July 21, 2010

The Honorable Harry Reid
Majority Leader
United States Senate
522 Hart Senate Office Bldg
Washington, DC 20510

The Honorable Mitch McConnell
Minority Leader
United States Senate
361-A Russell Senate Office Bldg
Washington, DC 20510

Re: IPO Opposition to Amendments to the Federal Trade Commission Act in the July 1, 2010 Amendment to H.R. 4899

Dear Majority Leader Reid and Minority Leader McConnell:

The Intellectual Property Owners Association ("IPO") writes to express its opposition to an amendment to the Federal Trade Commission Act (15 U.S.C. § 44 *et seq.*) contained in H.R. 4899, an otherwise unrelated war supplemental spending bill passed by the House of Representatives on July 1, 2010.

IPO is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in intellectual property rights. IPO's membership includes more than 200 companies and more than 11,000 individuals involved in the association either through their companies or as inventors, authors, executives, or law firm members. The businesses and valuable patent rights owned by all IPO members, particularly members from the pharmaceutical industry, would be significantly impacted by this amendment if it becomes law.

The amendment, entitled the "Preserve Access to Affordable Generics Act," would add a new Section 28 to the FTC Act. In general, this amendment would presume the illegality of so-called "reverse payment" settlements of pharmaceutical patent litigation, defined broadly as any settlement in which an innovator pharmaceutical company gives something of value to a generic litigant and the generic litigant agrees not to research, develop, manufacture, market or sell a product under its Abbreviated New Drug Application ("ANDA") for a period of time.

Specifically, the amendment passed by the House[1] would create a presumption of anticompetitive effects and illegality where an ANDA filer receives anything of value (other than the right to enter the market before patent expiration or a payment of reasonable litigation expenses up to $7.5 million) and the ANDA filer agrees to limit or forgo research, development, manufacturing, marketing or sales of the ANDA product. The presumption could be rebutted only if the parties to the agreement demonstrate by clear and convincing

[1] "On motion that the House concur in the Senate amendment to the text with the second portion of the divided question [amendment 2]. Agreed to by the Yeas and Nays: 239 – 182." *See* CR H5371-5383.

evidence that the procompetitive effects of the agreement outweigh the anticompetitive effects of the agreement. The amendment would also increase the penalties for a violation of the new Section 28 by authorizing a civil penalty up to three times the value received by any party that is attributable to the violation.

By imposing such a presumption, the amendment would upset the careful balance of the Hatch-Waxman Act, which provides an expedited approval pathway for generic pharmaceutical manufacturers without undermining the innovator pharmaceutical developer's incentives to continue investment and development for life-saving and life-altering medicines. The Hatch-Waxman Act has successfully permitted legitimate questions of patent infringement to be resolved while the U.S. Food and Drug Administration is considering whether a proposed generic drug meets the bioequivalency and other safety and efficacy standards of the food and drug laws. In this way, it supports strong patent rights while giving generic companies an early opportunity to test those rights in court without risking damages.

As recognized in the Hatch-Waxman Act, our strong patent system has encouraged capital investment by innovator companies in costly and risky laboratory research and clinical trials to develop new pharmaceutical products that extend life and alleviate human suffering. A collateral effect of this continuous cycle of innovation is the eventual availability of a greater number of generic products. Without the protection of a robust patent system, pharmaceutical products can be easily copied with little investment, interrupting the cycle of new investment in research and clinical trials for the development of new drugs.

The amendment undermines pharmaceutical patents by imposing a presumption that any settlement involving a payment to the generic applicant is to protect an undeserved patent. This is a false rationale because it disregards the presumption of validity that accompanies a patent issued by the U.S. Patent and Trademark Office and ignores the unequal economic situation of the innovator company and the generic applicant. In typical patent litigations, a competing product is already out on the market, and damages can be more easily determined. In such cases, when entering into a settlement, a patent holder commonly induces the competitor with something of value, either to reduce or waive damages. In contrast, under Hatch-Waxman, the patent holder may not yet have the right to recover any damages, so the only thing of value it can offer a generic company may be cash or other assets. In a Hatch-Waxman case, the innovator company often has significant business at risk, including manufacturing plants, sales and marketing employees, and the need to use current revenue to carry out expensive clinical trials on the next generation of innovative medicines. By contrast, the generic company has nothing at risk other than the legal fees it pays in order to challenge the patent early. The Hatch-Waxman Act itself contains no restrictions on settlement of the patent litigation it engenders, permitting the parties to arrive at settlements that make business sense, subject to the limits of the patent at issue in the litigation.

