IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA ("PhRMA"), 950 F Street, NW Suite 300 Washington, DC 20004, Plaintiff, v. Federal Trade Commission ("FTC"), 600 Pennsylvania Avenue, NW Washington, DC 20580, Defendant.	Case No. _____ COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA"), by and through undersigned counsel, files this Complaint for Declaratory and Injunctive Relief against Defendant Federal Trade Commission ("FTC" or "Commission"), alleging as follows:

NATURE OF THE ACTION

1. This is a lawsuit under the Administrative Procedure Act ("APA"), 5 U.S.C. § 500 et seq.

certain value. As part of that notification, parties to such a transaction are required to provide extensive information about their businesses and the assets being transferred, and cannot consummate the transaction until the appropriate antitrust agency reviews it. Because review of a proposed acquisition is frequently a lengthy process, companies incur significant expense, uncertainty, and delay before consummating a transaction covered by the Act.

2. Transactions in which a patent holder licenses a patent but retains manufacturing rights have never been considered "asset acquisitions" that trigger the HSR Act's filing and reporting obligations. The proposed Rule changes the meaning of "asset acquisition" for a single industry, the pharmaceutical industry, and would now require pharmaceutical companies to file and report licensing transactions in which the licensor retains the right to manufacture or other co-rights that the Rule deems "commercially significant." As a result, the new Rule will treat transactions involving the pharmaceutical industry differently from those in every other industry and every other sector.

3. The proposed Rule is both contrary to the plain language of the statute and unsupported by record or fact. First, the HSR Act does not permit the Commission to issue a rule that expands the scope or coverage of the Act to a specific industry or set of industries. The plain language of the statute mandates that the Act's notification burdens affect every "person"—that is, every industry—equally. In addition to the plain language of the statute, the Act's substantial legislative history confirms that Congress specifically chose not to vest the Commission with the authority to promulgate rules that impose notification requirements on a single industry or group of industries. Indeed, the final Act deleted a Senate proposal that would have specifically granted that authority to the Commission. Instead, Congress gave the Commission only the right to exempt certain classes of persons from the Act's otherwise

generally applicable requirements. It thus specifically fails to grant the Commission the authority to do what the Commission has purported to do here.

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its own knowledge and experience, in support of the Rule. Thus, under the plain language of the statute as well as the plain requirements of the APA, the proposed Rule must fail.

JURISDICTION AND VENUE

6. This Court has jurisdiction under 28 U.S.C. § 1331 because this action arises under the HSR Act and the APA.

7. Venue is proper in this Court under 28 U.S.C. § 1391(e)(1)(C) because this is an action against an agency of the United States that resides in this judicial district, plaintiff also resides in this judicial district, and a substantial part of the events and omissions giving rise to this action occurred in this judicial district.

8. This Court can grant declaratory relief under 28 U.S.C. § 2201, provide injunctive relief under 28 U.S.C. § 2202, and "shall hold unlawful and set aside agency actions, findings, and conclusions found to be (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; . . . (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, [or] (D) without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (C), and (D).

PARTIES

9. Plaintiff is a trade association headquartered in Washington, DC.

10. Plaintiff represents the country's leading biopharmaceutical researchers and biotechnology companies. Its members are: AbbVie; Alkermes plc.; Amgen Inc.; Arena Pharmaceuticals, Inc.; Astellas Pharma US, Inc.; AstraZeneca Pharmaceuticals LP; Auxilium Pharmaceuticals, Inc.; Bayer HealthCare LLC; Biogen Idec Inc.; BioMarin Pharmaceuticals, Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Bristol-Myers Squibb Company; Celgene Corporation; CSL Behring, L.L.C.; Cubist Pharmaceuticals, Inc.; Daiichi Sankyo, Inc.; Dendreon

