IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SMITHKLINE BEECHAM CORPORATION, SMITHKLINE BEECHAM P.L.C., and BEECHAM GROUP, P.L.C.	)	**Civil Action**
v.	)	**Case No. 99-CV-4304** **Case No. 00-CV-4888** **Case No. 01-CV-159** **Case No. 01-CV-2169**
APOTEX CORPORATION, APOTEX, INC. and TORPHARM, INC.	)	**Judge R. Barclay Surrick**
MITHKLINE BEECHAM CORPORATION, SMITHKLINE BEECHAM P.L.C., and BEECHAM GROUP, P.L.C.,	)	Civil Action
v.	)	Case No. 99-CV-2926 Case No. 00-CV-5953 Case No. 02-CV-1484
GENEVA PHARMACEUTICALS, INC.	)	
SMITHKLINE BEECHAM CORPORATION, SMITHKLINE BEECHAM P.L.C., and BEECHAM GROUP, P.L.C.,	)	Civil Action
v.	)	Case No. 00-CV-1393 Case No. 00-CV-6464 Case No. 00-CV-2602
ZENITH GOLDLINE PHARMACEUTICALS, INC. and SUMIKA FINE CHEMICAL CO., LTD.	)	
SMITHKLINE BEECHAM CORPORATION and BEECHAM GROUP, P.L.C.,	)	Civil Action
v.	)	Case No. 01-CV-1027 Case No. 01-CV-3364
ALPHAPHARM PTY, LTD.	)	
SMITHKLINE BEECHAM CORPORATION and BEECHAM GROUP, P.L.C.,	)	Civil Action
v.	)	Case No. 01-CV-2981
ANDRX PHARMACEUTICALS, INC., ANDRX PHARMACEUTICALS, L.L.C., and BASF CORPORATION	)	

MEMORANDUM OF LAW OF FEDERAL TRADECOMMISSION AS *AMICUS CURIAE* CONCERNING TORPHARM'S CROSS MOTION FOR ENTRY OF AN AMENDED ORDER

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On December 20, 2002, this Court issued an order holding certain claims of U.S. Patent Nos. 6,113,944 ("'944 patent") and 6,172,233 ("'233 patent"), owned by SmithKline Beecham Corp. and SmithKline Beecham P.L.C. ("SmithKline"), invalid for lack of novelty. Apotex Corporation, Apotex, Inc. and Torpharm, Inc. ("Apotex") have filed a motion to amend this order to require SmithKline to seek removal of the listings of the '944 and '233 patents from the Food and Drug Administration's ("FDA's") *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"). To aid the Court in its consideration of this motion, the Federal Trade Commission ("FTC" or "Commission") submits this brief as *amicus curiae* to discuss the potential for improperly-maintained Orange Book listings to serve as barriers to competition, and to advise the Court of the substantial pro-consumer benefits of an appropriate de-listing remedy. The Commission takes no position on the ultimate issue before the Court, i.e., whether de-listing is appropriate on the facts of this particular case.

I. SUMMARY

The Commission is an independent administrative agency charged with promoting the efficient functioning of the marketplace by taking actions against commercial practices injurious to consumers. As discussed in more detail below, the Commission has developed significant expertise regarding the pharmaceutical industry and the operation of the Hatch-Waxman Amendments,[1] through, *inter alia*, empirical analyses of competition in the pharmaceutical industry, the investigation and prosecution of antitrust enforcement actions, testimony before Congress, the submission of comments with the FDA, and the filing of *amicus* briefs. Based on this experience, the Commission believes that the Court may benefit from its perspective with respect to three issues pertinent to the pending motion.

First, empirical analyses show that, because generic drugs are typically far less expensive

[1] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. § 68b, 21 U.S.C. §§ 301, 355, 360cc, and 35 U.S.C. §§ 156, 271, 282 (1984)) ("Hatch-Waxman" or "Hatch-Waxman Amendments").

than their corresponding brand-name versions, competition from generic drugs can deliver large savings to consumers. For example, a Congressional Budget Office ("CBO") study found that, for drugs available in both generic and brand-name versions, the average price of a generic prescription was approximately half of the average price of a brand-name prescription.[2] In this case, SmithKline's U.S. sales of Paxil have been approximately $2 billion a year. Given the typical price reduction found to occur upon generic entry, the savings to consumers from generic entry in Paxil might approach $30 million per month.

Second, in July 2002, the Commission completed an industry-wide study of 104 drug products for which at least one Abbreviated New Drug Application ("ANDA") was filed from the beginning of 1992 through the end of 2000 ("Generic Drug Study").[3] The Generic Drug Study included an analysis of competitive issues raised by the 30-month stay provision of the Hatch-Waxman Amendments. In the Study, Paxil is identified as one of only eight drugs (out of the 104 drug products studied) for which the brand-name company listed patents in the Orange Book *after* a generic drug manufacturer filed its ANDA. By listing patents after the ANDA is filed, the brand-name company can obtain additional 30-month stays of FDA approval of the generic applicant's ANDA. In this case, the stays SmithKline obtained by listing the '233 and '944 patents are the latest in a chain extending 35 months beyond the initial 30-month stay. These stays continue to prevent the FDA from approving generic applicants' ANDAs for Paxil.

