to begin the commercial marketing of its drug until the date that is after the expiration of the 180-day exclusivity period awarded to another applicant with respect to the drug.

H.R. 1506 would also amend the Patent Act such that the holder of an Orange Book-listed patent

[29]Press Release, *Pallone Unveils Policy Solutions to Lower Prescription Drug Prices* (Mar. 18, 2019), available at https://pallone.house.gov/media/press-releases/pallone-unveils-policy-solutions-lower-prescription-drug-prices (last visited May 11, 2019).

would only be allowed to enforce its patent under the provisions of the Hatch-Waxman Act pertaining to ANDA and 505(b)(2) filings; the patent holder would be precluded from seeking any remedy under the general infringement provisions of the Patent Act. In particular, the bill would amend 35 U.S.C. 271(e) by adding at the end the following:

> The exclusive remedy under this section for infringement of a patent for which the Secretary of Health and Human Services has published information pursuant to subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act shall be an action brought under this subsection within the 45-day period described in subsection (j)(5)(B)(iii) or (c)(3)(C) of section 505 of the Federal Food, Drug, and Cosmetic Act.

This provision would seem to severely penalize the holders of Orange Book-listed patents. Not only would the patent owner forfeit the ability to enforce its patent against a generic competitor after the expiration of the 45-day window for filing a Hatch-Waxman lawsuit, it would be unable to enforce its listed patents at all against an infringer that has not filed for approval of its drug under an ANDA or 505(b)(2) abbreviated approval pathway.

To summarize, H.R. 1506 would significantly complicate and increase the ambiguity of the Hatch-Waxman Act, which is already notorious for its complexity and ambiguity. The bill appears to simultaneously devalue both Orange Book-listed patents and 180-day exclusivity.

CONCLUSION

Trying to keep track of all the legislative activity centered on drug pricing and generic competition is a fast-moving target, but it appears likely that some aspects of the proposed legislation will be enacted. The likely result will be an even-more-complicated statutory framework regulating brand-generic disputes. Whether this will translate into lower drug prices without a reduction in the incentive for innovation remains an open question.

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