Appendix B

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RE: *HSR IP Rulemaking, Project No. P989316* -- Comments of PhRMA on Notice of Proposed Rulemaking Regarding Certain Licensing Transactions in Pharmaceutical Industry

On behalf of our client, the Pharmaceutical Research and Manufacturers of America ("PhRMA"), we welcome the opportunity to provide comments on the above-referenced Notice of Proposed Rulemaking issued by the Federal Trade Commission ("FTC") and published in the Federal Register on August 20, 2012 (the "NPR").[1]

The NPR proposes significant changes in the Hart-Scott-Rodino Antitrust Improvements Act's, 15 U.S.C. § 18a ("HSR Act" or the "Act"), prenotification requirements that would apply only to the pharmaceutical industry. In particular, the proposed amendments would expand the requirements of the HSR Act to pharmaceutical patent licensing transactions that grant the licensee an exclusive right to use and commercialize a patent in a specific therapeutic area, but in which the patent holder retains certain rights 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.

PhRMA respectfully urges the FTC not to adopt the proposed rules. The proposed rules constitute an unprecedented attempt by the agency to increase the HSR Act requirements for a single industry and raise a number of fundamental concerns. PhRMA's principal concerns are highlighted below and discussed in more detail in these comments:

- Nothing in the HSR Act authorizes the FTC to expand and increase the Act's coverage and burdens to only a single industry to the exclusion of all others. To the contrary, the HSR Act is a statute of general application that must be applied even-handedly to all "persons," except as Congress expressly authorizes. While Congress granted the FTC the right to *exempt* certain classes of persons from the Act's requirements, it declined to do the opposite and, in fact, specifically refused to authorize the FTC to *expand* the HSR requirements only for a single class of trade.

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[1] 77 FED. REG. 50,057-62 (Aug. 20, 2012).

- The proposed discriminatory treatment of the pharmaceutical industry in the proposed HSR rule amendments directly conflicts with the principles of non-discrimination in antitrust enforcement espoused by the U.S. antitrust agencies globally. *See, e.g.,* APEC-OECD Integrated Checklist On Regulatory Reform[2] ("Non-discrimination means that laws and policies should *refrain from applying different requirements or procedures to different firms, goods, services or countries. . . . New and proposed regulation should be examined to ensure that it does not have avoidable de facto discriminatory effects*") (emphasis added).

- Likewise, even assuming a legislative basis for the proposed HSR changes exists, the proposed rulemaking fails to comply with the Administrative Procedure Act, 5 U.S.C. § 553 *et seq.* ("APA"). Among other APA problems with the proposed rules, there is no basis for treating the pharmaceutical industry differently from other industries with regard to HSR reporting of intellectual property licensing transactions. The NPR fails to point to any evidence to justify such adverse discrimination or to suggest that licensing transactions in this industry are more likely to create adverse competitive effects. In fact, the types of intellectual property licensing transactions targeted by the proposed HSR amendments are by no means limited to the pharmaceutical industry. They frequently occur in many other industries where innovators may turn to third parties to collaborate on development and commercialization and where the licensor and licensee possess the same economic incentives as those attributed to pharmaceutical companies in the NPR.

- The proposed rulemaking does not comply with the Paperwork Reduction Act.

I. The Proposed Rulemaking Materially Affects PhRMA's Membership

PhRMA represents the country's leading research-based biopharmaceutical companies. PhRMA's mission is to advocate in support of public policies that encourage discovery of life-saving and life-enhancing new medicines for patients by pharmaceutical and biotechnology research companies. These policies are directly undermined by rules or regulations that unnecessarily increase the transaction costs and delays associated with arrangements that facilitate the discovery and introduction of new medicines. Similarly, regulation that is not transparent and that unjustifiably inflicts costs and burdens uniquely on the pharmaceutical industry runs counter to the public policies supported by PhRMA and its membership.

The proposed amendments, if adopted, would result in a material increase in the number of HSR filings required by pharmaceutical companies, with associated increased expense and transaction delay. By the FTC's own estimates, the proposed amended rules would increase by nearly 50% the number of HSR filings required annually by members of the pharmaceutical industry.[3]

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[2] *Available at* http://www.oecd.org/regreform/34989455.pdf at A4.

[3] The FTC estimates that the new HSR rules, if adopted, would result in 30 additional HSR filings per year. *See* 77 FED. REG. 50,060. According to the most recent HSR Annual Report, there were 75 filings during FY 2011 in "chemical manufacturing," of which pharmaceutical, including biologic, manufacturing accounted for an unspecified subset. Thus, an increase of nearly 50% in the number of pharmaceutical HSR filings is a conservative

II. The Proposed Amended Rules Are Not Authorized by the HSR Act

PhRMA is concerned that the proposed rulemaking exceeds the FTC's authority under the HSR Act, both due to the proposed rule's discriminatory treatment of the pharmaceutical industry and because, more generally, the proposed rule does not fit within the rulemaking authority granted by Congress in the statute.

A. The HSR Act Does Not Permit the FTC to Expand the Act's Coverage and Burdens to Only a Single Industry

By its plain language, the HSR Act is a statute of general application that does not authorize the FTC to increase the HSR filing requirements for a single class of persons to the exclusion of all others. The HSR Act explicitly applies to all "persons" who participate in an acquisition that meets the Act's thresholds unless the acquisition is specifically exempted by the Act. *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* . . . .") (emphasis added). By making the Act applicable to all persons without distinction as to class of trade, Congress expressed its intent that all persons be subject to the same standards and treated equally under the Act. Insofar as exceptions to this general rule might apply, Congress specifically limited these exceptions to *exemptions* from the Act's requirements as opposed to the *imposition of heightened obligations* on certain "persons." *See* 15 U.S.C. § 18a(c).

The HSR Act's legislative history conclusively reinforces this result. The Senate bill proposed a provision that would have allowed the FTC, after consultation with the Justice Department, "to require pre-merger notifications from particular companies or industries or from any class or category of persons."[4] Specifically, the Senate bill included language authorizing the FTC and DoJ to promulgate rules requiring filings by limited "classes or categories" of persons in transactions for which all other persons were not required to file.[5] This provision, however, was deliberately deleted from the House bill and was not included in the conference bill which became the HSR Act, as enacted. In explaining the deletion, Representative Rodino stated that "[i]n the view of the House conferees, the coverage of this bill should be decided by Congress -- not the FTC and the Justice Department."[6]

The FTC's rulemaking practice and policy since the HSR Act's enactment has remained true to these principles for decades – until now. In the 36 years since the HSR Act was enacted, the FTC has never promulgated an HSR rule that increases the Act's requirement for only a single industry, nor has it even tried to do so until now. Instead, consistent with the HSR Act's

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estimate of the additional burden; the actual percentage increase is likely greater. *See* Hart-Scott-Rodino Annual Report, Fiscal Year 2011, at 6, *available at* http://www.ftc.gov/os/2012/06/2011hsrreport.pdf.

[4] *See* 122 CONG. REC. 29342 (Sept. 8, 1976) (statement of Sen. Hart, referring to S. REP NO. 94-803)

[5] *See* S. 1284 (May 6, 1976)

[6] *See* 122 CONG. REC. 30877 (Sept. 16, 1976) (statement of Rep. Rodino).

mandate, the FTC has always used its rulemaking authority either to grant exemptions or to promulgate rules that, like the HSR Act itself, are generally applicable to all industries.[7]

The proposed amendments to the HSR rules described in the NPR directly conflict with the HSR Act and the FTC's longstanding rulemaking practice in this regard.[8] As the FTC acknowledges in the NPR, the proposed amendments do not constitute an "exemption" from the HSR Act.[9] In fact, they constitute the exact opposite of an exemption by attempting to impose upon the pharmaceutical industry new, more onerous filing requirements that would not apply to any other industry rather than relieving filing requirements as under an exemption. Respectfully, there is no statutory basis for this unprecedented use of the HSR rules.

Established principles of statutory interpretation further buttress this conclusion. Statutes of general application, like the HSR Act, may not be applied selectively to a limited class of persons, absent explicit Congressional authorization.[10] Equally settled is that, because the HSR Act subjects persons to substantial penalties for non-compliance,[11] the statute must be strictly construed so as not to infer powers to the agency beyond those specifically granted in the statutory text.[12] As discussed above, Congress nowhere granted the FTC authority to increase the HSR Act's reporting burden for only a single industry, but instead limited the FTC's power to differentiate between industries solely by granting exemptions from the Act to those "classes of persons" who "are not likely to violate the antitrust laws."[13]

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[7] *See e.g.,* 75 FED. REG. 57,110 (Sept. 17, 2010) (adopting changes to HSR rules governing information and documents to be included with HSR form; changes applicable to all industries); 70 FED. REG. 11,502 (March 8, 2005) (HSR rule changes concerning treatment of LLC's and other unincorporated entities; changes applicable to all industries).

[8] "[T]he longstanding interpretation placed on a statute by an agency charged with its administration" is entitled to great weight, especially when the agency attempts to diverge from this longstanding interpretation. *See Bell Aerospace Co.*, 416 U.S. 267, 274-75 (1974); *Chamber of Commerce v. NLRB,* 856 F.Supp.2d 778, 795 (D.S.C. 2012) (agency's longstanding rulemaking practice contradicted interpretation of supposed rulemaking authority that agency relied upon to propose new rule).

