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.*, challenging as unauthorized agency action a Rule recently promulgated by the FTC. 78 FED. REG. 68,705. The Rule was issued under the Hart Scott Rodino Antitrust Improvements Act, 15 U.S.C. § 18a ("HSR Act" or "Act"), which requires that all persons meeting certain size thresholds provide the FTC and Department of Justice ("Justice Department") advance notification before consummating certain asset acquisitions above a

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 refused* to grant the Commission the authority to do what the Commission has purported to do here.

4. Second, the Rule is defective because it fails to comply with the APA. Among other APA problems with the proposed Rule is that it is arbitrary and capricious because the Commission provided no reasoned, data-driven basis for treating the pharmaceutical industry differently from other industries with regard to reporting these intellectual property licensing transactions. The Commission recognizes that the licenses the Rule targets are not limited to the pharmaceutical industry, but claims that they are "prevalent" and "*almost* solely occur in the pharmaceutical industry," according to the "knowledge" and "experience" of its Premerger Notification Office ("PNO"). 78 FED. REG. 68,708 (emphasis added). The Commission failed, however, to identify specific facts supporting the PNO's claimed knowledge and experience, and instead provided only vague generalities: that unidentified "[p]ractitioners who represent clients in the pharmaceutical industry have *often* sought guidance" from the PNO on the reportability of such licenses, and that the PNO's guidance has thus "*generally* been limited to the pharmaceutical industry." *Id.* Confronted with a sworn economic study, submitted by Plaintiff during the notice and comment period, that included empirical evidence and analysis conclusively demonstrating that these types of licenses are, in fact, common in the technology industry and many other industries, the FTC simply asserted, with no study at all, that "these are not the kinds of exclusive patent licenses covered by the final rule." *Id.* at 68,709 n.21. This is plainly insufficient under the requirements of the APA.

5. Consequently, not only does the Commission lack the statutory authority to single out the pharmaceutical industry for special treatment under the HSR Act, the Commission has failed to provide any reasoned articulation, apart from a generalized and non-specific reliance on

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)(A)-(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.; Theravance, Inc.; Vifor Pharma; Vivus, Inc.; and Xoma Ltd.

11. Plaintiff's members collectively employ more than 650,000 Americans working to develop new medicines that help patients fight disease and live longer, healthier lives.

12. One of Plaintiff's important responsibilities is representing the interests of its members in public policy advocacy and regulatory matters, including matters relevant to the Rule, before the courts, Congress, the Executive Branch, and independent regulatory agencies of the federal government.

13. Plaintiff has associational standing because (i) its members would otherwise have standing to sue in their own right; (ii) the interests it seeks to protect are germane to the organization's purpose; and (iii) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.

14. Plaintiff's members are the direct targets of the Rule, which "applies only to patents covering products whose manufacture and sale would generate revenues in NAICS

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

former status as an independent competitor is difficult at best, and frequently impossible." *Id.* at 8.

21. The HSR Act thus requires pre-closing notification to the FTC and Justice Department for only those types of transactions that "are the most likely to 'substantially lessen competition' [and] are by far the most difficult to unscramble." *Id.* at 11.

22. The HSR Act establishes the federal premerger notification program, which the FTC and Justice Department jointly administer.

23. Under that program, parties proposing certain merger or acquisition transactions must submit premerger filings to the PNO. The parties must not consummate the proposed transaction before the end of the 30-day waiting period specified in the Act, unless the government grants early termination of that period.

24. The FTC or Justice Department may request more information at the end of that 30-day period and thus extend the time during which the parties are prohibited from closing their merger or acquisition. Compliance with this "second request" typically requires the parties to gather, review, analyze, and produce to the government a significant number of electronic and hard copy documents, nearly always with the assistance of numerous lawyers and economists.

25. The HSR Act explicitly applies to every "person" undertaking to participate in a merger or acquisition that meets the Act's threshold requirements unless the Act itself or the FTC grants a specific exemption. 15 U.S.C. § 18a.

26. The Act specifies the transactions that are subject to premerger notification. 15 U.S.C. § 18a(a). Most mergers and acquisitions valued at more than $70.9 million (subject to annual adjustment, 15 U.S.C. § 18a(a)(2)) must be reported under the Act.

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 form and contain[s] such documentary material and information" as is "necessary and appropriate" to enable the FTC and Justice Department to determine whether that acquisition may, if consummated, violate the antitrust laws. 15 U.S.C. § 18a(d).