The amendment also inappropriately defines "delay" of market entry by assuming that the appropriate date for market entry is the date on which the generic product is first approved by FDA. This definition completely disregards the presumed validity of the patent in suit. A

generic product's entry into the market is not "delayed" if the reason it cannot enter is because it would infringe a patent. The Hatch-Waxman Act carefully respects the presumption of validity by providing for injunctions, damages for commercial infringement, and an extension of the approval date of the infringing generic ANDA product.[2]

IPO opposes the proposed amendment because current antitrust law, which makes illegal any agreement "in restraint of trade" is adequate to challenge anticompetitive settlement agreements. The amendment would undermine legitimate, valuable patent rights by presuming, incorrectly, that a patent's lawful right to exclude is suspect when exercised to stop infringement of patents covering pharmaceutical products. IPO believes that the courts should be trusted to protect competition against the improper expansion of a patentee's lawful monopoly as a result of a settlement by applying existing antitrust case law to the specific facts relating to a challenged settlement. If a settlement gives the patent holder a broader market exclusion than it is entitled to under patent law, judicial decisions suggest that a reverse payment settlement will be ruled unlawful. The Second Circuit Court of Appeals is currently considering a petition it invited to consider this issue *en banc*,[3] showing that the courts are fully capable of addressing this issue without legislative intervention.

The presumption of illegality in the amendment runs counter to the statutory presumption of validity that attaches to issued U.S. patents. The amendment shifts the evidentiary burden from the government's having to prove conduct "in restraint of trade" to the defendants' having to prove the procompetitive effects of their settlement by *clear and convincing evidence*. Even competitively neutral agreements are deemed illegal in this amendment. This presumption of illegality is inappropriate, as courts have consistently found that such settlements are lawful under existing antitrust law when they fall within the scope of the patent's right to exclude.[4] The amendment's new burdens diminish patent rights by placing a clear and convincing evidentiary burden on the patentee to persuade the fact finder of the patent's validity and its power to exclude competition by infringing products. This provision is inconsistent with the patent statute, which expressly provides that that a patent is presumed to be valid and that the burden to prove patent invalidity rests with the party asserting invalidity.[5]

IPO believes that the likely result of the amendment will be a reduction in potentially beneficial settlements that provide for certain generic product launches before the expiration of the litigated patent, as well as potentially higher generic drug prices. By broadly attacking any settlement that includes transfer of "anything of value," the amendment would prevent standard settlement negotiating strategies, such as entering into a "side deal" for fair value to bridge the gap in the parties' positions. The amendment's approach of adopting a presumption that any such settlement is illegal will make entering into such settlements

[2] 35 U.S.C. § 271(e)(4)(C).
[3] *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 604 F.3d 98 (2d Cir. 2010).
[4] *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 604 F.3d 98 (2d Cir. 2010); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005), *as amended*, 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 127 S. Ct. 3001 (2007).
[5] 35 U.S.C. § 282.

impractical. If faced with the increased risk of losing an FTC enforcement proceeding, an ANDA filer may choose to litigate a case to judgment and risk losing on the merits. If a generic company cannot settle a lawsuit it has provoked by filing an ANDA and challenging the patents covering a drug product, it may choose not to bring a challenge in the first instance. Once embroiled in complex and expensive litigation, the generic company's cost of bringing its product to market continues to mount, and these costs may be passed on to the consumer. Imposing harsh disincentives to settlement will bog down the courts with complex and protracted litigation that is expensive for the litigants and increases the cost of bringing products to market. Voluntary resolution of complex litigation should be encouraged, not discouraged.