Corporation; Eisai Inc.; Eli Lilly and Company; EMD Serono; Ferring Pharmaceuticals, Inc. GlaxoSmithKline; Grifols USA, LLC; Horizon Pharma, Inc.; Ikaria, Inc.; Ipsen Biopharmaceuticals, Inc.; Johnson & Johnson; Lundbeck Inc.; Merck & Co., Inc.; Merck Human Health Division - U.S. Human Health; Merck Research Laboratories; Merck Vaccine Division; Novartis Pharmaceuticals Corporation; Novo Nordisk, Inc.; ONYX Pharmaceuticals, Inc.; Orexigen Therapeutics, Inc.; Otsuka America Pharmaceutical, Inc. (OAPI); Otsuka America Pharmaceuticals (OAP); Otsuka Maryland Medicinal Laboratories (OMML); Otsuka Pharmaceuticals Development & Commercialization, Inc. (OPDC); Pfizer Inc.; Purdue Pharma L.P.; Sanofi; Sanofi Pasteur; Shionogi Inc.; Sigma-Tau Pharmaceuticals, Inc.; Sucampo Pharmaceuticals, Inc.; Sunovion Pharmaceuticals Inc.; Takeda Pharmaceuticals U.S.A., Inc.

Industry Group 3254 [the code for "Pharmaceutical and Medicine Manufacturing"]. " 16 C.F.R. § 801.2(g)(1).

15. Plaintiff's members have standing to sue in their own right, because they will suffer injury-in-fact that is actual and imminent, and concrete and particularized, which injury is directly caused by the Rule and will be redressed by a favorable decision in this case.

16. Defendant FTC is an independent federal agency responsible for administering the HSR ACT and subject to the APA. See 5 U.S.C. § 551(1); 15 U.S.C. § 41. Its headquarters are located at 600 Pennsylvania Avenue, NW, Washington, DC.

17. Because this is "an action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority," the federal government's sovereign immunity does not preclude this suit. 5 U.S.C. § 702.

THE HSR ACT

18. In 1976, Congress enacted the HSR Act, which amended the Clayton Act, 15 U.S.C. § 12 et seq., to assist the FTC and Justice Department in discerning anticompetitive mergers or acquisitions, and specifically to "give[] the government antitrust agencies a fair and reasonable opportunity to detect and investigate large mergers of questionable legality before they are consummated." H. Rep., No. 94-1373 at 5.

19. Congress viewed this pre-consummation review as necessary to allow the agencies a "meaningful chance to win a premerger injunction—which is often the only effective and realistic remedy against large, illegal mergers." Id.

20. Congress aimed the Act at mergers in which "[t]he independent identity of the acquired firm disappears" because it was concerned that "restoring the acquired firm to its

27. The Act requires the FTC to issue rules, following the APA's notice-and-comment procedures, for the limited purpose of ensuring that a required notification is "in such

THE RULEMAKING

The FTC's Notice of Proposed Rulemaking

31. On August 20 2012, the FTC published a "Notice of Proposed Rulemaking Regarding Certain Licensing Transactions in the Pharmaceutical Industry." 77 FED. REG. 50,057-62 (Aug. 20, 2012) ("NPR") (Appendix A).

32. The NPR proposed significant changes to the HSR Act premerger notification requirements that would, for the first time in the history of the Act, single out and burden one industry with additional notification requirements.

33. Specifically, the FTC proposed amending 16 C.F.R. § 801.2 (which provides the coverage rules for "acquiring]TJ -287-10(a)4(c)4(qui)-2(r)-7(e)4(d pe)4(r)3(s)-1(ohe)4()5(o)2(r)5( )5(o)

terms used in the Act and regulations) to add entirely new definitions for terms Congress did not include in the HSR Act: "all commercially significant rights," "limited manufacturing rights," and "co-rights."

36. The fact that these new terms apply only to the pharmaceutical sector is made clear by both the explicit cross-reference to 16 C.F.R. § 801.2(g) and the repeated references to "therapeutic areas" and "specific indications."

37. The effect of these modifications is to expand the scope of HSR reporting obligations to include those licensing transactions in the pharmaceutical industry in which the licensor has retained manufacturing rights or co-development, co-promotion, co-marketing, or co-commercialization rights. Under the proposed Rule, identical transactions in other industries remain exempt from the HSR Act's reporting obligations.

38. While this Rule singles out the pharmaceutical industry for special treatment, the FTC acknowledged that these types of licenses were used in other industries, see id. at 50,059 (advising "[p]arties dealing with exclusive rights to a patent in other industries [to] consult PNO staff"), but asserted that these pharmaceutical license agreements were, "in the PNO's experience, unlike that seen in any other industry." The FTC suggested that this was due to what it perceived as "unique incentives for the use of exclusive licenses" in the pharmaceutical industry. Id.