Finally, under *Abbott Laboratories v. Novopharm Ltd.*, 104 F.3d 1305, 1309 (Fed. Cir. 1997), the Commission believes that a de-listing remedy is consistent with this Court's order holding SmithKline's listed patent claims invalid. By maintaining a patent listing in the Orange Book after a judgment of invalidity, a branded drug manufacturer may continue to benefit from

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[2] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* ("Congressional Budget Office Study"), 33, table 5 (1998), *available at* <ftp://ftp.cbo.gov/6xx/doc655/pharm.pdf>.

[3] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration* ("Generic Drug Study") (2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

the 30-month stay on FDA approval of generic versions of the drug product for which the branded firm listed the patent. The FDA views its role in administering the Orange Book as solely ministerial, and does not de-list a patent unless the brand-name company requests it to do so. Accordingly, absent an order requiring the brand-name company to seek de-listing, the firm may continue to enjoy the stay's protection from generic competition. Such an outcome contrasts with ordinary rules of patent litigation, pursuant to which a patent held invalid by a district court cannot be used prospectively during the pendency of appeal. The Court therefore properly may consider whether the continued listing of SmithKline's patents may extend the patent monopoly in a manner inconsistent with its judgment of invalidity. *See Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1333 (Fed. Cir. 2001) (confirming de-listing as a potential remedy in a patent infringement action).

II. STATEMENT OF INTEREST OF *AMICUS CURIAE*

The FTC's statutory mission is to protect consumers. The Commission enforces, *inter alia*, Section 5 of the Federal Trade Commission Act, which prohibits "[u]nfair methods of competition."[4]

The Commission has developed significant expertise regarding the pharmaceutical industry and the operation of the Hatch-Waxman Amendments. As noted above, the Commission recently completed its Generic Drug Study, a Congressionally-requested, industry-wide study of generic drug competition that provides a detailed explanation of how generic competition has developed under Hatch-Waxman.[5] In addition, Commission staff have conducted empirical analyses of competition in the pharmaceutical industry, including in-depth studies by the staff of the

[4] 15 U.S.C. § 45(a)(1) (2002).

[5] *See supra* note 3.

Commission's Bureau of Economics.[6] The Commission has provided testimony before Congress,[7] and Commission staff have filed comments with the FDA concerning specific issues relating to Orange Book patent listings.[8]

The Commission also has brought several antitrust enforcement actions affecting both the branded and generic drug industries.[9] These actions include a recent consent order settling charges that a brand-name company improperly acquired and listed a patent in the Orange Book, creating an anticompetitive barrier to generic entry.[10] Further, the Commission has several pending public and non-public investigations concerning the potential anticompetitive effects of

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[6] Roy Levy, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* (1999), *available at* <http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf>.

[7] Prepared Statement of the Federal Trade Commission before the Committee on Energy and Commerce, Subcommittee on Health, United States House of Representatives (October 9, 2002), *available at* <http://www.ftc.gov/os/2002/10/generictestimony021009.pdf>; Testimony of the Federal Trade Commission before the Committee on Commerce, Science and Transportation, United States Senate (April 23, 2002), *available at* <http://www.ftc.gov/os/2002/04/pharmtestimony.htm>; Testimony of the Federal Trade Commission before the Committee on the Judiciary, United States Senate, *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements* (May 24, 2001), *available at* <http://www.ftc.gov/os/2001/05/pharmtstmy.htm>.

[8] *See Applications for FDA Approval to Market a New Drug*, Comments of the United States Federal Trade Commission before the Food and Drug Administration (Dec. 23, 2002), *available at* <http://www.fda.gov/ohrms/dockets/dockets/02n0417/02N-0417_emc-000001-01.pdf>; *Clarify Issues Relating to Patent Listings in the Orange Book*, Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission (May 21, 2000).

[9] *See, e.g.*, *Biovail Corp. and Elan Corp. PLC*, Docket No. C-4057 (Aug. 15, 2002) (consent order); *Schering-Plough Corp., Upsher-Smith Labs., and American Home Products Corp.*, Docket No. 9297 (consent order as to American Home Products) (Apr. 2, 2002), *Schering Plough Corp.*, 2002 FTC LEXIS 40 (June 27, 2002) (initial decision), *appeal argued*, No. 9297 (FTC Jan. 7, 2003); *FTC v. Mylan Labs., Inc.*, 62 F. Supp. 2d 25 (D.D.C. 1999); *Hoechst Marion Roussel, Inc.*, Docket No. 9293 (May 8, 2001) (consent order); *Abbott Labs.*, Docket No. C-3945 (May 22, 2000) (consent order); *Geneva Pharms., Inc.*, Docket No. C-3946 (May 22, 2000) (consent order); *Roche Holding Ltd.*, 125 FTC 919 (1998) (consent order); *Ciba-Geigy Ltd.*, 123 FTC 842 (1997) (consent order); *Hoechst AG*, 120 FTC 1010 (1995) (consent order). For a discussion of FTC enforcement actions in the pharmaceutical industry, *see generally FTC Antitrust Actions in Health Care Services and Products, available at* <http://www.ftc.gov./bc/healthindex.htm>.