[9] *See* 77 FED. REG. at 50,058 (citing the basis for the proposed rule as 15 U.S.C. § 18a(d)(2)(A) and (d)(2)(C), but not the exemption provision in 15 U.S.C. § 18a(d)(2)(B)). Indeed, the power to grant exemptions to a rule of general application does not equate to the right to adversely discriminate against a class of persons. *See Burlington Northern R.R. v. Bair,* 60 F.3d 410, 413 (8th Cir. 1995) (holding that tax scheme illegally discriminated against railroads because it subjected railroad property to taxation under a purported tax of general application that exempted nearly all other industries), *cert. denied,* 516 U.S. 1113 (1996); *see also Department of Revenue v. ACF Indus.,* 510 U.S. 332, 345 (1994).

[10] *See* 2 N. Singer et al., *Sutherland on Statutes and Statutory Construction* § 40:2 at 215-16, 226 (7th ed. 2009) (Statutes of general application require "uniformity . . . to prevent granting to any person, or class of persons, the privileges or immunities which do not belong to all persons").

[11] *See* 15 U.S.C. § 18a(g)(1).

[12] *See* 3 *Sutherland* § 60:4 at 301 ("A statute that merely imposes penalties in civil cases is commonly regarded as subject to strict construction in its entire application."); *see also Commissioner of Internal Revenue v. Acker*, 361 U.S. 87, 91 (1959); *First Nat'l Bk. of Gordon v. Dept. of Treasury*, 911 F.2d 57, 65 (9th Cir. 1990).

[13] 15 U.S.C. § 18a(d)(2)(A).

Congress knows full well how to subject the pharmaceutical industry to increased antitrust filing requirements when that is Congress' intent; it did so clearly and explicitly in the 2003 amendments to the Social Security and Medicare acts.[14] Its failure to do so in either the HSR Act itself, or in any subsequent amendments, casts further doubt on the FTC's rulemaking authority here.[15]

Furthermore, the kind of industry sector discrimination that pervades the proposed HSR rule amendments is directly at odds with the principles of non-discrimination in antitrust enforcement espoused by the U.S. antitrust agencies internationally, before significant policymaking bodies. *See* APEC-OECD Integrated Checklist On Regulatory Reform:

> ***Non-discrimination means that laws and policies should refrain from applying different requirements or procedures to different firms, goods, services or countries***. This includes discrimination either against or in favour of a particular firm or category of firms . . . ***New and proposed regulation should be examined to ensure that it does not have avoidable de facto discriminatory effects.***

(Emphasis added).[16] For example, in a 2009 submission to the Organisation for Economic Co-operation and Development, the FTC and DoJ emphasized that U.S. antitrust law does not favor certain industries over others, and noted that "competition policy, not industrial policy, is the main organising principle of the United States' economic policy, not just a special detail engrafted onto one form of industrial intervention or another."[17]

Thus, not only do the proposed HSR rule amendments exceed the statutory authority granted by Congress and represent a sharp departure from the norm of HSR rulemaking, they also run contrary to the policy positions espoused by both U.S. antitrust agencies in widely-respected international antitrust policymaking fora. PhRMA respectfully urges the FTC to reconsider the proposed rulemaking in light of these considerations.

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[14] *See* Section 1112, Subtitle B, Title XI, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, 2461-63, *codified at* 21 U.S.C. § 355 nt.

[15] *See Chamber of Commerce v. NLRB,* 856 F.Supp.2d at 795 (rejecting agency's proposed notice-posting rule because "Congress clearly knows how to include a notice-posting statute requirement in a federal labor statue when it desires to do so").

[16] *Available at* http://www.oecd.org/regreform/34989455.pdf at A4. *See also* FTC HEARINGS ON GLOBAL AND INNOVATION-BASED COMPETITION (Nov. 21, 1995) ("The other basic commitment is non-discrimination, that is not to discriminate in the application or development of standards . . ..") *available at* http://www.ftc.gov/opp/global/GC112195.shtm.

[17] Competition Policy, Industrial Policy And National Champions, Answers of the United States to Questionnaire Part II: "The Relationship between Competition and Industrial Policies in Promoting Economic Development," DAF/COMP/GF/WD(2009)37.

B. The Proposed Amended HSR Rules Are Otherwise Beyond the FTC's Rulemaking Authority

The agency rulemaking provisions in the HSR Act do not authorize the proposed HSR rule amendments set forth in the NPR. Sub-section (d)(2)(A) of the HSR Act, 15 U.S.C. § 18a(d)(2)(A), only grants the FTC authority to "define the terms used in this section." The NPR's proposal to make the amendments exclusively applicable to the pharmaceutical industry is not a definition of a term used in the statute. The NPR acknowledges as much by not proposing to include that provision in the "Definitions" section of the HSR rules, 16 CFR § 801.1.[18]

More importantly, the authority to define terms used in the HSR Act does not authorize the FTC to rewrite the HSR Act to permit adverse discrimination against a single industry. It is well-established that where, as here, Congress has expressed its intention on the question at issue, the agency's rulemaking authority cannot be used in a manner inconsistent with that intention.[19] As the Supreme Court has emphasized, an agency's proposed rulemaking "is always subject to check by the terms of the [enacting] legislation . . . ."[20] This means that an agency may not disregard the substantive provisions of the HSR Act by relying in isolation on its rulemaking authority granted under the Act.[21] And, the FTC "cannot use its definitional authority to expand its own" role under the underlying statute.[22]

Accordingly, the FTC's authority to define terms used in the HSR Act provides no basis for the agency to expand and increase the Act's coverage and burdens to only a single industry to the exclusion of all others. As explained above, the HSR Act and its legislative history conclusively establish that Congress did not grant the FTC any rulemaking authority in this regard; in fact, Congress explicitly rejected it. The proposed rulemaking set forth in the NPR therefore is not authorized by the rulemaking provisions in 15 U.S.C. § 18a(d)(2).[23]

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[18] 77 FED. REG. 50,061.

[19] *See Bell Atl. Tel. Cos. v. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997); *Hammontree v. NLRB*, 894 F.2d 438, 441 (D.C. Cir. 1990).

[20] *INS v. Chadha*, 462 U.S. 919, 953 n.16 (1983).

[21] *Am. Fed'n of Labor & Cong. of Indus. Orgs. v. Chao*, 409 F.3d 377, 384 (D.C. Cir. 2005)

[22] *See Am. Bankers Ass'n v. SEC*, 804 F.2d 739, 755 (D.C. Cir. 1986); *FAIC Securities, Inc. v. U.S.*, 768 F.2d 352, 362 (D.C. Cir. 1985).

[23] Similar problems attach to the FTC's reliance on its rulemaking authority under 15 U.S.C. § 18a(d)(2)(C). Furthermore, there is no apparent reason, let alone any explanation in the NPR, as to why the rules are "necessary and appropriate" to carry out the purposes of the HSR Act, a fundamental prerequisite to the FTC's rulemaking under 15 U.S.C. § 18a(d)(2)(C). Congress intended the HSR Act to be limited in scope so that it reached only those mergers and acquisitions that are both the most likely to substantially lessen competition and the most difficult to unscramble. *See* H.R. Rep. No. 94-1373 (July 28, 1976) at 11. More specifically, the Act was designed to enable the antitrust agencies to seek injunctive relief in the types of transactions for which adequate post-consummation relief would be extremely difficult because "the assets, technology, and management of the merging firms are hopelessly and irreversibly scrambled together." *Id.* at 5. Yet, the FTC cites no basis to conclude that the types of pharmaceutical licensing transactions that would be covered by the proposed amendments are among the transactions that are most likely to substantially lessen competition under Section 7 of the Clayton Act. This is not surprising. As the NPR acknowledges, the exclusive pharmaceutical licensing transactions covered by the proposed

III. The Proposed Rulemaking Fails to Comply With the Administrative Procedure Act

Even assuming a legislative authorization for the proposed rulemaking exists, the proposed rulemaking raises serious concerns under the APA. The FTC neither has provided a reasoned explanation, supported by evidence, to justify discriminatory treatment of the pharmaceutical industry nor has it justified expansion of the HSR Act to require prenotification reporting of the pharmaceutical licensing transactions at issue.

The rationales offered in the NPR for the proposed amendments' application only to the pharmaceutical industry are that (i) "in the PNO staff's experience, these arrangements have been limited to the pharmaceutical industry" and (ii) "[i]n [the FTC's] view, the pharmaceutical industry presents unique incentives for the use of exclusive licenses."[24] According to the FTC, the incentives of pharmaceutical licensors and licensees are unique because development of pharmaceutical products involves substantial uncertainty and considerable financial investment by the exclusive licensee such that "the licensee wants the exclusive right to as much of these profits as possible to recoup its costs. The result is an exclusive license agreement that is, in the [FTC's] experience, unlike that seen in any other industry."[25]

These explanations are manifestly insufficient to support the proposed rulemaking. First, an "agency's conclusory or unsupported suppositions" are an insufficient basis for rulemaking under the APA.[26] Rather, especially in situations, as here, where an agency's rulemaking departs from its longstanding practice, it "must supply a reasoned analysis" to justify the agency action.[27] "One of the abiding principles of administrative law is that when agencies refuse to treat like cases alike, they act arbitrarily, in violation of the [APA]."[28] For this reason, even when an agency is authorized by enabling legislation to apply different standards to different persons, the agency "must do more than simply point out differences between the cases" to justify disparate treatment.[29]

HSR amendments often involve product concepts at a very early stage in development. Such product concepts usually are many years away from potential Food and Drug Administration ("FDA") approval and even farther away from possible commercialization, making them too remote and speculative to have the potential to "substantially lessen competition," the standard set out in Clayton Act Section 7. Nor does the FTC so much as claim that the proposed rule amendments are needed to prevent the "scrambling of the eggs" concern that is a central purpose of HSR premerger notification. Such a showing would be extremely difficult for the agency to make. The kinds of patent licensing transactions reached by the proposed HSR rule amendments do not entail irreversible integration between the parties. The licensor continues to function as an independent entity, in many cases owning and operating the manufacturing capacity and expertise for the patented product, as well as maintaining ownership of the intellectual property.