39. The FTC acknowledged that it had no actual knowledge of these types of licensing agreements in the pharmaceutical industry or any other industry because these licenses

seeking informal guidance from the PNO on “exclusive licenses in the pharmaceutical industry.” Id.

40. The NPR did not quantify the number or frequency of these requests for informal guidance or the actual use of these types of licenses in the pharmaceutical or any other industry.

41.

contravened the anti-discrimination principles that U.S. antitrust agencies have long advocated; and

(iii) the Rule would result in a material increase in the number of HSR filings from pharmaceutical companies, with substantial associated expense, uncertainty, and transaction delay.

45.

the HSR Act and violate the APA because the NPR lacked a reasoned explanation or factual basis as to why the targeted transactions are anticompetitive, and the record included no empirical study or other basis demonstrating the proposed Rule's utility. Thus, the Rule would discriminate against the pharmaceutical industry without justification or explanation.

The FTC's Final Rule

50. A full six months after publication of its NPR, the FTC issued the final Rule on November 6, 2013. It was in all material respects no different from the proposed Rule and was published in the Federal Register on November 15, 2013. 78 FED. REG. 68,705–13. (Appendix D.) The final Rule becomes effective on December 16, 2013. *Id.* at 68,705.

51. The Rule is limited to the pharmaceutical industry. *Id.* at 68,706. It targets pharmaceutical companies with additional notification burdens when they enter into patent licensing transactions that grant the licensee a right to use and commercialize a patent in a specific therapeutic area or for a specific indication within a therapeutic area, but allow the patent holder to retain the right to manufacture the patented product, or to conduct a wide range of development and commercialization activities ("rights") for the product in the licensed therapeutic area. *Id.* at 68,710.

52. The FTC acknowledged that licenses with retained manufacturing rights had never been reportable "under PNO staff's prior approach." *Id.*

53. The Statement of Basis and Purpose accompanying the final Rule addressed Plaintiff's comments only summarily, simply asserting that the Commission's view was that the Rule was an appropriate exercise of its rulemaking authority and that it had complied with the APA.

54. The Commission claimed in the Statement of Basis and Purpose that the Rule was

61. Its sole response was to assert that the thousands of licenses studied by Dr. Varner "are not the kinds of exclusive patent licenses covered by the final rule." Id. at 68,709 n.21.

62. Finally, notwithstanding that the Commission states that it has "received filings for 66 transactions involving exclusive patent licenses . . . for pharmaceutical patents" in the past five years, the FTC does not identify even a single license of this type that has been challenged or unwound because of a substantial likelihood that it was anticompetitive. Id. at 68,708.

THE HSR ACT DOES NOT PERMIT THE FTC TO EXPAND THE SCOPE OF HSR REPORTING REQUIREMENTS TO A SPECIFIC INDUSTRY OR SPECIFIC INDUSTRIES

63. The HSR Act is a statute of general applicability. Its notification requirements apply equally to every "person" who participates in an acquisition meeting the Act's thresholds unless that acquisition is specifically exempted in subsection (c). See 15 U.S.C. § 18a(a) ("Except as exempted pursuant to subsection (c) of this section, no person shall acquire, directly or indirectly, any voting securities or assets of any other person . . . .") (emphases added).

64. The plain text of the HSR Act does not grant the FTC the power to expand reporting obligations to a specific "person" or group of "persons." Principles of statutory interpretation hold that absent explicit congressional authorization, statutes of general application may not be applied selectively to a limited class or limited classes of persons. In addition, statutes must be strictly construed when they, like the HSR Act, impose substantial penalties for noncompliance.

65. Congress expressly limited the FTC's authority under the HSR Act to four specific powers: (1) ensuring that notifications are in the appropriate form; (2) defining the Act's terms; (3) exempting from the Act classes of persons or transactions that are unlikely to violate the antitrust laws; and (4) prescribing other rules that are "necessary and appropriate" to ensure that the FTC and Justice Department can review in advance potentially unlawful acquisitions that

are the most difficult to unscramble. In no respect did Congress grant the FTC the authority to expand the scope or coverage of the HSR Act selectively to a single "person" or group of "persons."