[10] *Biovail Corp.*, Docket No. C-4060 (Oct. 2, 2002) (consent order), *available at* <http://www.ftc.gov/os/2002/10/biovaildo.pdf>.

improper patent listings in the Orange Book, including whether SmithKline's listing of certain patents constitutes an "unfair method of competition" in violation of Section 5 of the Federal Trade Commission Act.[11]

Finally, the Commission has filed *amicus* briefs in Hatch-Waxman litigiation pending in district courts. Most recently, the Commission filed as *amicus* in *In re Buspirone Antitrust Litigation*, MDL Dk. No. 1410 (S.D.N.Y. Jan. 8, 2002), an antitrust action concerning the alleged anticompetitive effects of an Orange Book listing.[12]

The Commission seeks to highlight consumer interests that the parties to this suit might not otherwise address. As discussed below, Orange Book listings can have great significance to generic market entry. Because the Commission's views may help the Court's disposition of Apotex's motion, the Commission respectfully requests to be heard as *amicus curiae*.

III. ANALYSIS

A. Background: Orange Book Listings Under the Hatch-Waxman Act

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as "Hatch-Waxman," to facilitate the entry of generic drugs while maintaining incentives to invest in new branded drug development.[13] Under Hatch-Waxman, a brand-name pharmaceutical company that has applied for FDA approval to produce a new drug must list in its New Drug Application ("NDA") certain patents relating to the drug that is the

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[11] The Paxil investigation was publicly disclosed as part of a subpoena enforcement action brought against SmithKline. *See FTC v. GlaxoSmithKline*, 294 F.3d 141 (D.C. Cir. 2002).

[12] *In re Buspirone Patent Litig. / In re Buspirone Antitrust Litig*., Memorandum of Law of *Amicus Curiae* the Federal Trade Commission in Opposition to Defendant's Motion to Dismiss (Jan. 8, 2002), *available at* <http://www.ftc.gov/os/2002/01/busparbrief.pdf>.

[13] *See* H.R. Rep. No. 98-857(I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647-48 (stating that the purposes of the legislation are "to make available more low cost generic drugs [and] to create a new incentive for increased expenditures for research and development of certain products which are subject to pre-market approval.").

subject of its application.[14] To be listed, *inter alia*, a patent must contain at least one valid product or method of use claim.[15] Once the FDA approves the brand-name company's NDA, the patents submitted with the NDA – and any patent information later submitted as amendments to that application – are listed in the FDA's Orange Book.[16]

The patents listed in the Orange Book then serve to prescribe the timing and approval of generic drug market entry. Generic drug manufacturers seeking expedited approval to market a generic version of an already-approved branded drug must submit an Abbreviated New Drug Application ("ANDA") to the FDA.[17] The FDA may not immediately approve an ANDA unless the applicant certifies that no patents are listed for the branded drug or that the listed patents have expired.[18] The FDA either will delay approval until any listed patents expire,[19] or, alternatively, an applicant may certify that the listed patents are "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the [ANDA] is submitted" (a "paragraph IV

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[14] 21 U.S.C. § 355(b)(1), (c)(2) (2002); *see also* 21 C.F.R. § 314.53(b) (2003).

[15] *Id.* Patents claiming only processes of making or manufacturing a drug are not listable. *Id.* Moreover, the patent's product or method of use claims must be ones "with respect to which a claim of patent infringement reasonably could be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1) (2002). Among other things, one cannot reasonably assert a claim of infringement of a patent claim that has been held invalid. *See Int'l Med. Prosthetics Research Assoc., Inc. v. Gore Enter. Holdings, Inc.*, 787 F.2d 572, 575 (Fed. Cir. 1986) ("[If] the patent is invalid . . . no liability for the infringement can therefore exist."); *see also* H.R. Rep. No. 98-857, part II at 26 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2710 (it is only an act of patent infringement to submit an ANDA for a listed drug "(1) which is claimed in a *valid product patent*, or (2) a use of which is claimed in a valid use patent . . . .") (emphasis added).

[16] 21 U.S.C. § 355(j)(7)(A)(iii) (2002).

[17] *Id.* at § 355(j) (2002); 21 C.F.R. § 314.94 (2003). A generic manufacturer may also submit a so-called "paper" NDA to seek approval to produce a generic product. *See* 21 U.S.C. § 355(b)(2) (2002). "Paper" NDAs are also subject to the patent certification and 30-month stay provisions outlined below. *See id.* at. § 355(c)(3) (2002).

[18] 21 U.S.C. § 355(j)(2)(A)(vii)(I-II), (j)(5)(B)(i) (2002).