[24] 77 FED. REG. 50,059.

[25] *Id.*

[26] *McDonnell Douglas Corp. v. U.S. Dep't of the Air Force*, 375 F.3d 1182, 1186-87 (D.C. Cir. 2004).

[27] *Checkosky v. SEC*, 23 F.3d 452, 487 (D.C. Cir. 1994) (J. Randolph).

[28] *Id.* at 483 (citations omitted).

[29] *Id.*

A. The FTC Has Failed to Provide Good Reasons, Let Alone a Reasoned Explanation, to Support the Proposed Rulemaking

The APA requires that an agency, among other things, "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'"[30] "[T]he agency must show that there are good reasons for [a] new policy."[31]

Here, the FTC has failed to provide any reasoned basis for the proposed rulemaking. The NPR is especially deficient in its failure to demonstrate the requisite "good reasons" needed to justify the new FTC rules. In lieu of facts and analysis, the FTC offers up only its own "expertise," and provides no evidence whatsoever in support of its own subjective assessment. It is fundamental that, if an agency can simply suggest that its own experience is sufficient to support APA rulemaking, then it essentially bootstraps itself around the APA requirement of having to provide evidence and a reasoned explanation of why a rule change is warranted and appropriate. As the Supreme Court has long admonished, an agency's reliance on its own purported expertise as a basis for rulemaking is an insufficient substitute for "reasoned findings-which alone make effective judicial review possible. [Otherwise, the requirement of reasoned findings] would become lost in the haze of so-called expertise. Administrative expertise would then be on its way to becoming 'a monster which rules with no practical limits on its discretion.' That is impermissible under the Administrative Procedure Act."[32] Thus, "[t]he requirements for administrative action [are] strict and demanding," and the FTC's "analysis must be justified by reference to objective evidence," rather than based on mere "administrative expertise."[33]

Independent of all the other concerns that PhRMA has about the proposed rulemaking, the FTC's failure to identify or develop any objective facts to support either the need for additional rulemaking or to demonstrate how the proposed amendments will address the perceived deficiencies consistent with the core purposes of the HSR Act makes the rulemaking problematic under the APA.[34]

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[30] *Motor Vehicle Ass'n v. State Farm Mut. Auto Ins.*, 463 U.S. 29, 43 (1983) (citation omitted).

[31] *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

[32] *Baltimore & Ohio R.R. Co. v. Aberdeen & Rockfish R.R. Co.*, 393 U.S. 87, 91-92 (1968) (citation omitted).

[33] *See Burlington Truck Lines, Inc. v. U.S.*, 371 U.S. 156, 167-168 (1962); *Baltimore & Ohio R.R.*, 393 U.S. at 91-92; *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 850 (1971), *cert. denied*, 406 U.S. 950 (1972).

[34] As discussed in more detail above at note 23, the FTC has not identified any reasonable ground for subjecting these licensing arrangements to the HSR Act's requirements. Nothing provided in the NPR suggests that these transactions are likely to be among those that are more likely to "substantially lessen competition" and, if so, result in the kinds of "irreversible scrambling" that Congress sought to address through the HSR Act. In fact, the FTC does not reference a single problematic transaction involving similar kinds of patent licenses that would justify their inclusion within the HSR Act. Nor, to our knowledge, has the FTC or DoJ ever challenged a consummated patent license arrangement that resembles the types targeted by the new rules.

B. The FTC's Stated Assumptions Are Incorrect and Do Not Support Discriminatory Treatment of the Pharmaceutical Industry

As noted above, the FTC justifies the creation of a special HSR reporting obligation applying only to the pharmaceutical industry based on its subjective conclusion that the incentives of pharmaceutical licensors and licensees are "unique" and "result [in] an exclusive license agreement ... unlike that seen in any other industry."[35] Even if the FTC had the statutory authority to call out a single industry for increased particularized treatment under the HSR Act, it remains that the FTC's conclusion about the "uniqueness" of pharmaceutical licenses is incorrect. Licensing transactions involving pharmaceutical companies are functionally no different from licensing transactions occurring in any number of other industries. In this respect as well, the FTC has failed to articulate a reasonable basis for the proposed rulemaking.

1. The Licenses at Issue Are Not Unique to the Pharmaceutical Industry Nor Are the Incentives of Pharmaceutical Licensors and Licensees

The kinds of licensing transactions described by the NPR are not limited to the pharmaceutical industry. If they were, there would be no need to promulgate an industry-specific rule because a rule of general application would have the same practical effect as the proposed rulemaking. In fact, an analysis by Dr. Thomas Varner of intellectual property license agreements submitted to the Securities and Exchange Commission ("SEC") shows 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, to name just a few.[36] The prevalence of agreements with these provisions across so many industries is not surprising for two reasons. First, all licensors are motivated to maximize the royalties they receive from their licensees, and hence, will take steps to improve the likelihood of the licensee's commercial success with the technology.[37] Second, licensors often possess considerable expertise (beyond owning the licensed patent technology) that are in the interest of the licensor to share with the licensee in order to improve the odds of the licensed products' commercial success.[38]

Nor are the incentives described in the NPR unique to licensors and licensees in the pharmaceutical industry. Many industries – in fact, all industries with incentives to transfer IP from small-scale to larger-scale commercialization parties – present the very same incentives for exclusive licenses as those attributed in the NPR to the pharmaceutical industry.[39] For example, the same incentives described in the NPR could readily be attributed to licensors and licensees in any industry where products require substantial investment for research and development or prior

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[35] 77 FED. REG. 50,059.

[36] *See* Declaration of Dr. Thomas R. Varner ("Varner Dec."), submitted as Attachment A to these Comments, ¶¶ 2, 7, 23.

[37] *Id.* ¶¶ 7, 19-21.

[38] *Id.*

[39] *Id.* ¶¶ 7-8, 12-21.

regulatory approvals in order to commercialize, or any industry where small-scale R&D requires the complementary application of scale-up, regulatory, and commercialization resources, provided by a licensee, in order to come to market. The FTC has pointed to no evidence to support its assertion that licensing incentives are "unique" to the pharmaceutical industry. By contrast, a comparison of royalty provisions in exclusive license agreements in the pharmaceutical industry with royalty provisions in other industries belies this assertion by showing that licensors and licensees across industries structure such provisions very similarly.[40]

2. A Licensor's Retaining Limited Manufacturing Rights for Pharmaceuticals Is Not Functionally Different From a Licensor's Retaining Those Rights in Other Industries

Other assertions about the pharmaceutical industry in the NPR also lack support and are misplaced. In particular, the NPR asserts that, "in licensing arrangements in the pharmaceutical industry, the right to manufacture is far less important than the right to commercialize."[41] The only basis offered by the FTC for this conclusion consists of the following few sentences:

> [T]he right to manufacture is often retained by the licensor who has the relevant manufacturing expertise and facilities. As a result, pharmaceutical companies often enter into licenses in which the licensee receives the exclusive right to use and sell under the license, but the licensor retains the right to manufacture exclusively for the licensee. As the licensor is manufacturing solely for the use of the licensee, this is substantively the same as giving the licensee the exclusive right to manufacture, use, and sell the product(s) covered by the license.[42]

But this observation applies equally to all industries in which these kinds of arrangements occur and is in no way unique to the pharmaceutical industry. According to the logic in the NPR, whenever a licensor grants a licensee the exclusive right to use and sell a patented product but retains the right to manufacture such product exclusively for the licensee, the licensor's rights are, by definition, limited in nature and less important than the licensee's right to commercialize. If this logic holds true, it makes no difference which industry or product is involved.

The FTC nowhere points to any evidence that shows that patent licensors' manufacturing rights in the pharmaceutical industry are any less important than the manufacturing rights of licensors in other industries. To the contrary, as Dr. Varner explains, marketplace realities make pharmaceutical manufacturing at least as important to a medicine's commercial success as manufacturing in many other industries is to the commercial success of their products.[43] For

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[40] *Id.* ¶ 21.

[41] 77 FED. REG. 50,059.