At least two widely publicized settlements (or proposed settlements) demonstrate that settlement agreements discouraged by the amendment are procompetitive, because they may provide market entry of a generic before the generic company would otherwise have been able to enter, that is, at the expiration of a valid and enforceable patent. The settlement in the Tamoxifen patent litigation permitted the generic company to market an authorized generic version of tamoxifen citrate nearly ten years before expiration of the patent and other exclusivities.[6] That patent was later upheld as valid.[7] Absent the settlement, the generic entry would have been precluded for ten additional years.[8] In the case of a proposed 2006 settlement between Bristol-Myers Squibb and Sanofi-Aventis with Apotex, relating to litigation regarding a patent covering Plavix, a proposed settlement would have included a payment to Apotex and permitted Apotex to enter the market eight months before patent expiration.[9] The FTC and state attorneys general rejected the proposed deal and it was never consummated.[10] The patent at issue was ultimately found to be valid.[11] Consequently, the launch of a generic version of Plavix must wait until expiration of the patent at issue in

[6] *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005), *as amended*, 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 127 S. Ct. 3001 (2007).
[7] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006).
[8] *Id.*
[9] *See* http://www.bloomberg.com/apps/news?pid=newsarchive&sid=azIasehZ_GYI&refer=home (accessed July 17, 2010).
[10] The originally proposed agreement included BMS's promise not to launch an authorized generic. *See* http://www.ftc.gov/os/caselist/0610235/090327bristolmyerscmpt.pdf and http://www.businesswire.com/portal/site/bms/permalink/?ndmViewId=news_view&newsId=20081211006113&newsLang=en (accessed July 17, 2010). After the FTC suggested it would not approve an agreement including such a promise, a revised settlement was submitted. This revised settlement was investigated by the U.S. Department of Justice after Apotex suggested that BMS had orally promised not to launch an authorized generic. BMS settled this investigation by entering a guilty plea and paying a fine. *See* http://www.businesswire.com/portal/site/bms/permalink/?ndmViewId=news_view&newsId=20081211006243&newsLang=en (accessed July 17, 2010). BMS also paid a fine to the FTC for failing to disclose all of the terms of its revised settlement with Apotex. *See* http://www.ftc.gov/opa/2009/03/bmsplavix.shtm (accessed July 17, 2010). These investigations occurred after the original proposed settlement was rejected by the FTC and other regulators, and are not relevant to the point made here, that if the settlement had been approved, it would have led to a launch of generic Plavix well before patent expiration.
[11] *Sanofi-Synthelabo v. Apotex Inc.*, No. 02 Civ. 2255 (S.D.N.Y. June 19, 2007), *aff'd*, 550 F.3d 1075, 1087-1090 (Fed. Cir. 2008).

November 2011, depriving consumers of a generic version of one of the most widely prescribed drugs in history for months longer than the original settlement would have allowed.

The amendment's expected savings are not supported by solid evidence and analysis. The Congressional Budget Office estimate of savings cited by Appropriations Committee Chairman David Obey (D-WI) relies on outdated and uninformative FTC statistics about the "typical" outcomes of ANDA patent litigation. Based on information from FTC, CBO assumes in its January 2010 estimate of the savings from S.369, a substantively identical bill, that the amendment would accelerate the entry of generic drugs affected by the bill by roughly 17 months, on average. (The CBO's updated June 16, 2010, estimate relies on the same methodology.) The CBO goes on to reduce the expected savings to account for fewer generic patent challenges, but it does not take into account the additional spending that would be required for drugs where generic entry is delayed beyond a date that would have been agreed to in a settlement, that is not consummated because of the risk created by the newly authorized FTC enforcement and penalties. The CBO analysis suffers from the same fundamental flaw as the amendment: it denies the procompetitive effects that necessarily flow from a settlement that allows generic entry earlier than patent expiration.

The FTC already has broad powers to monitor Hatch-Waxman settlement agreements and to take action to enforce its powers to protect competition and consumers. The Medicare Modernization Act of 2003 requires drug companies to file settlement agreements with the FTC and U.S. Department of Justice. Section 5 of the FTC Act empowers the FTC to bring enforcement actions to stop unfair methods of competition and deceptive commercial practices. The FTC is empowered to hold a hearing, and then issue a report and a cease and desist order. The FTC may seek monetary redress if the designated misconduct persists. The amendment would drastically augment these powers and also prohibitively increase the potential penalty for a finding of illegality.

For these reasons, IPO is strongly opposed to the amendment to the Federal Trade Commission Act (15 U.S.C. § 44 *et seq.*) contained in H.R. 4899 and appreciates your consideration of its members' interests in connection with this important issue.

Sincerely,

Herbert C. Wamsley
Executive Director, IPO

cc: Senate Appropriations Chairman Inouye, Senate Appropriations Vice Chairman Cochran, Senate Judiciary Chairman Leahy, Senate Judiciary Ranking Member Sessions
--