Hatch-Waxman to impede competition.[2] In addition, the Commission released a study entitled "Generic Drug Entry Prior to Patent Expiration" ("*FTC Generic Drug Study*") in July 2002. That study found that certain provisions of Hatch-Waxman were susceptible to strategies to delay consumer access to generic alternatives to brand-name drug products.[3] Based on its findings in that study, the Commission provided comments to FDA regarding proposed amendments to its regulations governing Orange Book listings and administration of the 30-month stay provision.[4] Following Commission testimony on the operation of the Hatch-Waxman Act,[5] Congress adopted the study's two major recommendations in its recent amendments to Hatch-Waxman.[6] The Commission has gained expertise regarding competition in the pharmaceutical industry through other means as well. For instance, the Commission staff has conducted empirical analyses of competition in the pharmaceutical industry, including in-depth studies by the staff of the Bureau of Economics.[7]

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[2] For a recent listing and discussion of all FTC pharmaceutical enforcement actions, *see FTC Antitrust Actions In Pharmaceutical Services and Products* (Oct. 2004), *available at* <http://www.ftc.gov/bc/0410rxupdate.pdf>.

[3] *See Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

[4] *Comments of the Federal Trade Commission, In the Matter of Applications for FDA Approval to Market a New Drug; Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications* (Dec. 3, 2002), *available at* <http://www.ftc.gov/be/v030002.pdf>.

[5] *Prepared Statement of the Federal Trade Commission Before the Committee on Judiciary, United States Senate* (Aug. 1, 2003), *available at* <http://www.ftc.gov/os/2003/08/030801pharmtest.htm.>; *Prepared Statement of the Federal Trade Commission Before the Committee on Judiciary, United States Senate* (June 17, 2003), *available at* <http://www.ftc.gov/os/2003/06/030617pharmtestimony.htm>.

[6] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Title XI, Access to Affordable Pharmaceuticals, PL 108-173, 117 Stat. 2066 (Dec. 8, 2003) (hereinafter, "MMA").

[7] Bureau of Economics Staff Report, Federal Trade Commission, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* (Mar. 1999), *available at* <http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf>; David Reiffen and Michael R. Ward, *Generic Drug Industry Dynamics*, Bureau of Economics Working Paper No. 248 (Feb. 2002), *available at* <http://www.ftc.gov/be/econwork.htm>.

implications for competition in the pharmaceutical industry. A brand-name drug manufacturer seeking to market a new drug product must first obtain FDA approval by filing a New Drug Application ("NDA"). At the time the NDA is filed, the brand-name company must provide FDA with information regarding patents that cover the drug that is the subject of its NDA.[8] FDA lists these patents in a publication entitled "Approved Drug Products with Therapeutic Equivalence," commonly known as the "Orange Book." To obtain approval of a generic version of a brand-name drug, a generic applicant files an Abbreviated New Drug Application ("ANDA"). The ANDA must contain, among other things, a certification regarding each patent listed in the Orange Book for the relevant NDA.[9] One way to satisfy this requirement is to provide a "Paragraph IV certification," asserting that a listed patent is invalid or not infringed. An ANDA applicant filing a Paragraph IV certification must serve notice on the patent owner and the NDA holder.[10]

By listing a patent in the Orange Book, a brand-name drug company begins the process that may potentially trigger two provisions of the Hatch-Waxman Act – the 30-month stay provision and the 180-day exclusivity provision. Under the 30-month stay provision, if a patent holder brings an infringement suit within 45 days of receiving notice of an ANDA filer's Paragraph IV certification, that suit triggers an automatic 30-month stay of FDA approval of the ANDA.[11] Under the 180-day exclusivity provision, subsequent generic applicants filing ANDAs for the same drug containing a Paragraph IV certification may not receive final FDA approval until 180 days after either (1) the first ANDA applicant that submitted a Paragraph IV certification begins commercial marketing, or (2) a court decision holding that the relevant patent is invalid or not infringed.[12]

The 30-month stay provision and the 180-day exclusivity provision of the 1984 Hatch-Waxman Act were amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).[13] Under sections 1101(1) and 1102(b) of the MMA, the 1984 version of these provisions applies to IVAX's ANDA, which was filed with the relevant Paragraph IV certifications before the effective date of the revised statue. Although we focus on the 1984 version of the statute for that reason, the principles we discuss are equally valid for the MMA's revised provisions, as explained below.

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[8] 21 U.S.C. § 355(b)(1).

[9] *Id.* § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12)(i)-(iii).

[10] 21 C.F.R. § 314.95(a).

[11] 21 U.S.C. § 355(j)(5)(B)(iii) (2002).

[12] *Id.* § 355(j)(5)(B)(iv) (2002).

[13] Title XI, Access to Affordable Pharmaceuticals, PL 108-173, 117 Stat. 2066 (Dec. 8, 2003).

[14] IVAX Citizen Petition at 12-13.

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Were IVAX's petition to be granted, it would prevent additional generic simvastatin products from reaching consumers until 180 days after expiration of the '784 patent's pediatric exclusivity period.

In support of its petition, IVAX points to FDA's regulation at 21 C.F.R. § 314.94(a)(12)(viii)(B) prohibiting the delisting of certain patents that had been the subject of a lawsuit. That regulation states:

> A patent that is the subject of a lawsuit under § 314.107(c) shall not be removed from the list until FDA determines either that no delay in effective dates of approval is required under that section as a result of the lawsuit, that the patent has expired, or that any such period of delay in effective dates of approval is ended.[18]

This regulation prohibiting delisting does not apply here because the '481 and '520 patents were never "the subject of a lawsuit." In spite of this, IVAX argues that the requirement of a lawsuit should be read out of the regulation because it refers to a "lawsuit under § 314.107(c)" and 21 C.F.R. § 314.107(c) no longer pertains to a lawsuit.