[42] *Id.*

[43] Varner Dec. ¶¶ 24-29. Government studies show that chemical manufacturing (including pharmaceuticals) are consistently among the most highly compensated manufacturing jobs relative to other industries, and are also among

example, pharmaceutical manufacturing is heavily regulated by the FDA, with manufacturers required to adhere to Current Good Manufacturing Practice regulations contained in 21 CFR §§ 210 *et seq*. A licensor's ability to achieve and maintain compliance with FDA standards is clearly an important variable of a pharmaceutical's ultimate commercial success. This is especially true for biologics, so-called "large molecule" products, which are typically even more complicated to produce than "small molecule" drugs.[44] Contrary to what the NPR suggests, therefore, the right to manufacture in the pharmaceutical industry cannot generally be characterized as "far less important than the right to commercialize."[45]

3. The Proposed Treatment of Co-Rights in Pharmaceutical Licensing Transactions Also Is Inconsistent With the HSR Act

The APA problems associated with the FTC's proposed rulemaking are compounded by the discriminatory treatment of co-rights retained by licensors in the pharmaceutical industry. Under the proposed rulemaking, a pharmaceutical licensor's retaining rights to co-develop, co-market, or co-commercialize the licensed product together with the licensee would not render the license non-exclusive for purposes of the HSR Act.[46] The NPR states that, while not formalized in the HSR rules, this is already the FTC's current policy for treating co-rights in all industries such that the proposed amendments to the HSR rules would not change the FTC's approach.[47]

But there are several concerns raised by the proposed rulemaking's treatment of a patent owner's retaining co-rights in the pharmaceutical industry. A threshold concern is that the FTC's current policy for treatment of co-rights is unclear at best and, therefore, susceptible to inconsistent interpretations among industry members and practitioners alike. *See, e.g.,* Informal Staff Opinion 0806009-801.2, dated June 10, 2008[48] (no HSR filing required when the licensor and licensee "each would retain rights to the IP it is granting to the other for purposes of the co-development and co-promotion of the new products."). At the very least, given this lack of clarity, the proposed rulemaking's exclusive application to the pharmaceutical industry gives rise to the same concern of discriminatory treatment that taints the other proposed amendments to the HSR rules. Nor has the FTC offered any basis for, let alone justified, disparate treatment of the pharmaceutical industry with respect to retention of co-rights. To the contrary, the FTC's

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the least susceptible to outsourcing. BLS, *Compensation Costs in Manufacturing Across Industries and Countries, 1975–2007*, Monthly Labor Review, June 2010, *available at* http://www.bls.gov/opub/mlr/2010/06/art3full.pdf; CBO, *Factors Underlying the Decline in Manufacturing Employment Since 2000*, Economic and Budget Issue Brief, December 23, 2008, *available at* http://digitalcommons.ilr.cornell.edu/cgi/viewcontent.cgi?article=1590&context=key_workplace. These studies are inconsistent with the NPR's premise that manufacturing is relatively unimportant in the pharmaceutical industry.

[44] Varner Dec. ¶¶ 28-29.

[45] 77 FED. REG. 50,059.

[46] *Id.*

[47] *Id.*

[48] *Available at* http://ftc.gov/bc/hsr/informal/opinions/0806009.htm.

position in the NPR is that the same standard for analyzing co-rights under the HSR Act should and already does apply to all industries.[49]

Equally of concern is the lack of reasoned explanation by the agency for the proposed amendment's blanket treatment of a pharmaceutical licensor's retaining of co-rights. The NPR proposes a standard that would not 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.[50] The NPR states that the amended rules' proposed blanket treatment of co-rights is based on the FTC's view that the "licensor generally retains co-rights to assist the licensee in maximizing the licensee's sales of the licensed product so that the licensor might have a more robust royalty revenue stream or other revenue sharing arrangement."[51] First of all, it bears repeating that the incentive to maximize profitability to the licensor is likely the same regardless of the industry involved. Moreover, co-rights in all industries, including but certainly not limited to the pharmaceutical industry, can and do take a number of forms and create varying levels of retained rights for the patent owner. Patent owners might retain these rights for a host of different reasons, with a wide range of licensor-licensee involvement, and an equally wide range, perhaps undefined at the outset, of subsidiary rights to be retained by the licensor. A blanket rule that makes the nature, extent, and other terms of co-rights retained by a licensor irrelevant to the transaction's HSR reportability is at a minimum overbroad and inconsistent with the HSR Act's coverage of only acquisitions that transfer beneficial ownership of assets.

This concern is illustrated by the fact pattern presented in Informal Staff Opinion 0806009-801.2, cited above. In the situation presented there, Company A and Company B entered into a licensing transaction that involved various dimensions of co-development and co-promotion of patented technology. Company A and Company B agreed to co-develop and co-promote a Combination Product that would be developed partially from Company A's IP. Company A granted Company B a license under which Company B had the exclusive right to sell the Combination Product in exchange for a portion of revenues to be remitted to Company A. Company A, however, retained co-promote rights to the Combination Product. The transaction was deemed non-reportable because Company A retained rights to its IP for purposes of the co-development and co-promotion of the Combination Product.

It is unclear whether the above fact pattern would require an HSR filing for pharmaceutical companies under the proposed HSR amendments. It at least begs the question whether the conclusion stated in the interpretation was wrong at the time, or whether it properly reflected a nuanced judgment as to the great variability of the significance of retained co-rights. At a minimum, the blanket, indiscriminate nature of the proposed rules' treatment of a

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[49] 77 FED. REG. 50,059.

[50] Specifically, the proposed HSR rule amendments define "co-rights" as "shared rights retained by the patent holder to assist the recipient of the exclusive patent rights in developing and commercializing the product covered by the patent. These co-rights include, but are not limited to, co-development, co-promotion, co-marketing, and co-commercialization." *Id.* at 50,061.

[51] *Id.* at 50,059.

pharmaceutical licensor's retention of co-rights gives rise to concern that such transactions might be perceived as reportable when the FTC in the recent past has viewed the IP transfer insufficient to trigger HSR reportability.

IV. The Proposed Rulemaking Does Not Comply With the Paperwork Reduction Act

In the NPR, the FTC specifically invited comments on, among other issues, "whether the proposed collections of information are necessary for the proper performance of the functions" of the FTC and "the accuracy of the Commission's estimate of the burden of the proposed collections of information."[52] These issues pertain to the FTC's compliance obligations under the Paperwork Reduction Act ("PRA"), which requires the Office of Management and Budget to determine "whether the collection of information by an agency is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility for the agency." 44 U.S.C. § 3504(c). An overarching goal of the PRA is to minimize the compliance burden on individuals and businesses resulting from the collection of information by the federal government. *See* 44 U.S.C. § 3501(1).

In light of the proposed rulemaking's many flaws, PhRMA has grave doubts that the proposed rulemaking satisfies the requirements of the PRA. As described above, the FTC has failed to explain, let alone demonstrate, the need for the proposed rulemaking to effectuate the purposes of the HSR Act. Against this failure, it is difficult to view almost any increase, let alone a substantial increase in the number of HSR filings -- by the FTC's estimate, filings for approximately 30 more transactions per year -- as "necessary" to the proper performance of the FTC's functions under the HSR Act.

This lack of necessity is magnified when one considers the true costs and burdens that the amended HSR rules, if adopted, would inflict on businesses, including many small businesses that the NPR acknowledges are resource-constrained.[53] As noted at the outset, the proposed amended rules would increase by at least 50% the number of HSR filings required annually by members of the pharmaceutical industry. (*See infra*, p. 2 & n.3) While the FTC estimated the total incremental costs to companies of these increased HSR filings to be $ 1,225,000, this estimate grossly understates the actual costs to individuals and businesses that would result annually from these increased HSR filings.

The costs that businesses face when required to file HSR forms with the FTC and DoJ include filing fees, costs associated with collection of information and documents necessary for completion of the HSR form (including required attachments), and costs associated with responding to requests, if any, by the agency for additional information. As shown below, these costs would be substantial, with small businesses bearing a significant brunt of them.

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[52] 77 FED. REG. 50,061.

[53] *Id.* at 50,059 (recognizing that one of the transacting parties, typically the licensor, often will "not have the financial resources to shepherd the compound through the approval process required by the FDA").

- **Filing Fees**: The current HSR filing fee per transaction ranges from $45,000 to $280,000, depending on the value of the transaction. As a result, based upon the FTC's estimate of an annual increase of 30 HSR reportable transactions, companies subject to the proposed HSR rule amendments each year would be forced to expend between $1,350,000 to $8,400,000 in filing fees alone. Even at the low end, the increased cost of the statutory filing fee *alone* exceeds the FTC's entire cost estimate in the NPR.

- **Form Preparation, Including Document Collection.** Based upon our experience and discussions with various PhRMA members, the costs incurred in connection with preparation and completion of HSR forms are at least $15,000 per party for straightforward transactions, with this amount potentially much higher in complicated transactions where an analysis of whether the transaction is HSR reportable is required. This estimate includes only the attorneys' fees for time associated with collection and review of materials, such as so-called "Item 4(c)" and "Item 4(d)" documents, that must be included with an HSR filing as well as for completion of the HSR form itself. Based upon this estimate, and the FTC's estimate that 60 additional HSR filings (one by each transacting party for each of the 30 additional reportable transactions per year) would be required annually, we conservatively estimate that the annual cost increase to businesses from form preparation alone would be $900,000. This amount increases to well over $1,000,000 when one factors in the time expended by in-house counsel and company employees to assist in the collection of information and materials needed for the filing of the HSR form.