66. Where Congress has expressed its intention on the precise question at issue, the agency's rulemaking authority cannot be used in a manner inconsistent with that intention. For example, an agency cannot "use its definitional authority to expand its own" role under the underlying statute. Am. Bankers Ass'n v. SEC, 804 F.2d 739, 755 (D.C. Cir. 1995).

67. The Act's legislative history confirms that Congress intended for the notification burdens to apply equally to every "person" unless Congress or the FTC explicitly granted an exemption from coverage. During debate over the Act, the Senate proposed a provision that would have specifically permitted the FTC to impose additional or special reporting requirements selectively for certain "persons" or industries. Congress specifically considered

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found across numerous non-pharmaceutical industries, including the chemical, electronics, and medical device industries. His analysis also concluded that the incentives for such transactions in the pharmaceutical industry are found across numerous other industries.

73. The FTC did not include any sworn statement, study, or other empirical basis to contradict Dr. Varner's findings. The FTC did not refer to any studies quantifying the need to impose a notification requirement for the types of pharmaceutical licenses it targets. It did not refer to any studies quantifying the prevalence of these types of licenses in the pharmaceutical industry compared to other industries. It did not refer to any studies quantifying even a single case of an anticompetitive license of this type, or to any studies demonstrating that such licenses could not be unwound after the fact.

74. Instead, the FTC simply asserted, without any supporting expert evidence or quantification, that these types of licenses were prevalent in the pharmaceutical industry and n ot in other industries.

75. Additionally, the FTC provided no reasoned explanation for why the targeted licenses now warrant premerger notification when they were non-reportable throughout the prior 37-year history of the HSR Act. Along with the final Rule, the FTC offered no factual support or evidentiary basis that even remotely suggests that these types of licenses are potentially anticompetitive when used in the pharmaceutical industry, but not when they are used in other industries.

76. The FTC's rulemaking did not contain an empirical basis for the Rule's necessity. Instead, the FTC simply relied on conclusory references to the "experience" and "knowledge" of its PNO. The FTC stated that (i) in "the PNO's experience, the pharmaceutical industry is the only industry in which parties regularly enter into exclusive patent licenses that transfer all

commercially significant rights," (ii) that "it is the only industry to the PNO's knowledge in which exclusive patent licenses are prevalent," and (iii) that "requests for guidance on the treatment of exclusive patent licensing arrangements have nearly always come from practitioners in the pharmaceutical industry." 78 FED. REG. 68,708-09 (emphases added).

77. Notably, however, the FTC's rulemaking repeatedly qualified the PNO's "experience," hedging that "requests for guidance on the treatment of exclusive patent licensing transactions have generally been limited to the pharmaceutical industry," "the PNO typically does not see exclusive transfers of rights to a patent or part of a patent outside the pharmaceutical context," and "the PNO has found that exclusive patent licensing agreements that transfer all of the rights to commercially use a patent or part of a patent almost solely occur in the pharmaceutical industry." *Id.* at 68,708 (emphases added). The FTC included in the public record no factual findings or analysis explaining its repeated qualifications of its "experience."

78. Nor did the FTC respond to Plaintiff's comment that the Rule is contrary to the principles of non-discrimination that U.S. antitrust agencies have espoused before significant policymaking bodies abroad. See, e.g., APEC-OECD Integrated Checklist on Regulatory

80. Plaintiff's members enter into numerous licensing arrangements each year, with almost infinite variation in terms, and it is overwhelmingly likely that the Rule will cover many more than 30 of their licenses, at a substantially higher cost to Plaintiff's members.

81. Moreover, the Rule will increase delays, risks, and expense not only for the dozens and dozens of HSR filings the Commission estimates its Rule will demand, but also for the many additional licenses that will require legal and economic analysis to determine whether they fall within the Rule.