[19] *Id.* at § 355(j)(2)(A)(vii)(III), (j)(5)(B)(ii).

certification").[20] When an NDA holder receives notice of a paragraph IV certification, it may sue the ANDA applicant for patent infringement.[21] For patents listed in the Orange Book, the initiation of such a patent infringement suit triggers an automatic 30-month stay during which the FDA may not approve the ANDA, unless the suit is resolved earlier in favor of the generic.[22]

In contrast, for patents not listed in the Orange Book, a branded firm's recourse is to sue a generic company for patent infringement in the district courts under ordinary federal litigation procedures, without the benefit of a 30-month stay.[23] To prevent sale of the generic product before conclusion of the suit, a branded firm must obtain a preliminary injunction, which requires that it demonstrate a likelihood of success on the merits, among other factors.[24]

Although an Orange Book listing has significant legal and competitive implications, the FDA's role in supervising Orange Book listings is limited. As one court has stated, "the FDA's listing should not create any presumption that [a] patent was correctly listed."[25] The FDA has

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[20] *Id*. at § 355(j)(2)(A)(vii)(IV).

[21] *Id*. at § 355(j)(5)(B)(iii) (2002); *see also* 35 U.S.C. § 271(e)(2)(A) (2002).

[22] *Id.* For ANDAs filed before March 2000 (such as the ANDA in this case), the FDA considers the patent litigation to be resolved only when the time for taking an appeal of a district court decision has lapsed or an appeal has been decided. *See* Center for Drug Evaluation and Research, Food and Drug Administration, *Guidance for Industry: Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act* (March 2000), *available at* <http://www.fda.gov/cder/guidance/3659fnl.htm>. For ANDAs filed after March 2000, the FDA follows the approach of *Mylan Pharms. Inc. v. Shalala*, 81 F. Supp. 2d 30 (D.D.C. 2000) (holding that a district court decision of invalidity triggers ANDA approval). *Id.* Thus, for ANDAs filed before March 2000, the 30-month stay continues to block FDA approval even after a district court decision in favor of the generic, because of the additional time required to reach an appellate decision. For an example of the time between district court and appellate decisions, see *Upjohn Co. v. Mova Pharm. Corp*., 225 F.3d 1306 (Fed. Cir. 2000), which issued on Sept. 11, 2000, concerning *Upjohn Co. v. Mova Pharm. Corp*., 31 F. Supp. 2d 211 (D.P.R. 1998), which issued on Aug. 25, 1998.

[23] *See* 35 U.S.C. § 271 (2002); *see also Glaxo, Inc. v. Novopharm, Ltd*., 110 F.3d 1562, 1564 (Fed. Cir. 1997) (declaratory relief action under § 271(g)).

[24] *See, e.g., Purdue Pharms. L.P. v. Boehringer Ingelheim, GmbH*, 237 F.3d 1359, 1362-63 (Fed. Cir. 2001).

[25] *Ben Venue Labs., Inc. v. Novartis Pharm. Corp*., 10 F. Supp. 2d 446, 456 (D.N.J. 1998).

repeatedly stated that it lacks the resources and expertise to scrutinize patent information in the Orange Book, and that its role in patent listings is solely ministerial.[26] If a party disputes the accuracy of a listed patent, then the FDA will only request that the NDA holder confirm that the listed patent information is correct.[27] Unless the NDA holder itself withdraws or amends its listed patent information, the FDA will not remove the patent listings from the Orange Book.[28] As long as the patent remains listed, the brand-name company can continue to benefit from a 30-month stay of FDA approval of ANDAs, by initiating a patent suit against generic applicants.[29]

B. Consumers Benefit From Generic Entry

Generic pharmaceutical entry results in substantial consumer savings. The Commission's Generic Drug Study found that the empirical economics literature "points to significant short-run competitive impacts of generic entry that can lead to substantial benefits for consumers of prescription drugs."[30] A noteworthy feature of this literature is that it indicates that generic entrants gain significant market share at the expense of their rival brand-name drug companies after their entry, because they enter with products priced substantially below the branded product price. One article concluded, as the Generic Drug Study reports, that "generic entry results in somewhat higher prices for brand-name prescription drugs (in light of factors such as inelastic

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[26] *See, e.g.*, Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,343-45 (1994) (codified at 21 C.F.R. § 314); 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 Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 67 Fed. Reg. 65,448, 65,453 (2002) (to be codified at 21 C.F.R. § 314); *see also aaiPharma Inc. v. Thompson*, 296 F.3d 227, 238-39 (4th Cir. 2002); *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1377-78 (Fed. Cir. 2002); *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1329 (Fed. Cir. 2001).

[27] 21 C.F.R. § 314.53(f) (2003).

[28] *Id.*; *see also* 59 Fed. Reg. 50,338, 50,344 (1994).