- **Responding to Additional Information Requests.** The extent and scope of post-filing requests for more information from the staff of the antitrust agency reviewing the reported transaction can range widely depending on the staff, companies, assets, and transaction involved, as well as when the request is made in the initial HSR waiting period. When an antitrust agency issues a Request for Additional Information (a "Second Request") pursuant to 15 U.S.C. 18a(e), the costs associated with an HSR filing increase exponentially. According to estimates compiled by the Antitrust Section of the American Bar Association in 2006, compliance with a Second Request on average costs about $ 5 million per transaction and up to $20 million in very complex cases.[54] According to the most recent HSR Annual Report, in FY 2011 the agencies issued Second Requests in 8% of HSR-reportable transactions involving the chemical, including pharmaceutical, manufacturing industries.[55] Applying this 8% to the 30 additional HSR-reportable transactions estimated by the FTC yields between 2

[54] Comments of the Section of Antitrust Law, ABA, in Response to the Antitrust Modernization Commission's Request for Public Comment Regarding the HSR Second Request Process (2006), at 4.

[55] *See* Hart-Scott-Rodino Annual Report, Fiscal Year 2011, at 6 *available at* http://www.ftc.gov/os/2012/06/2011hsrreport.pdf.

> and 3 additional Second Requests annually. An additional 2 to 3 Second Requests per year would result in approximately $10 million to $15 million in increased annual costs to businesses, on average.

Accordingly, the NPR materially underestimates the costs that businesses would need to incur under the proposed expansion of HSR filing obligations reflected in the proposed rulemaking. Furthermore, it fails to factor in the significant increase in time and resources that the proposed rules would impose on the antitrust agencies. While understating the costs of additional filings under the proposed rule, the NPR is silent as to its benefit, particularly a quantification of benefits as necessary to conduct a cost-benefit analysis.

V. Conclusion

The proposed rulemaking's unprecedented effort to impose increased HSR filing obligations on a single industry faces fundamental problems under the HSR Act, the FTC's longstanding rulemaking practice and advocacy internationally, the APA, and the PRA. Especially when viewed in their totality and with the amendments' lack of demonstrated necessity, these considerations warrant the agency's withdrawal of the proposed rulemaking. PhRMA thanks the agency in advance for its consideration of these comments.

Respectfully submitted,

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RE: ***HSR IP Rulemaking, Project No. P989316*** **-- Comments of PhRMA on Notice of Proposed Rulemaking Regarding Certain Licensing Transactions in Pharmaceutical Industry**

Attachment A
to PhRMA Comments

RE: *HSR IP Rulemaking, Project No. P989316* -- Notice of Proposed Rulemaking Regarding Certain Licensing Transactions in Pharmaceutical Industry

DECLARATION OF THOMAS R. VARNER, PH.D.

I. QUALIFICATIONS

1. I am a Vice President with Economists Incorporated, an economic consulting firm with offices in Washington, D.C., and San Francisco, CA. I received an M.B.A. degree from the University of California at Berkeley in 1987 and a Ph.D. degree in Engineering-Economic Systems & Operations Research from Stanford University in 1997. I have taught microeconomics, econometrics, and financial economics courses in the Economics Department at the University of California at Davis. I specialize in economic, financial, and statistical analysis. Prior to my economics career I was a licensed Professional Engineer for 12 years. My hourly billing rate is $485. For over ten years I have served as either consulting or testifying expert on a variety of legal matters including intellectual property, antitrust, and general business litigation.

2. In the course of my work as an economist and consultant, I have collected and reviewed thousands of technology licenses across numerous industries including the computer software and hardware, electronics, medical device, pharmaceutical, telecommunication, and chemical industries, among others. This experience includes not only work I have performed for clients over the years but also the review of technology licenses collected from publicly available exhibits filed by registrants to the U.S. Securities and Exchange Commission ("SEC") in connection with my research. I have published a number of findings from my technology license

research in peer-reviewed journals.[1] I have also spoken at professional conferences and seminars on intellectual property litigation and technology licensing. I am a member of the American Economics Association, the National Association of Business Economics, and the Licensing Executives Society. Details of my qualifications and prior testimony experience are provided in the attached copy of my curriculum vitae in Exhibit 1.

II. BACKGROUND AND ASSIGNMENT

3. I have been retained by counsel for the Pharmaceutical Research and Manufacturers of America (PhRMA), Baker Botts L.L.P., to review and comment on certain economic issues related to the U.S. Federal Trade Commission's ("FTC's") recently issued Notice of Proposed Rulemaking (published in the Federal Register on August 20, 2012) ("NPR") addressing modification of the premerger notification rules related to patent licensing.[2] The proposed rules state that they provide "a framework for determining when a transaction involving the transfer of rights to a patent in the pharmaceutical, including biologics, and medicine manufacturing industry (North American Industry Classification System Industry Group 3254) ('pharmaceutical industry') is reportable under the Hart Scott Rodino Act ('the Act' or 'HSR')."[3] HSR, and rules promulgated under the Act, require "parties to certain mergers and acquisitions to file reports with the Federal Trade Commission…and to wait a specified period of

[1] Varner, Thomas R., "An Economic Perspective on Patent Licensing Structure and Provisions," *Business Economics*, Vol. 46 (4), October 2011; Varner, Thomas R., "Technology Royalty Rates in SEC Filings," *les Nouvelles*, Journal of the Licensing Executives Society International, Vol. XLV, No. 3, September 2010, pp. 120-127.
[2] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, pp. 50057-062. 16 CFR Part 801, Premerger Notification; Reporting and Waiting Period Requirements.
[3] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50057.

time before consummating such transactions."[4] The FTC has in the past viewed certain exclusive patent licenses as "potentially reportable" transactions.[5]

4. In evaluating whether a patent license is a reportable transaction, the FTC's Premerger Notification Office ("PNO") analyzes "transactions by focusing on whether the exclusive rights to 'make, use and sell' under a patent were being transferred by the license."[6] The NPR states that the FTC's policy and practice until now has been that if a licensor retained rights to manufacture the covered product, the "PNO staff viewed this as a non-reportable event because the license appeared essentially to be a distribution agreement."[7] In contrast to this policy and practice, the proposed new rules in the NPR state, "if the licensor retains the right to manufacture exclusively for the licensee, it is a potentially reportable asset acquisition because all commercially significant rights…will still have passed to the licensee."[8]

5. The proposed rules apply only to "transfers of patent rights within NAICS Industry Group 3254" (*i.e.,* the pharmaceutical industry).[9] The proposed rules state:

> Patent rights are transferred if and only if all commercially significant rights to a patent as defined in § 801.1(o), 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 in § 801.1(p), or co-rights, as defined in § 801.1(q).[10]

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[4] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50057.
[5] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50058.
[6] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50058.
[7] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50059.
[8] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50059.
[9] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50061, § 801.2 (g), NAICS Industry Group 3254 includes: 325411 Medical and Botanical Manufacturing; 325412 Pharmaceutical Preparation Manufacturing; 325413 In-Vitro Diagnostic Substance Manufacturing; and 325414 Biological Product (except Diagnostic) Manufacturing.
[10] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50061, § 801.2 (g) (3).

Thus, the proposed rules specifically target exclusive patent licenses for pharmaceutical products in which the licensor (*i.e.,* the patent holder) may retain "limited manufacturing rights" and/or "co-rights."[11]

III. SUMMARY OF FINDINGS

6. The FTC's proposed rules are restricted to exclusive patent licenses in the pharmaceutical and biologics industry in which the licensor retains certain manufacturing rights and/or other "co-rights." The FTC's explanations for the proposed rules include assertions that "the pharmaceutical industry presents unique incentives for the use of exclusive licenses,"[12] that in the pharmaceutical industry "a licensor also often retains co-rights in granting an exclusive license,"[13] and that "in licensing arrangements in the pharmaceutical industry, the right to manufacture is far less important than the right to commercialize."[14] These assertions, as well as others made in the NPR, are either unsupported in the NPR and/or are contrary to my observations of technology licenses across numerous industries.

7. The incentives that exist for licensors and licensees in the pharmaceutical industry also exist for licensing parties in other industries; consequently, technology licenses that include retained manufacturing rights and "co-rights" are also found in agreements in non-pharmaceutical industries. Licensors in any industry are motivated to maximize the profits from royalties they receive, and hence, will take steps to improve the likelihood of the licensee's commercial success with the technology. Also, licensors often possess considerable expertise (beyond owning the licensed patent technology) and it is often in the licensor's interest to share

[11] "Co-rights" are defined in the NPR as follows: "[S]hared rights retained by the patent holder to assist the recipient of the exclusive patent rights in developing and commercializing the product covered by the patent. These co-rights include, but are not limited to, co-development, co-promotion, co-marketing and co-commercialization." Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50061, § 801.1 (q).
[12] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50059.
[13] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50059.
[14] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50059.

this expertise with the licensee in order to improve the odds of the licensed products' commercial success. Indicators of the common incentives across industries include the following:

- The frequency with which technology "know-how" is included in patent licenses in the pharmaceutical industry is similar to the frequency with which "know-how" is included in patent licenses in non-pharmaceutical industries.
- The median royalty rates observed among pharmaceutical patent licenses are similar to median royalty rates observed for patent licenses in other industries.
- Technology licenses that include retained manufacturing rights are found in non-pharmaceutical industries, including the chemical, electronics, and medical device industries.

8. Non-pharmaceutical industries such as the medical device industry and the chemical industry also face significant regulatory approval processes to bring certain products to market. These industries also face similar economic incentives for innovator entities to partner with third parties in order to efficiently surmount regulatory requirements to commercialize.