82. Even on the FTC's estimate of 30 additional filings, however, the additional expenses Plaintiff's members will bear will be substantial. All HSR filings require a filing fee; the amount depends on the fair market value of the transaction, as determined by the y6(le)-4(e)6(q)2

analyses, and thus in all likelihood more precise valuations. Id. At a minimum, 30 additional notifications would mean 60 separate filings, and would thus burden Plaintiff's members with additional expenses that range from an average of roughly $3,000,000 (60 forms at $50,000

discovery and advancement of life-saving and life-enhancing new medicines by pharmaceutical and biotechnology research companies, including strong intellectual property incentives for new medicines and transparent, effective regulation. The Rule is counter to the effective creation and commercialization of new medicines and, by needlessly imposing additional and significant

limited to granting exemptions from the Act to "classes of persons" that "are not likely to violate the antitrust laws." 15 U.S.C. § 18a(d)(2)(A).

92. The Commission's failure to identify even a single patent license of the type now targeted by the Rule that has been challenged or unwound as potentially anticompetitive by the FTC or Justice Department demonstrates that the Rule is not "necessary and appropriate" under 15 U.S.C. § 18a(d)(2)(C).

93.

98. The FTC failed to examine the relevant data and articulate a satisfactory explanation for the Rule. The explanations it offered are conclusory, unsupported, and manifestly insufficient.

99. In addition, the Commission failed to adequately respond to significant comments in the record, and offered no empirical basis to controvert the declaration of Dr. Thomas Varner, an economist who studied the use of intellectual property licenses and found that the arrangements the FTC's Rule targets are prevalent in the chemical, electronics, and medical device industries.

100. Adoption of the Rule was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law. Plaintiff is therefore entitled to relief under 5 U.S.C. §§ 702 and 706(2)(A).

COUNT THREE:

The rulemaking was without observance of procedure required by law

101. Plaintiff incorporates by reference the allegations of the preceding paragraphs.

102. A reviewing court "shall hold unlawful and set aside agency action, findings, and conclusions found to be without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

103. When an agency promulgates a rule, it "shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." 5 U.S.C. § 553(c). This requirement compels an agency to set forth in a Notice of Proposed Rulemaking the most critical factual material and reasoning on which it relied to formulate proposed regulations.

104. The Notice of Proposed Rulemaking did not fairly apprise the public of the basis and rationale for the Rule. Among other things, it provided no sufficient rationale for its

decision to limit the Rule to the pharmaceutical industry. In addition, it failed to articulate any factual basis, other than generalized allusions to the FTC's "experience," for singling out the pharmaceutical industry. Those generalized references to the FTC's "experience" were repeatedly and highly qualified, and concede that these types of licenses are, in fact, employed in many industries in addition to the pharmaceutical industry.

105. The Notice of Proposed Rulemaking also failed to provide fair notice of various aspects of the Rule. The FTC's suggestion that the Rule "may" apply to other industries, without establishing any relevant regulatory provisions for those industries, effectively deprived the public of its ability to comment on the Rule, as commenters were unable to make crucial determinations regarding the actual operation and effect of the proposed regulatory regime.

106. Plaintiff is therefore entitled to relief under 5 U.S.C. §§ 702 and 706(2)(D).

COUNT FOUR:

Declaratory Judgment

107. Plaintiff incorporates by reference the allegations of the previous paragraphs.

108. As demonstrated by the foregoing allegations, there is an actual controversy of sufficient immediacy and concreteness relating to the legal rights and duties of Plaintiff's members to warrant relief under 28 U.S.C. § 2201.

109. The harm to Plaintiff's members as a direct and indirect result of the FTC's conduct is sufficiently real and imminent to warrant the issuance of a conclusive declaratory judgment clarifying the legal relations of the parties.

PRAYER FOR RELIEF

WHEREFORE, Plai

2. Vacate and set aside the Rule;

3. Permanently enjoin and restrain the FTC and its officers, agents, employees, and successors, and all persons acting in concert or participating with the FTC from enforcing, applying, or implementing (or requiring others to enforce, apply, or implement) the Rule;

4. Award Plaintiff its costs of litigation, including reasonable attorneys' fees, pursuant to 28 U.S.C. § 2412; and

5. Grant Plaintiff such other relief as the Court deems just and proper.

Dated: December 12, 2013

Respectfully submitted,

/s/ Joseph A. Ostoyich

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