28. The Act also permits, but does not require, the FTC to promulgate rules, in compliance with the APA's notice-and-comment procedures, for other specified purposes. Thus, it may:

"(A) define the terms used in this section;

(B) exempt, from the requirements of this section, classes of persons, acquisitions, transfers, or transactions which are not likely to violate the antitrust laws; and

(C) prescribe such other rules as may be necessary and appropriate to carry out the purposes of this section." *Id.*

29. An effort in the Senate to authorize the FTC, in consultation with the Justice Department, "to require pre-merger notifications from particular companies or industries or from any class or category of persons," was deleted in the House and was not included in the conference bill that became the HSR Act. 122 CONG. REC. 29,342 (Sept. 8, 1976) (referring to S. 1284 (May 6, 1976)).

30. In explaining the decision to delete this provision from the House bill and the HSR Act, Representative Peter W. Rodino (one of the Act's sponsors as well as the then-Chairman of the House Judiciary Committee), stated that "[i]n the view of the House conferees, the coverage of this the coverage of this bill should be decided by Congress—not the FTC and the Justice Department." 122 CONG. REC. 30,877 (1976).

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 and acquired persons" under the Act) to extend the HSR Act's coverage to those "persons" engaged in the transfer of certain patent rights in the pharmaceutical sector.

34. This proposed new Rule stated: "(1) This paragraph applies only to patents covering products whose manufacture and sale would generate revenues in NAICS Industry Group 3254 [the codes involving the pharmaceutical industry]; (2) The transfer of patent rights covered by this paragraph constitutes an asset acquisition; and (3) Patent rights are transferred if and only if all commercially significant rights to a patent, as defined [by the proposed Rule], for any therapeutic area (or specific indication within a therapeutic area) are transferred to another entity. All commercially significant rights are transferred even if the patent holder retains limited manufacturing rights, as defined [by the proposed Rule], or co-rights, as defined [by the proposed Rule]." *Id.* at 50,061.

35. To provide greater precision for this new, industry-specific meaning of "acquiring and acquired persons," the FTC further proposed amending 16 C.F.R. § 801.1 (which defines

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." *Id.* 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 had never been reportable under PNO guidance. By its own account, its "experience" was derived from conversations with unidentified "practitioners" in the pharmaceutical industry

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. Nor did the NPR offer any basis for the FTC's assertion that the unidentified practitioners seeking informal guidance sought it on behalf of pharmaceutical companies.

42. The FTC pointed to three parts of the HSR Act to support its claimed authority to issue the first-of-its kind Rule: (a) its mandate to require that notification "be in such form and contain such documentary material and information" as is "necessary and appropriate" to determine whether the proposed transaction would be unlawful, (b) its authority "to define terms used in the Act," and (c) its ability to prescribe other rules as may be "necessary and appropriate to carry out the purposes of" the Act. *Id.* at 50,058.

Plaintiff's Opposition During the Notice-and-Comment Period

43. In October 2012, Plaintiff timely filed written comments opposing the proposed Rule. (Appendix B.)

44. Plaintiff's comments raised substantial objections to the proposed Rule, including the following:

(i) the HSR Act's notification burdens apply equally to every "person" and the Act prohibits the FTC from imposing additional burdens that target only a single industry;

(ii) the FTC's proposed Rule violated the APA because it failed to provide a reasoned basis, supported by evidence, for targeting the pharmaceutical industry with additional notification burdens, and by arbitrarily and capriciously doing so

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. Plaintiff's comments noted that the FTC's claimed "experience" was insufficiently supported under the APA and that the NPR did not cite even *a single license of this type* that the FTC (or Justice Department) tried to challenge or unwind because it was anticompetitive.

46. Plaintiff attached to its comments a 20-page sworn declaration from an expert economist, Dr. Thomas Varner. Dr. Varner holds an M.B.A. from the University of California at Berkeley and a Ph.D. in Engineering-Economic Systems & Operations Research from Stanford University, and serves as Vice President at Economists Incorporated, where he specializes in economic, financial, and statistical analysis.

47. Dr. Varner's 20-page declaration summarized his analysis of thousands of licensing transactions in a wide range of industries, including the chemical, electronics, and medical device industries, and concluded that patent licenses of the sort targeted by the Rule are common in many industries and are not unique to the pharmaceutical industry.