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

[30] Generic Drug Study at 9.

demand among users of brand-name products), but large decreases in the prices of corresponding generic drugs."[31] In addition, another study found that generic prices were lower when there was multiple generic entry.[32]

The Congressional Budget Office study is consistent with this economic literature. According to the CBO, the first generic manufacturer to enter the market typically charges 70-80% of the brand manufacturer's price.[33] As additional generic versions enter the market, the generic price drops, sometimes decreasing to a level of less than 50% of the brand price.[34] The CBO estimated that, in 1994, the availability of generic drugs saved purchasers between $8 to $10 billion on prescription drugs at retail pharmacies.[35] This number can be expected to grow substantially in the future, because in the next five years, patents on drugs with annual sales in excess of $50 billion will expire.[36]

Such benefits of generic drug entry can be expected in the event of generic entry against SmithKline's Paxil drug product. Paxil's U.S. sales in 2002 were approximately $2 billion.[37] Based on the typical price reductions seen on blockbuster drugs, savings to consumers from generic entry on Paxil could be almost $30 million per month.[38] In addition to Apotex, at least five other generic applicants have filed ANDAs currently pending before the FDA on Paxil, and an

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[31] *See id.*

[32] *See id.*

[33] Congressional Budget Office Study at 33, table 5.

[34] *Id.*

[35] *Id.* at xiii, 13.

[36] Christopher Bowe and Victoria Griffith, *Proposal on Patents Set to Hit Revenues of Drug Companies*, Fin. Times (USA Edition), Oct. 22, 2002, at 2.

[37] *See* GlaxoSmithKline, *Pharmaceutical Sales - Nine Months Ended 30th September 2002, available at* <http://www.gsk.com/financial/rpt_q32002.htm>.

[38] This calculation assumes the following: $2.0 billion market x 70% market share obtained by generic following entry x 25% price reduction.

additional applicant has filed a "paper" NDA for a generic version of the drug.[39] The bulk of these applicants have been subject to a stay based on SmithKline's listings of either the '233 or '944 patents.[40] Further, according to Apotex, the stays based on these two listings are the only stays barring the FDA's final approval of its ANDA.[41] If these patents are de-listed and the stays generated by these patents are terminated, the '233 and '944 patents can no longer impede FDA approval of Apotex's or other generic competitors' ANDAs.[42] Further, consumers benefit when patents lacking justification for listing are expunged from the Orange Book. De-listing such patents prevents the brand-name company from using them to maintain 30-month stays that bar competitive entry by all potential generic rivals.

C. Multiple Post-ANDA Orange Book Patent Listings, and Litigation Involving Those Patents, Postpone Generic Drug Entry

The Commission's Generic Drug Study was based on information received by the

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[39] *See SmithKline Beecham Corp. v. Pentech Pharms., Inc*., 2002 U.S. Dist. LEXIS 6203 at *7-*8 (N.D. Ill. April 3, 2002) (noting that Pentech had filed an ANDA for paroxetine hydrochloride); *SmithKline Beecham Corp. v. Geneva Pharm., Inc*., 2001 U.S. Dist. LEXIS 17434 at *20 n.12 (E.D. Pa. Sept. 28, 2001) (listing Alphapharm, Andrx/BASF, Apotex, Geneva, and Zenith as having filed ANDAs for paroxetine hydrochloride);*see also Synthon Successfully Concludes First Paroxetine MRP*, May 16, 2001, *available at* <http://www.synthon.nl/5-press-010516-1.html>) ("In the U.S., Synthon Pharmaceuticals, Ltd. has submitted a New Drug Application (NDA) [for paroxetine] in September of last year.").

[40] *See SmithKline Beecham Corp*., 2002 U.S. Dist. LEXIS 6203 at *7-*8;*SmithKline Beecham Corp*., 2001 U.S. Dist. LEXIS 17434 at *9-*14; *SmithKline Beecham v. Synthon Pharms., Ltd*., 210 F.R.D. 163, 165 (M.D.N.C. 2002) (collectively, indicating that SmithKline sued all of the generics except Andrx and Pentech on either the '233 or '944 patents).

[41] *See* Torpharm's Cross Motion for Entry of an Amended Order at 3-4; s*ee also* Food and Drug Administration, *New and Generic Drug Approvals: 1998-2003* (under product name, paroxetine hydrochloride tablets), *available at* <http://www.fda.gov/cder/approval/index.htm> (indicating that Apotex has received tentative FDA approval to market its generic Paxil product). A 30-month stay from another of SmithKline's patents, U.S. Patent No. 6,080,759, is set to expire next month. Generic Drug Study at 52.

[42] While a generic may choose to enter a market during the pendency of patent litigation, the Commission found in its Generic Drug Study that generic applicants defending patent infringement suits generally did not enter the market until after a district court order holding that the brand's patent was invalid or not infringed. Generic Drug Study at 22.