In its current formulation, § 314.107(c) follows the 180-day exclusivity provision of the 1984 Hatch-Waxman Act by stating that a subsequent ANDA containing a Paragraph IV certification will not be approved until at least 180 days after either the first ANDA filer begins commercial marketing or a court decision on the relevant patent. However, as IVAX notes, FDA's original version of § 314.107(c) required that a first ANDA applicant "successfully defend" a Paragraph IV patent infringement lawsuit to be eligible for the 180-day exclusivity.[19] After the court struck down the "successful defense requirement" in *Mova v. Shalala*,[20] FDA removed the reference to a lawsuit in §314.107(c) to eliminate the "successful defense requirement."[21] FDA did not, however, revise the delisting regulation, which continues to prohibit the delisting of patents that are the "subject of a lawsuit under §314.107(c)."

Because of this incongruity in the delisting regulation, IVAX argues that the regulation must be interpreted to prohibit the delisting of a patent whenever a generic company has established its "right" to the 180-day exclusivity by being the first ANDA applicant to submit a Paragraph IV certification, regardless of whether the patent was the subject of successful litigation or the reasons for the delisting:

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[18] 21 C.F.R. § 314.94(a)(12)(viii)(B).

[19] *See* 59 Fed. Reg. 50,338, 50,367 (Oct. 3, 1994).

[20] 955 F. Supp. 128 (D.D.C. 1997), *aff'd*, 140 F.3d 1060 (D.C. Cir. 1998).

[21] 63 Fed. Reg. 59,710 (Nov. 5, 1998).

> When the right to a 180-day exclusivity period has accrued to an ANDA applicant, however, FDA's regulations prohibit the removal of a patent from the Orange Book for as long as the ANDA applicant remains eligible for the 180-day exclusivity, the patent expires, or the 180-day exclusivity period has elapsed. § 314.94(a)(12)(viii)(B). The prohibition against delisting a patent in this circumstance is for the sole purpose of enforcing an ANDA applicant's right to180-day exclusivity, and is not based on the accuracy or relevance of the patent information. Therefore, the NDA applicant has no say in the listing of a patent to enforce 180-day exclusivity after an ANDA applicant becomes eligible for it.[22]

The Negative Implications of IVAX's Citizen Petition

Were FDA to adopt IVAX's interpretation of the pertinent regulations, an NDA holder could no longer correct an improper Orange Book patent listing following the submission of a Paragraph IV certification for that patent, regardless of whether the delisting was motivated by a clarification or better understanding of the listing requirements, an FDA inquiry, an FTC investigation, or even an FTC or district court order requiring the delisting. Such a rule would have significant, negative implications for competition in the pharmaceutical industry, to the detriment of consumers.

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[22] IVAX Citizen Petition at 2-3.

[23] Consumers saved roughly $8-10 billion by purchasing generic equivalents of brand-name drugs in 1994 alone. Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, ix (July 1998), *available at* <ftp://ftp.cbo.gov/6xx/doc655/pharm.pdf>.

[24] R. Caves, et al., *Patent Expiration, Entry and Competition in the U.S. Pharm. Indus.*, Brooking Papers on Economic Activity: Microeconomics, 36, table 9 (1991).

[25] *In the Matter of Biovail Corp.*

[28] *FTC Generic Drug Study* at 39-40, 48-50.

[29] MMA § 1101(a).

[30] *See FTC Generic Drug Study* at vii-viii, 34, 57, 63.

[31] For an in-depth discussion of this issue, *see* Brief of Amicus Curiae, Federal Trade Commission,

generic drugs.[32]9

[32] *See* H.R. Rep. No. 98-857(I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. at 2647-48.

[33] The 1984 version of the 180-day marketing exclusivity provision provided:

> If the [subsequent ANDA] contains a [paragraph IV certification] and is for a drug for which a previous [ANDA] has been submitted [containing a paragraph IV certification], the [subsequent ANDA] shall be made effective not earlier than one hundred and eighty days after - (I) [the first filer's commercial marketing] or (II) [a court decision], whichever is earlier.

U.S.C. § 355(j)(5)(B)(iii) (2002). The MMA limited the trigger for the 180-day exclusivity to commercial marketing, but also established several "forfeiture events," including a court decision, by which the first ANDA filer could lose its exclusivity. MMA § 1102(a). Significantly, the MMA, like the 1984 version of the 180-day provision, delays approval of only those subsequent ANDAs containing a Paragraph IV certification.

Thus, the statute and regulations do not support IVAX's premise that the 180-day exclusivity be treated as a right that cannot be altered by changed circumstances such as delisting of the patent. Certainly, nothing in the statute prevents removing improperly and erroneously listed patents from the Orange Book. On the contrary, the structures of both the 1984 Hatch-Waxman Act and the MMA recognize that circumstances change over time and exclusivity may be lost. The MMA goes farther by allowing ANDA applicants to challenge patent listings in a counterclaim and by listing withdrawal of a patent from the Orange Book as a forfeiture event for the 180-day exclusivity.[38] The pertinent regulation prevents delisting only of those patents that have been successfully challenged by the first ANDA filer, in order to protect the incentive to challenge weak patents provided by the 180-day exclusivity.

Conclusion

Because IVAX's proposed rule preventing the delisting of patents from the Orange Book is based on a flawed view of its entitlement to the 180-day exclusivity period, and because that rule would have significant negative implications for competition in the pharmaceutical industry, to the detriment of consumers, we urge FDA to reject it.

We appreciate your consideration of this matter.

By direction of the Commission.

Donald S. Clark
Secretary

[38] MMA §§ 1101(a)(2)(C), 1102(a)(2).