48. In the winter and spring of 2013, Plaintiff reiterated its objections in separate meetings with each of the FTC Commissioners, as reflected in memoranda summarizing those communications. (Appendix C.)

49. In its meetings with each Commissioner, Plaintiff emphasized that the proposed Rule would, if promulgated, constitute an unauthorized expansion of the FTC's authority under

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 ("co-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 not "expanding the HSR requirements to parties or transactions not covered by the Act," but was "simply clarifying" that it now regarded those types of licenses to be reportable when licensor and licensee are members of the pharmaceutical industry. *Id.* at 68,709.

55. The FTC further claimed to have "broad authority" to issue rules to facilitate the review of large transactions, and maintained that the HSR Act did not limit that broad authority. *Id.*

56. The Statement of Basis and Purpose did not incorporate any empirical evidence demonstrating that these types of licenses were, in fact, unique to the pharmaceutical industry.

57. On the contrary, the FTC recognized that "it is possible" that these types of licenses are used in other industries and conceded that "[t]here are many kinds of exclusive licensing agreements in other industries that involve the retention of manufacturing rights." *Id.* at 68,708.

58. The FTC continued to maintain, on the strength of nothing more than the PNO staff's "experience," that the targeted transactions typically occurred in the pharmaceutical industry. *Id.*

59. Yet, by the FTC's own account, "the PNO has not processed filings related to those kinds of exclusive licenses in any other industry in the past five years," principally because its own guidance was that these types of licenses were non-reportable. *Id.*

60. Nor did the FTC provide any expert declaration or other evidence to counter Dr. Varner's declaration and evidence that these types of patent licenses are commonplace in many industries.

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 specific "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 and expressly rejected that proposal, reserving unto itself the sole authority to extend the Act's reach to specific subsets of "persons."

68. Consistent with that limitation on its authority, throughout the 37-year history of the HSR Act, the FTC has never before attempted to impose additional reporting obligations selectively on subgroups of "persons" under the Act.

THE RULEMAKING VIOLATED THE APA

The FTC's Notice of Proposed Rulemaking articulated no reasoned, empirical basis for targeting the pharmaceutical industry with additional notification burdens.

69. The FTC recognized that patent licenses with retained manufacturing rights are used in industries other than the pharmaceutical industry. The NPR provided no empirical basis or reasoned explanation for its contention that the license agreements in the pharmaceutical industry are, "in the PNO's experience, unlike that seen in any other industry." *Id.* at 50,059.

Stating only that it perceived there to be "unique incentives for the use of exclusive licenses" in the pharmaceutical industry, the FTC made no attempt to ground its alleged perception on hard facts or solid evidence. *Id.* It referred only to the PNO's "experience providing advice regarding the transfer of rights to a patent through exclusive licenses in the pharmaceutical industry," *id.*, but failed to explain how it determined "uniqueness" without any experience giving similar advice regarding exclusive licenses to companies in other industries. Also wholly unexplained is why the FTC believed it was necessary to promulgate a Rule clarifying the reporting requirements for licenses in the pharmaceutical industry alone and not in the other industries in which they are used.

70. Nor did the NPR provide any basis for the proposed Rule's disparate treatment of retained co-rights. Further, the NPR did not provide any reasoned basis for its failure to distinguish between the kinds, magnitude, scope, or other terms of the co-rights being retained for purposes of an otherwise exclusive license's reportability under the HSR Act.

In issuing the final Rule, the FTC failed to examine the relevant data and articulate a sufficient explanation.

71. Plaintiff's expert, Dr. Varner, studied a wide range of licenses in many industries, and concluded that licensing transactions in the pharmaceutical industry are functionally no different from licensing transactions in a number of other industries, that the incentives in the pharmaceutical industry are not unique, and that these types of licenses are common in many industries and not unique to the pharmaceutical industry.

72. Dr. Varner's report described his analysis of intellectual property license agreements identified by a range of companies across different industries in their Securities and Exchange Commission filings. Dr. Varner's analysis demonstrated that licensing arrangements under which the licensor retains rights to manufacture the licensed product and/or co-rights are

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 not 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 Reform at 6, available at www.oecd.org/regreform/34989455.pdf ("laws and policies should refrain from applying different requirements or procedures to different . . . goods [or] services").

THE IMPACT OF THE RULE

79. The FTC estimates that the Rule will require Plaintiff's members and others in the pharmaceutical industry to notify an additional 30 transactions to the FTC and Justice Department, at a cost of more than $1,000,000 each year. 77 FED. REG. 50,060; 78 FED. REG. 68,712.