Commission in response to special orders served in 2001 on 28 brand-name companies and over 50 generic drug companies.[43] The Study was limited to ANDAs that contained a paragraph IV certification, that is, a certification that the listed patent was invalid or would not be infringed by the generic drug. The Commission received information regarding 483 ANDAs containing paragraph IV certifications, which related to 130 unique brand-name drug products (as measured by unique NDAs). The Commission's study covered the 104 drug products (of 130 total) for which at least one ANDA had been filed after January 1, 1992.[44]

A major focus of the Generic Drug Study was how the 30-month stay provision has influenced the development of generic drug competition. To begin with, the Commission found that one 30-month period to resolve disputes over patents listed in the Orange Book prior to the ANDA's filing date was, on average, unlikely to delay generic entry, because it approximated the time necessary for FDA review and approval of the ANDA, and the duration of a patent lawsuit.[45] FDA approval of generic applicants that filed paragraph IV certifications and were not sued took, on average, 25 months and 15 days from the filing date. The average time between the filing of the complaint and a district court decision in litigation between the brand-name company and first or second generic applicants was remarkably similar: on average it took 25 months and 13 days. (The average time between the complaint and an appellate decision was 37 months and 20 days.)[46]

Before 1998, litigation between a brand and first or second generic typically involved, at most, one 30-month stay, and was completed prior to the end of the stay period. After 1998, however, the data received by the Commission showed two significant changes emerging.[47] First, before 1998, only one case involving a "blockbuster" drug alleged infringement of as many as

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[43] *Id*. at 3.

[44] *Id*. at 10.

[45] *Id*. at iv.

[46] *Id*. at 39.

[47] *Id*.

three patents. After 1998, however, the majority of cases involving drugs with significant sales alleged infringement of three or more patents. The effect of this increase in the number of patents in suit was to lengthen the average time to obtain a court decision. As of June 1, 2002, in six of the seven suits that had been pending for more than 30 months without a district court decision, the brand-name company had alleged infringement of at least three patents.[48]

An even more significant effect in delaying generic drug entry resulted from the second trend identified in the Generic Drug Study, relating to the listing of later-issued patents (that is, patents obtained by the brand-name company after receiving NDA approval). If patents issued to the brand-name company are listed *before* the generic applicant files its ANDA, a brand-name company's suit on those patents will generate only one 30-month stay, even though multiple patents are at issue in the litigation. If the later-issued patent is listed *after* the generic applicant has filed its ANDA, however, the brand-name company obtains an additional 30-month stay (either consecutive to or overlapping the first 30-month stay), triggered by the generic applicant's certification that it does not infringe the later-issued patent.[49]

The Commission found eight drug products involving such later-issued patents with more than one 30-month stay. For the eight drug products, the additional delay of FDA approval, beyond the first 30 months, ranged from four to 40 months. The Commission also found that "[i]n all of the 4 cases so far with a court decision on the validity or infringement of a later-issued patent, the patent has been found either invalid or not infringed by the ANDA."[50] The Study further noted:

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[48] *Id.* at 39-40.

[49] *Id*. at 40. The FDA recently proposed regulations to permit only one 30-month stay per ANDA; however, the FDA is still reviewing comments on the proposal. *See* 67 Fed. Reg. at 65,448.

[50] Generic Drug Study at 40. Because the Study was completed in July 2002, this finding does not take into account the Court's ruling in the present action. The Court's invalidity holding on SmithKline's '233 and '944 patents, both of which were listed after the Apotex ANDA filing, squarely fits this pattern.

> Moreover, most of the later-issued patents in the Orange Book raise questions about whether the FDA's patent listing requirements have been met. For example, many of the later-issued patents do not appear to claim the approved drug product or an approved use of the drug. Recent court opinions hold that Hatch-Waxman does not provide a right of action through which generic applicants may challenge a patent listing in the Orange Book. Thus, to terminate a second 30-month stay, a generic applicant's only recourse is to obtain a decision of a court on patent infringement or invalidity.[51]

SmithKline's filings with respect to Paxil illustrate (and, indeed, lie at the extreme end of) the trends noted in the Study. SmithKline has listed nine patents for Paxil, eight of which were listed after Apotex filed its ANDA in March 1998 – generating more 30-month stays than any other drug product within the scope of the Study.[52] The 30-month stay generated by SmithKline's lawsuit based on U.S. Patent No. 4,721,723 – the only patent listed in the Orange Book at the time Apotex filed its ANDA – expired in approximately November 2000.[53] Since Apotex's initial ANDA filing, however, SmithKline has obtained four additional overlapping 30-month stays, including stays from the '944 and '233 patent listings, which extended the block on generic competition for a total of 65 months. The last of those stays (generated by the '233 listing) will end in September 2003, provided that SmithKline does not obtain additional stays by listing more patents.[54] The five 30-month stays for Paxil are the most identified in the Study. (SmithKline also has obtained multiple 30-month stays against other generic applicants for Paxil.)[55]

In summary, the stay of generic drug competition against Paxil, which now has run to nearly five years, is not within the ordinary range of stays under Hatch-Waxman. Rather, of the 104 drugs that were the subject of the Commission's Generic Drug Study, Paxil has received

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[51] *Id.*

[52] *Id.* at 51.

[53] *Id.*

[54] *Id.* at 52, Figure 4-1.

[55] *Id.* at 51, n.23.

more 30-month stays than any other drug; the total number of months for which FDA approval has been stayed is longer than any other drug except one; and more patents have been listed after the ANDA filing than any other drug product within the scope of the Study.

