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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 *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,<sup>1</sup> through, *inter alia*, empirical analyses of competition in the pharmaceutical industry. The Commission has also conducted numerous studies and reports on the pharmaceutical industry, including the following:

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<sup>1</sup> 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.<sup>2</sup> 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

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<sup>2</sup> 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>>.

<sup>3</sup> 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."<sup>4</sup>

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.<sup>5</sup> In addition, Commission staff have conducted empirical analyses of

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<sup>4</sup> 15 U.S.C. § 45(a)(1) (2002).

<sup>5</sup> *See supra* note 3.

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<sup>6</sup> 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>>.

<sup>7</sup> Prepared Statement of the Federal w3h

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.<sup>11</sup>

Finally, the Commission has filed *amicus* briefs in Hatch-Waxman litigation pending in district courts. Most recently, the Commission filed an *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.<sup>12</sup>

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

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<sup>11</sup> 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).

<sup>12</sup> *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>>.

<sup>13</sup> 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.").



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<sup>20</sup> *Id.* at § 355(j)(2)(A)(vii)(IV).

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

<sup>22</sup> *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 <

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<sup>26</sup> 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 *aiPharma Inc. v. Thompson*, 296 F.3d 227, 238-39 (4th Cir. 2002); *Andrx Pharms., Inc. v. Biovail Corp.*

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<sup>31</sup> *See id.*

<sup>32</sup> *See id.*

<sup>33</sup> Congressional Budget Office Study at 33, table 5.

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at xiii, 13.

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

<sup>37</sup> *See* GlaxoSmithKline, *Pharmaceutical Sales - Nine Months Ended 30<sup>th</sup> September 2002*, available at

additional applicant has filed a “paper” NDA for a generic version of the drug.<sup>39</sup> The bulk of these applicants have been subject to a stay based on SmithKline’s listings of either the ‘233 or ‘944 patents.<sup>40</sup> Further, according to Apotex, the stays based on these two listings are the only stays barring the FDA’s final approval of its ANDA.<sup>41</sup> 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.<sup>42</sup> 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

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<sup>39</sup> 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.”).

<sup>40</sup> 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).

<sup>41</sup> See Torpharm’s Cross Motion for Entry of an Amended Order at 3-4; see 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.

<sup>42</sup> 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.<sup>43</sup> 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.<sup>44</sup>

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.<sup>45</sup> 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.)<sup>46</sup>

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.<sup>47</sup> First, before 1998, only one case involving a "blockbuster" drug alleged infringement of as many as

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<sup>43</sup> *Id.* at 3.

<sup>44</sup> *Id.* at 10.

<sup>45</sup> *Id.* at iv.

<sup>46</sup> *Id.* at 39.

<sup>47</sup> *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.<sup>48</sup>

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.<sup>49</sup>

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.”<sup>50</sup> The Study further noted:

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<sup>48</sup> *Id.* at 39-40.

<sup>49</sup> *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.

<sup>50</sup> 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.<sup>51</sup>

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.<sup>52</sup> 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.<sup>53</sup> 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.<sup>54</sup> 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.)<sup>55</sup>

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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<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at 51.

<sup>53</sup> *Id.*

<sup>54</sup> *Id.* at 52, Figure 4-1.

<sup>55</sup> *Id.* at 51, n.23.



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.<sup>58</sup> 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.<sup>59</sup> In 1995, two manufacturers, Novopharm and Geneva, each filed an ANDA to produce a generic version of Abbott’s drug.<sup>60</sup> 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.<sup>61</sup> 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.<sup>62</sup> 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).<sup>63</sup>

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

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<sup>58</sup> 104 F.3d at 1305, 1309 (Fed. Cir. 1997).

<sup>59</sup> *Id.* at 1307.

<sup>60</sup> *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.

<sup>61</sup> *Id.*

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

<sup>63</sup> 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.*



to seek patent de-listing,<sup>70</sup> 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.<sup>71</sup> 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.<sup>72</sup> 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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<sup>70</sup> 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.

<sup>71</sup> 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).

<sup>72</sup> 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.<sup>73</sup>

#### 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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<sup>73</sup> See discussion *supra*, note 56 (collecting cases).