9. The NPR asserts that "in the pharmaceutical industry, the right to manufacture is far less important than the right to commercialize."[15] The NPR fails to provide support for this assertion; for example, there is no comparison of manufacturing costs (or cost of goods sold) across different industries, which comparison would be relevant to the relative importance of manufacturing rights for the pharmaceutical industry compared with other industries. In fact, manufacturing rights in the pharmaceutical industry, just as in other industries, can be an important part of the patent licensing process, as illustrated by, among other things, the inclusion of grants to "manufacturing patents" and "manufacturing know-how" in pharmaceutical licenses. Furthermore, as discussed below, manufacturing processes play an especially important role in the area of therapeutic biological products—one of the sectors included in the proposed rules' definition of the pharmaceutical industry.

[15] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50059.

10. Thus, the "unique incentives" the NPR describes as the basis for the proposed rules are not unique to the pharmaceutical industry, nor are exclusive licenses with retained manufacturing rights "limited to the pharmaceutical industry."

IV. ANALYSIS OF FINDINGS

A. Proposed Rules Lack Support for Characterizing "Unique Incentives" for Pharmaceutical Industry Licenses

11. The NPR states, "In the PNO's view, the pharmaceutical industry presents unique incentives for the use of exclusive licenses."[16] The NPR bases this statement on the assertion that "[an] innovator does not have the financial resources to shepherd the compound through the approval process required by the FDA, nor to effectively market or promote it in drug form after FDA approval."[17]

12. However, in my experience, this situation does not make licensing incentives in the pharmaceutical industry unique, nor is it the case that "these arrangements have been limited to the pharmaceutical industry."[18] A number of industries face extensive regulatory approval processes before their products can be brought to market, and thus have incentives for innovator entities to work with partners who may have more extensive regulatory experience and commercialization capabilities. Similarly, many technology agreements from non-pharmaceutical industries involve the transfer of exclusive patent rights and yet specify that the licensor retains manufacturing rights.

[16] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50059.
[17] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50059.
[18] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50059.

13. One industry that illustrates both of these points is the medical device industry.[19] Certain classes of medical devices need to be reviewed and approved by the FDA's Center for Devices and Radiological Health ("CDRH") before they can be offered for sale. This process is discussed in the CDRH's website:

> FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States. In addition, CDRH regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.
>
> Medical devices are classified into Class I, II, and III. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval. A description of device classification and a link to the Product Classification Database is available at "Classification of Medical Devices."[20]

14. One study of over two hundred medical technology companies found "the average total cost for participants to bring a low- to moderate-risk 510(k) product from concept to clearance was approximately $31 million, with $24 million spent on FDA-dependent and/or related activities. For a higher-risk PMA[21] product, the average total cost from concept to

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[19] Medical devices are not all included in the NPR's proposed definition of pharmaceutical and biologic industries. Medical devices are classified in the following NAICS codes:
325413 In-Vitro Diagnostic Substances Manufacturing
334510 Electro-medical and Electrotherapeutic Apparatus Manufacturing
334517 Irradiation Apparatus Manufacturing
339112 Surgical and Medical Instrument Manufacturing
339113 Surgical Appliances and Supplies Manufacturing
339114 Dental Equipment and Supplies Manufacturing
339115 Ophthalmic Goods Manufacturing
See "Medical Devices Industry Assessment," International Trade Administration, Department of Commerce, http://ita.doc.gov/td/health/medical%20device%20industry%20assessment%20final%20ii%203-24-10.pdf.

[20] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/overview/default.htm. Also see Johnson, Judith A., "FDA Regulation of Medical Devices" published by the Congressional Research Service, 6/25/12, http://www.fas.org/sgp/crs/misc/R42130.pdf.

[21] "PMA" refers to Premarket Approval Application, essentially the medical device analogue to the New Drug Application (NDA) process for pharmaceuticals. See FDA, "PMA Approvals/General Information,"

approval was approximately $94 million, with $75 million spent on stages linked to the FDA."[22] Another study estimated that, "The development of a medical device from concept to product launch typically takes between 4-10 years and costs between $5 and $300 million dollars depending on the complexity of the device and required regulatory process. There are approximately 40 PMA devices approved each year by the FDA and an additional 3,000 510 (k) clearances."[23]

15. The chemical industry is another industry whose products are often subject to extensive regulatory review, and where, as a result, licensing arrangements are not uncommon among innovator and third parties. A guide published by the International Sanitary Supply Association, Inc. ("ISSA") states, "Chemical cleaning products may be subject to a variety of federal labeling, hazard communication and/or registration requirements promulgated by OSHA [Occupational Health and Safety Administration], EPA [Environmental Protection Agency], FDA, CPSC [Consumer Product Safety Commission], DOT [Department of Transportation], and other agencies."[24] Chemical pesticides are subject to reviews by the EPA that address (1) product chemistry, (2) human and environmental assessment for food safety, (3) tolerance information (consisting of information about pesticide residues on food), (4) proof that the manufacturing process is reliable, and (5) labeling information (occupational data, directions for use, and appropriate warnings).[25]

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http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/default.htm.

[22] "FDA Impact on U.S. Medical Technology Innovation: A Survey of Over 200 Medical Technology Companies," November 2010, p. 7.

[23] Alfred E. Mann Foundation for Biomedical Engineering, http://www.mannfbe.org/commercialize/approval-process.htm, downloaded 10/18/12.

[24] ISSA (International Sanitary Supply Association) "General Guide to Chemical Cleaning Product Regulation," Introduction, http://www.issa.com/data/files/articles/88/generalchemical.pdf.

[25] EPA website for pesticide product registration procedures, http://www.epa.gov/pesticides/factsheets/registration.htm. Also see "Rigorous Federal Approval Process Exists for New Chemicals," from the American Chemistry Council,

16. Thus, the "unique incentives" the NPR describes are not unique to the pharmaceutical industry because other industries can face similar regulatory issues and commercialization costs. Furthermore, exclusive licenses with retained manufacturing rights, rather than being "limited to the pharmaceutical industry" as claimed in the NPR,[26] are also found in other industries. Below I describe examples of such licenses in the chemical, electronics, and medical device industries. Thus, contrary to the assertions made in the NPR, the incentives described in the NPR are neither "unique" to the pharmaceutical industry, nor are exclusive patent licenses with retained manufacturing rights limited to the pharmaceutical industry.

B. Structure of Pharmaceutical Technology Licenses Are Not Unique to the Pharmaceutical Industry

17. The NPR's suggestion that there are aspects of technology licenses that are unique to the pharmaceutical industry both in form and motivation is incorrect in my experience.[27] The NPR states:

> In the pharmaceutical industry, a licensor also often retains co-rights in granting an exclusive license. Co-rights cover the shared responsibility for seeing the licensed product through the Food and Drug Administration ("FDA") approval process and then marketing and promoting the product. For example, the licensee is granted the exclusive right to make, use and sell a product, but the patent holder retains the right to co-develop and co-market the product along with the licensee. The licensor generally retains co-rights to assist the licensee in maximizing the licensee's sales of the licensed product so that the licensor might have a more robust royalty revenue stream or other revenue sharing arrangement.[28]

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http://www.americanchemistry.com/ProductsTechnology/Rigorous-Federal-Approval-Process-Exists-for-New-Chemicals.pdf

[26] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50059.

[27] *E.g.*, "As a result of these unique incentives and because, in the PNO staff's experience, these arrangements have been limited to the pharmaceutical industry…," Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50059.

[28] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50059.

18. As I address above, the prevalence of regulatory approval factors is not unique to the pharmaceutical industry. Several non-pharmaceutical industries face rigorous regulatory approval regimes, often involving numerous federal agencies, not just the FDA. Regarding the incentive to include "co-rights" to co-develop and co-market the licensed products, basic economic principles would suggest that a licensor, regardless of industry, will commit incremental resources (or costs) up to the point that the resulting incremental benefits are equal (*i.e.*, following the basic microeconomic principle that profit maximization occurs when marginal benefits equal marginal costs).

19. One measure of the added efforts a licensor will take to maximize its profits is the frequency with which "know-how" is included in patent licenses. "Know-how" often includes information about development of the patented technology, manufacturing expertise, and market/commercialization analyses of patented products. Patent licenses that include "know-how" often include obligations for the licensor to provide staff and resource support to assist the licensee in product development, commercialization, and marketing.

20. Based on my review of technology licenses, almost two-thirds of all patent licenses filed as material exhibits with the SEC include the transfer of technology "know-how," whereas only one-third of patent licenses are limited to only a grant of bare patent rights.[29] This ratio of patent plus know-how licenses versus bare patent licenses is approximately the same among pharmaceutical patent licenses as it is among non-pharmaceutical patent licenses. Thus, as measured by the inclusion of technology know-how, patent licenses in the pharmaceutical industry are similar to patent licenses in the non-pharmaceutical industry.

[29] Varner, Thomas R., "An Economic Perspective on Patent Licensing Structure and Provisions," *Business Economics*, Vol. 46 (4), October 2011. Also see, Thomas R. Varner, "Technology Royalty Rates in SEC Filings," *les Nouvelles*, Journal of the Licensing Executives Society International, Vol. XLV, No. 3, September 2010, pp. 120-127.