D. De-Listing a Patent to Give Effect to a Judgment Is an Appropriate Potential Remedy

In patent litigation outside the Hatch-Waxman context, a district court's judgment that a patent claim is invalid substantially terminates a patentee's ability to enforce the claim.[56] Accused infringers, as well as competitors who are not parties to the litigation, therefore ordinarily are free to market their products in reliance on the court's order, subject to the risk of reversal by an appellate court as well as any other pending patent litigation.[57] In patent litigation arising under Hatch-Waxman, however, the potential exists for a brand-name company to continue to benefit

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[56] A district court judgment of invalidity collaterally estops the patentee from asserting the patent claims as valid. *See Blonder-Tongue Labs., Inc. v. Univ. of Illinois Found.*, 402 U.S. 313, 332-33 (1971) (holding that a prior determination of patent invalidity may be asserted as a defense to a subsequent attempt to enforce the patent unless the patentee demonstrates that a full and fair opportunity to litigate was somehow denied in the first action); *Stevenson v. Sears, Roebuck & Co.*, 713 F.2d 705, 709 (Fed. Cir. 1983) (noting that the crucial inquiry for the court is whether the patentee had a full and fair opportunity to litigate the validity of the patent, and not whether the prior finding of invalidity was a correct one). Further, the law is well settled that the pendency of an appeal has no effect on the finality or binding effect of a trial court's holding on patent invalidity. *SSIH Equip. S.A. v. United States ITC*, 718 F.2d 365, 370 (Fed. Cir. 1983); *Pharmacia & Upjohn Co. v. Novopharm Ltd.*, 1999 U.S. Dist. LEXIS 1257 at *10 (N.D. Ill. Feb. 2, 1999) ("It is well-settled that, once a judgment is entered, that judgment is accorded an estoppel effect regardless of any pending postjudgment motions or appeals.").

[57] The Federal Circuit has held that following a district court decision invalidating the patent at issue, "[a patentee's] infringement claim has been adversely decided and [an accused infringer] has a legal right to do the act claimed to be infringing." *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1489 (Fed. Cir. 1986). This right to "do" a purportedly infringing act, i.e., sell or market an accused product, exists notwithstanding the possibility of an appellate reversal followed by a finding of infringement, and potential liability for pre-judgment interest and/or damages for the period between the trial court decision and appellate decision. The only method for a patentee to block sales of the accused product after a district court invalidity decision is to seek a stay of the order pending appeal. *See* Fed. R. App. P. 8(a)(1-2) (2002). To prevail on a stay, a movant must establish a strong likelihood of success on the merits or, failing that, nonetheless demonstrate a substantial case on the merits provided that the harm factors militate in its favor. *See Hilton v. Braunskill*, 481 U.S. 770, 778 (1987); *Standard Havens Prods. v. Gencor Indus.*, 897 F.2d 511 (Fed. Cir. 1990).

from an invalid patent claim by receiving Orange Book listing protections – i.e., insulation from generic competition – properly available only to valid patents.

The U.S. Court of Appeals for the Federal Circuit has twice confirmed the propriety of a de-listing remedy in patent infringement suits. In *Abbott Laboratories v. Novopharm Ltd*., the Federal Circuit affirmed the district court's order requiring a brand-name company to request de-listing of a patent in order to give effect to a judgment in a patent infringement case.[58] Abbott, the brand, held an approved NDA for terazosin hydrochloride, and had listed U.S. Patent No. 4,112,097 ("'097 patent") in the Orange Book as claiming that drug.[59] In 1995, two manufacturers, Novopharm and Geneva, each filed an ANDA to produce a generic version of Abbott's drug.[60] Using the Hatch-Waxman procedures, Abbott sued Geneva and Novopharm for infringement of the '097 patent, triggering a 30-month stay on final FDA approval of their applications.[61] The generic applicants moved to dismiss Abbott's complaint on the grounds that the '097 patent had expired, and for summary judgment on their counterclaim for declaratory judgment that the patent had expired.[62] The district court granted the generic applicants' motion to dismiss, holding that Abbott failed to state a claim of infringement of the '097 patent (rejecting Abbott's arguments that the patent's term had been extended).[63]

Geneva later moved to amend the judgment to require Abbott to seek de-listing of the '097

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[58] 104 F.3d at 1305, 1309 (Fed. Cir. 1997).

[59] *Id*. at 1307.

[60] *Id*., referring to 21 U.S.C. § 355(j)(4)(B)(iii) (1994), which provides for a 30-month stay where an ANDA applicant has made a paragraph IV certification.

[61] *Id*.

[62] *Abbott Labs. v. Novopharm Ltd*., 1996 WL 131498 at *1 (N.D. Ill. March 15, 1996); *see also* 104 F.3d at 1307.