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 filing parties. The filing fee for transactions between $70.9 million and $141.8 million is $45,000; the filing fee for transactions between $141.8 million and $709.1 million is $125,000; and the filing fee for transactions in excess of $709.1 million is $280,000. It is not unusual for notified pharmaceutical licensing transactions to incur this fee at the higher end of this range, because of the market value of these transactions. Thus, even taking the FTC's estimate of 30 additional filings, the filing fees alone will be a minimum of $1,350,000 each year and could range up to $8,400,000.

83. Furthermore, all parties incur significant costs associated with preparing the HSR notification form, which would be required from both the licensor and the licensee. The average cost of preparing the form is between $40,000 and $60,000 for each party, with a lower cost for a straightforward transaction (of roughly $15,000 to $20,000) and a higher cost for more complex transactions (often exceeding $100,000). The FTC estimates that roughly one-third (10) of the 30 additional transactions per year it believes the Rule will capture will require more complex

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 each) to $6,000,000 or more each year.

84. In addition, any transaction that receives a request by the FTC or Justice Department for more information, commonly referred to as a "second request," would likely force the companies involved to incur substantial additional fees for legal and economic analysis. The FTC's own analysis shows that 3-5% of all transactions receive second requests each year. Thus, using the FTC's estimate of 30 additional filings each year, Plaintiff and its members are likely to face several second requests as a result of the Rule. According to the ABA's most recent analysis, the average second request investigation imposes compliance costs of $5.2 million. ABA Section of Antitrust Law, *Controlling Costs of Antitrust Enforcement and Litigation* at 30 (Dec. 20, 2012), available at http://www.americanbar.org/content/dam/aba/administrative/antitrust_law/2013_ agenda_cost_efficiency_kolasky.authcheckdam.pdf.

85. In addition, because HSR–reportable transactions are subject to an initial mandatory waiting period, and the FTC has discretion to extend that period to conduct further investigation, the Rule will impose additional costs and burdens on Plaintiff's members. It will create delay and uncertainty for previously-unreportable pharmaceutical licensing transactions, and will most certainly prevent Plaintiff's members from quickly consummating licenses designed to get beneficial medicines to market, and all the more so when the FTC or Justice Department issues a second request.

86. The interests that Plaintiff seeks to protect are a core part of its purpose. Plaintiff advocates in support of public policies, for and on behalf of its members, that promote the

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 financial and resource burdens on Plaintiff's specifically-identified members, it will cause them unnecessary delay and uncertainty in attempting to bring new medicines to market.

87. Plaintiff is not seeking monetary damages. Therefore, neither the claim asserted nor the relief requested requires that an individual member of Plaintiff participate in the lawsuit.

88. Unless a permanent injunction issues, the Rule will cause immediate, irreparable damage to Plaintiff's members. The FTC will not suffer harm as a result of the issuance of injunctive relief. These types of licenses have been non-reportable for the entire 37-year history of the HSR Act, and the FTC and Justice Department retain authority to investigate them along with other non-reportable transactions they conclude will likely result in a substantial lessening of competition.

CLAIMS FOR RELIEF

COUNT ONE:
The Rule exceeds the FTC'S statutory authority under the HSR Act

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

90. A "reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

91. Congress did *not* grant the FTC authority to extend the HSR Act's reporting burden for certain patent licenses in a single industry without imposing the same requirement for the same transactions in other industries. Under the Act's express terms, the FTC's authority is

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. Because the Rule exceeds the FTC's authority under the HSR Act, it is unlawful and must be set aside. 5 U.S.C. § 706(2)(C).

COUNT TWO:

The Rule is arbitrary, capricious, and an abuse of discretion

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

95. A "reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, and an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(a)(A).

96. The APA requires an agency to examine the relevant data and articulate a reasoned explanation for its action that articulates a rational connection between the facts found and the course of action taken.

97. An agency's reliance on its own asserted expertise as the basis for a rulemaking is no substitute for reasoned findings. Without a reasoned analysis justified by reference to objective evidence, rather than mere "administrative expertise," the rulemaking cannot satisfy the requirements of the APA.

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, Plaintiff respectfully requests this Court order a speedy hearing of a declaratory judgment action pursuant to Fed. R. Civ. P. 57, enter judgment in its favor, and:

1. Declare that the Rule is unlawful and void;

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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