21. Furthermore, the NPR states, "Given its financial investment, the [pharmaceutical industry] licensee wants the exclusive right to as much of these profits as possible to recoup its costs. The result is an exclusive license agreement that is, in the PNO's experience, unlike that seen in any other industry."[30] Based on this statement, one would expect to see lower royalty rates for patent licenses in the pharmaceutical industry than in other industries, reflecting the licensee's desire to maximize retained profits. As part of my research of patent licenses I collected royalty rate data from thousands of technology licenses. I observed that the median royalty rates for patent licenses in the pharmaceutical industry are generally similar to median royalty rates found in patent licenses in non-pharmaceutical industries. For example, median running royalty rates (*i.e.*, royalties expressed as a percentage of sales) for bare patent licenses in the pharmaceutical industry were 3.0%, whereas median royalty rates for bare patent licenses were 3.5% in the medical device industry, 3.5% in the computer hardware industry, and 3.0% in the computer software industry.[31]

C. Exclusive Patent Licenses with Retained Manufacturing Rights Are Also Found in Non-Pharmaceutical Industries

22. The NPR states:

> [I]f the licensee was not granted the right to manufacture, but only the rights to use and sell, PNO staff viewed this as a nonreportable event because the license appeared essentially to be a distribution agreement. Yet, in licensing arrangements in the pharmaceutical industry, the right to manufacture is far less important than the right to commercialize. In fact, the right to manufacture is often retained by the licensor who has the relevant manufacturing expertise and facilities. As a result, pharmaceutical companies often enter into licenses in which the licensee receives the exclusive right to use and sell under the license, but the licensor retains the right to manufacture exclusively for the licensee.[32]

[30] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50059.
[31] Varner, Thomas R., "Technology Royalty Rates in SEC Filings," *les Nouvelles*, Journal of the Licensing Executives Society International, Vol. XLV, No. 3, September 2010, pp. 120-127. See Table 1, Running Royalty Rates by Agreement Type and Industry.
[32] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50059.

23. While pharmaceutical companies sometimes do enter into exclusive patent licenses in which the patent holder retains some manufacturing rights, my review of thousands of license agreements submitted to the SEC across many different industries shows that companies in other industries also enter into such agreements. For example, companies in the chemical, electronics, and medical device industries, among others, have entered into exclusive licenses involving patented technology in which the licensor (as the patent rights holder) licenses technology on an exclusive basis and retains manufacturing rights. Below is a sample of license agreements with such provisions:

- Chemical Industry: Licensor IOWC Technologies, Inc., entered into a Master Distributorship Agreement with Food Industry Technologies, Inc. in which IOWC Technologies licensed on an exclusive basis the rights to chemical disinfectant technology and retained the manufacturing rights. [33]
- Chemical Industry: Licensor Donlar Corporation entered into a Market Development and Distributorship Agreement with FMC Corporation (UK) Ltd. in which Donlar licensed on an exclusive basis biodegradable polyaspartic polymer technology and retained the manufacturing rights.[34]

[33] Exhibit 10.14, http://sec.gov/Archives/edgar/data/880242/000119312507102934/dex1014.htm, "1. a. IOWC hereby grants to Newco the exclusive right, on the terms and conditioned herein (as described in Section 4 below), to purchase, inventory, promote and resell Products, (as defined below in Section 2) within defined "Territory" as defined below in Section 3." The agreement covers U.S. Patents 6,146,725 ("Absorbent composition") and 6,328,929 ("Method of delivering disinfectant in an absorbent substrate"). The agreement was filed with the SEC by a licensee registered under SIC Code 2800 (Chemicals and Allied Products), which is listed under NAICS code 28 (Chemicals and Allied Products).

[34] Exhibit 10.6, http://sec.gov/Archives/edgar/data/1047175/0000950124-97-005153.txt, "A. Exclusive Appointment. Under the terms and conditions of this Agreement, DONLAR appoints FMC its sole and exclusive worldwide distributor for the sale of Products in the Field and FMC accepts such appointment. FMC's retention of its exclusive distributor status is conditioned on its purchase from DONLAR of the following quantity of Products...." "B. Technology and Exclusive Rights. DONLAR warrants and represents to FMC that (i) it possesses full rights, title and interest in and to any and all patents, know-how and other property rights in every jurisdiction throughout the world which may be necessary to make, distribute and use the Products in the Field throughout the world (and hereby grants FMC and its customers a license to practice the same throughout the duration of this Agreement),..." The licensor is registered with the SEC under SIC Code 2891(Adhesives & Sealants), which is listed under NAICS code 325520 (Adhesive Manufacturing), and the licensee is registered with the SEC under SIC code SIC: 2800 (Chemicals & Allied Products), which is currently grouped under NAICS code 28 (Chemicals and Allied Products). Donlar Corporation is currently listed as the assignee of 48 U.S. patents on the U.S.P.T.O. website, http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetahtml%2FPTO%2Fsearch-

- Chemical Industry: Licensors Heartland Technology Partners, LLC and Emend, LLC, entered into a License and Supply Agreement with Converted Organics, Inc. in which the licensors licensed on an exclusive basis wastewater concentrators technology and retained the manufacturing rights.[35]
- Chemical Industry: Licensor FT Solutions LLC entered into a Patent and Trademark Agreement with Rentech, Inc., in which FT Solutions licensed on an exclusive basis patented chemical process technologies and retained the catalyst manufacturing rights.[36]
- Electronic Components: Licensor Emcore Corporation entered into a Distributorship Agreement with Hakuto Co. Ltd., in which Emcore licensed on an exclusive basis semiconductor technologies and retained the manufacturing rights.[37]
- Electronic Components: Licensor Sanken Electric Co., Ltd., entered into a Distribution Agreement with Allegro MicroSystems, Inc. in which Sanken licensed on an exclusive basis semiconductor technologies and retained the manufacturing rights.[38]
- Medical Device Industry: Licensor Medi-Ject Corp. entered into an Exclusive License and Supply Agreement with Bio-Technology General Corp ("BTG")

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bool.html&r=0&f=S&l=50&TERM1=donlar+corporation&FIELD1=ASNM&co1=AND&TERM2=&FIELD2=&d=PTXT.

[35] Exhibit 10.35, http://sec.gov/Archives/edgar/data/1366340/000095012310030701/b78730exv10w35.htm. The licensor is registered with the SEC under SIC Code 2870 (Agriculture Chemicals), which is listed under NAICS code 325320 (Pesticide and Other Agricultural Chemical Manufacturing). Heartland Technology Partners is currently listed as the assignee of seven patents on the U.S.P.T.O. website, http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetahtml%2FPTO%2Fsearch-bool.html&r=0&f=S&l=50&TERM1=Heartland+Technology+&FIELD1=ASNM&co1=AND&TERM2=&FIELD2=&d=PTXT.

[36] Exhibit 10.5, http://sec.gov/Archives/edgar/data/868725/000119312504147170/dex105.htm. The licensee is registered with the SEC under SIC Code 2879 (Agriculture Chemicals), which is listed under NAICS code 325320 (Pesticide and Other Agricultural Chemical Manufacturing). There are four U.S. patents licensed from licensor to licensee listed in the agreement including additional U.S. and foreign patent applications.

[37] Exhibit 10.4, "Second Amended and Restated Distributorship Agreement," http://sec.gov/Archives/edgar/data/808326/0000950144-99-006379.txt. The licensor is currently registered with the SEC under SIC 3674 (Semiconductors and Related Devices), which is listed under NAICS code 334413 (Semiconductor and Related Device Manufacturing). Emcore Corporation is currently listed as the assignee of 162 U.S. patents on the U.S.P.T.O. website, http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetahtml%2FPTO%2Fsearch-bool.html&r=0&f=S&l=50&TERM1=emcore+corporation&FIELD1=ASNM&co1=AND&TERM2=&FIELD2=&d=PTXT.

[38] Exhibit 10.7, http://sec.gov/Archives/edgar/data/866291/000095013508001653/b65742a3exv10w7.txt. The licensor is currently registered with the SEC under SIC 3674 (Semiconductors and Related Devices) which is listed under NAICS code 334413 (Semiconductor and Related Device Manufacturing). Sanken Electric Co. is currently listed as the assignee of 355 U.S. patents on the U.S.P.T.O. website, http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetahtml%2FPTO%2Fsearch-bool.html&r=0&f=S&l=50&TERM1=sanken+electric+co&FIELD1=ASNM&co1=AND&TERM2=&FIELD2=&d=PTXT.

in which Medi-Ject licensed on an exclusive basis medical technology (needle-free injector devices) and retained the manufacturing rights.[39]

- Medical Device Industry: Licensor Gebauer Medizintechnik GmbH entered into a Manufacturing, Supply and Distribution Agreement with VisiJet, Inc. in which Gebauer licensed on an exclusive basis ophthalmic surgery apparatus technology and retained the manufacturing rights.[40]
- Medical Device Industry: Licensor Diametrics Medical, Inc. entered into a Distribution Agreement with Hewlett Packard Company in which Diametrics Medical licensed patented optical reflector and sensor technology on an exclusive basis (over a specified period of time) and retained the manufacturing rights. [41]
- Medical Device Industry: Licensor Unique Mobility, Inc. entered into a License Agreement and a Supply Agreement with Invacare Corporation in which Unique Mobility licensed patented motor technology for wheelchairs on an exclusive basis and retained the manufacturing rights.[42]

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[39] Exhibit 10.4, http://sec.gov/Archives/edgar/data/1016169/0001045969-00-000229.txt. "3.1 Medi-Ject hereby grants to BTG the Exclusive and sublicensable right in the Field in the Territory, under the Patent Rights and Medi-Ject Know How and Improvements only for the Field, to use, have used, sell and have sold, but not manufacture, the Device(s) in the Territory for the Term of this Agreement...4.1 Medi-Ject agrees to Exclusively supply and BTG agrees to purchase all its requirements of Device(s) in the Field and in the Territory from Medi-Ject for an initial term of the longer of five (5) years following the First Commercial Sale of a Device(s) in the Field in the Territory or expiration of the last material Patent Right coverage for Device(s)." The agreement was filed by a firm registered with the SEC under SIC Code 3841 (Surgical & Medical Instruments), which is listed under NAICS code 339113 (Surgical Appliance and Supplies Manufacturing). The agreement lists 13 U.S. patents as well as additional patent applications.