[63] 1996 WL 131498 at *1; *see also* 104 F.3d at 1307. The district court also granted summary judgment in favor of the generic applicants on the declaratory relief counterclaim. *Id*.

patent.[64] The district court granted the motion, stating that its judgment "has little effect without the change in listing," and that "[t]he Plaintiff should not be able to continue enjoying the benefits of a patent which we have deemed as expired."[65]

The Federal Circuit affirmed the district court's dismissal of Abbott's complaint and the de-listing order. *Abbott Labs.*, 104 F.3d at 1306. It expressly rejected Abbott's contention that the de-listing order erroneously assisted Geneva to "circumvent[]" the FDA's process for approving generic drugs.[66] The court of appeals recognized that pursuant to the FDA's regulations, the FDA would not approve a generic manufacturer's ANDA prior to the expiration of 30 months unless and until any appeal taken from the patent litigation was resolved in the generic's favor.[67] Ordinarily, therefore, a district court ruling favorable to a generic in the patent infringement suit would not affect the status of a generic's application to market the drug.[68]

Notwithstanding the FDA's policy, the Federal Circuit held that the district court was within its authority to order Abbott to request the FDA to remove the '097 patent from the Orange Book:

> The district court was properly concerned that its judgment would have "little effect" unless the Orange Book listing was removed. It took the least intrusive action to seek to enforce its judgment – merely ordering Abbott to remove the Orange Book listing.[69]

The Federal Circuit later restated this ruling in *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323, 1333 (Fed. Cir. 2001). Indeed, *Mylan* rejected an alternative means for private parties

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[64] *Abbott Labs. v. Geneva Pharms., Inc.*, 1996 U.S. Dist. LEXIS 9762 (N.D. Ill. April 9, 1996); *see also* 104 F.3d at 1307.

[65] 1996 U.S. Dist. LEXIS 9762 at *2; *see also* 104 F.3d at 1307.

[66] 104 F.3d at 1309.

[67] 104 F.3d at 1309. The FDA applied this policy to all ANDAs at the time of the Federal Circuit's *Abbott* decision. *Id.*; s*ee also* discussion *supra* note 22.

[68] *Abbott Labs.*, 104 F.3d at 1309.

[69] *Id.*

to seek patent de-listing,[70] noting the availability of a de-listing remedy pursuant to *Abbott*. *See Mylan Pharms., Inc.*, 268 F.3d at 1333 ("[A]s part of its inherent power to give effect to a judgment, a court may order the delisting of a patent in the context of a properly filed patent infringement suit," citing *Abbott Labs.*, 104 F.3d at 1309).

Thus, when a court issues an order that will serve as a basis for final judgment that a patent listed in the Orange Book is invalid, it is within the court's authority to require the patentee to de-list the patent to enforce its judgment.[71] Similarly, when a court holds specific claims of a patent invalid, it can likewise require the patentee to de-list its patent if the invalidated claims are the sole basis for the Orange Book listing.[72] This relief is narrowly-tailored. It is mandatory only as to the patentee and does not intrude upon the FDA's authority to govern the generic drug approval process. *See Abbott Labs.*, 104 F.3d at 1309 (rejecting Abbott's argument that the district court's de-listing order erroneously "circumvent[ed]" the FDA's approval process);*see also Abbott Labs.*, 1996 U.S. Dist. LEXIS 9762 at *2 ("Abbott's arguments involve the approval of new drugs whereas we are here dealing with whether the Orange Book should reflect our holding."). While the FDA is not obliged to grant NDA holders' requests, the FDA's regulations contemplate that the FDA will act on requests to withdraw or amend the patent information that serves as the basis for a patent listing. *See* 21 C.F.R. § 314.53(f) (2003) (allowing an NDA holder to "withdraw[]" or "amend[]" its patent information in response to a request from the FDA).

At the same time, de-listing relief may have a substantial impact beyond the parties to the

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[70] The court held that a declaratory relief action to "de-list" is unavailable under the patent laws because an improper patent listing is not a defense to patent infringement. *See Mylan Pharms., Inc.*, 268 F.3d at 1325, 1330.

[71] Invalid patents, like expired patents, may not be used prospectively to enjoin competition. *See, e.g., Bull v. Logetronics, Inc.*, 323 F. Supp. 115, 129 (E.D. Va. 1971) ("All the ideas of an expired or invalid patent are dedicated to the public."). Neither patent claims that have been held invalid, nor expired patent claims in an otherwise unlistable patent, were intended to preclude generic entry under Hatch-Waxman. *See* 21 U.S.C. § 355(j)(2)(A)(viii).

[72] *See* discussion *supra* p.6, note 15.

case. If the FDA de-lists the patent from the Orange Book, it removes a barrier to entry that affects any manufacturer that is considering seeking approval to produce a generic version of the listed drug. This relief is wholly consistent with a judgment of patent invalidity, which itself has broad preclusive effect.[73]

IV. CONCLUSION

For the foregoing reasons, the Federal Trade Commission respectfully urges the Court to grant its request to be heard as an *amicus* and to consider whether a limited de-listing remedy is necessary to enforce its partial summary judgment of invalidity.

Respectfully submitted,

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[73] *See* discussion *supra*, note 56 (collecting cases).