[40] Exhibit 10.10, http://sec.gov/Archives/edgar/data/1082249/000101968704001855/visijet_10qex10-10.txt. (Unredacted form of agreement obtained from the SEC under the Freedom of Information Act.) "2.1 EXCLUSIVE RIGHTS; CONSIDERATION. Subject to the terms and conditions of this Agreement including, without limitation, the closing conditions set forth in Section 18.10 hereof, Gebauer shall appoint VisiJet as Gebauer's exclusive distributor as of the Effective Date to market, sell and distribute the Products throughout the World ("Territory") during the Term..." The agreement was filed with the SEC by a licensee registered with the SEC under SIC Code 3841 (Surgical & Medical Instruments), which is currently NAICS code 339113 (Surgical Appliance and Supplies Manufacturing). The agreements lists U.S. patent No. 6,071,293, titled, "Automatic microkeratome."

[41] Exhibit 99.1, http://sec.gov/Archives/edgar/data/895380/0001045969-99-000562.txt. (Unredacted form of agreement obtained from the SEC under the Freedom of Information Act.) Ten U.S. patents are listed in agreement in addition to technology covered by foreign patents and foreign patent applications (from Appendix to agreement labeled "Exhibit 7.8 PATENT PORTFOLIO FOR NEOTREND AND PARATREND U.S."). The agreement was filed with the SEC by a licensee registered with the SEC under SIC Code 3841 (Surgical & Medical Instruments), which is listed under NAICS code 339113 (Surgical Appliance and Supplies Manufacturing).

[42] Exhibit 20.20 (License Agreement) http://sec.gov/Archives/edgar/data/315449/000089973302000027/licenseredacted.htm (Exhibit 10.19 (Supply Agreement) http://sec.gov/Archives/edgar/data/315449/000089973302000027/supplyredacted.htm. Agreement refers "Licensed Patents" without specifically listing the patents. The U.S. Patent and Trademark Office website lists 11 U.S. patents assigned to Unique Mobility as of 10/18/12, http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetahtml%2FPTO%2Fsearch-bool.html&r=0&f=S&l=50&TERM1=unique+mobility&FIELD1=ASNM&co1=AND&TERM2=&FIELD2=&d=PTXT. The licensor registered with the SEC under SIC Code 3679 (Electronic Components, NEC) and the licensee

D. The Importance of Manufacturing/Process Technology in the Pharmaceutical Industry

24. The NPR does not elaborate on its assertion that, "in licensing arrangements in the pharmaceutical industry, the right to manufacture is far less important than the right to commercialize."[43] For example, the NPR provides no comparison of manufacturing costs (or cost of goods sold) across pharmaceutical and non-pharmaceutical industries or even a discussion of how or why such costs vary between different NAICS codes within the NPR's definition of the "pharmaceutical industry." In my experience and research, the right to manufacture in pharmaceuticals can be important. This is illustrated by, among other things, the number of licensed patents associated with pharmaceutical or biologic manufacturing processes and technologies. Pharmaceutical products can be based on a number of patented technologies aside from patents covering the active ingredient(s), including patents based upon development, testing, process, and manufacturing technologies, among others.

25. In my study of technology licenses submitted to the SEC in the pharmaceutical industry I have found a number of agreements that refer to "manufacturing patents" or "process patents." The following are examples of licenses submitted to the SEC from parties registered under SIC code 2843 (which corresponds to NAICS code 325412 (Pharmaceutical Preparation Manufacturing)) which include a grant of manufacturing, process, or production patents:

- Alkermes, Inc. entered into a License and Collaboration Agreement with Cephalon, Inc. in which "Alkermes Manufacturing Patents" are specified.[44]

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registered with the SEC under SIC code 3842 (Orthopedic, Prosthetic & Surgical Appliances & Supplies), which is listed under two NAICS codes 334510 (Electromedical and Electrotherapeutic Apparatus Manufacturing) and 339113 (Surgical Appliance and Supplies Manufacturing).

[43] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50059.

[44] Exhibit 10.5(a), http://www.sec.gov/Archives/edgar/data/873364/000110465905037892/a05-12700_1ex10d5a.htm .

- Amgen Inc. entered into a License and Commercialization Agreement with InterMune Pharmaceuticals, Inc. in which "Manufacturing Patents" are specified.[45]
- Archemix Corp. entered into a License Agreement with Isis Pharmaceuticals, Inc. in which "Isis Manufacturing Patents" are specified.[46]
- Eli Lilly and Company entered into a Collaboration Agreement with Isis Pharmaceuticals, Inc. in which "Isis Manufacturing Patents," "Isis Core Technology Patent Rights," "Isis Blocking Patent Rights," and "Isis ASO Compound Patent Rights" are specified.[47]
- Genentech, Inc. entered into a License Agreement with Sensus Drug Development Corporation in which "Manufacturing Patents" are specified.[48]
- Orion Corporation entered into a License and Supply Agreement with GTX Inc. in which "Manufacturing Patents" are specified.[49]
- Regulus Therapeutics LLC entered into a Product Development and Commercialization Agreement with Glaxo Group Limited in which "Manufacturing Patents" are specified.[50]
- Threshold Pharmaceuticals Inc. entered into an Agreement with Baxter International Inc. in which "Manufacturing Patents" are specified.[51]
- Nitto Boseki Co., Ltd. entered into a License Agreement with GelTex Pharmaceuticals, Inc. in which "process Patents" are specified.[52]
- Northwest Biotherapeutics, Inc. entered into a Collaboration Agreement with Medarex, Inc. in which "Production Process Patents" are specified.[53]
- Merck & Co., Inc. entered into an Asset Transfer and License Agreement with Guilford Pharmaceuticals Inc. in which "Process Patents" are specified.[54]
- Avalon Pharmaceuticals, Inc. entered into a Collaboration Agreement with Mederex, Inc. in which "Production Process Patents" are specified."[55]
- Janssen Pharmaceuticals, NV entered into a License Agreement with Theravance, Inc. in which "Process Patents" were specified.[56]

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[45] Exhibit 10.39, http://www.sec.gov/Archives/edgar/data/1087432/000091205701526560/a2055229zex-10_39.htm.
[46] Exhibit 10.45, http://sec.gov/Archives/edgar/data/927829/000095013508008330/b72987s4exv10w45.htm.
[47] Exhibit 2.4 http://www.sec.gov/Archives/edgar/data/874015/000091205701530761/a2058321zex-2_4.txt.
[48] Exhibit 10.7, http://www.sec.gov/Archives/edgar/data/949175/0001012870-98-001904.txt.
[49] Exhibit 10.15, http://www.sec.gov/Archives/edgar/data/1260990/000095012303011376/g85196exv10w15.txt.
[50] Exhibit 10.2, http://sec.gov/Archives/edgar/data/874015/000110465908051496/a08-18933_1ex10d2.htm.
[51] Exhibit 10.6, http://www.sec.gov/Archives/edgar/data/1183765/000119312504059933/dex106.htm.
[52] Exhibit 10.21, http://www.sec.gov/Archives/edgar/data/1001425/0000950135-97-003389.txt.
[53] Exhibit 10.2, http://www.sec.gov/Archives/edgar/data/1072379/000109581101505498/v74443a1ex10-2.txt.
[54] Exhibit 2.01, http://www.sec.gov/Archives/edgar/data/918066/000095013303003831/w91648exv2w01.txt.
[55] Exhibit 10.3, http://www.sec.gov/Archives/edgar/data/1162192/000095013305001884/w07623exv10w3.htm.
[56] Exhibit 10.16, http://www.sec.gov/Archives/edgar/data/1080014/000104746904020116/a2136994zex-10_16.htm.

26. In addition to including "manufacturing" and "process" patents in technology licenses, licenses in the pharmaceutical industry may also include grants to "manufacturing know-how." The following description of "manufacturing know-how" is from a Collaboration Agreement between GelTex Pharmaceuticals, Inc. and Genzyme Corporation:

> "MANUFACTURING KNOW-HOW" shall mean all information, techniques, inventions, discoveries, improvements, practices, methods, knowledge, skill, experience and other technology, whether or not patentable or copyrightable, and any patent applications, patents or copyrights based thereon, relating to or necessary or useful for the production, packaging, storage and transportation of Collaboration Products, including without limitation manufacturing processes developed by Abbott and Dow Chemical pursuant to the Abbott Agreement and the Dow Research Agreement, respectively, specifications, acceptance criteria, manufacturing batch records, standard operating procedures, engineering plans, installation, operation and process qualification protocols for equipment, validation records, master files submitted to the FDA, process validation reports, environmental monitoring processes, test data including pharmacological, toxicological and clinical test data, cost data and employee training materials.[57]

27. The following examples highlight the importance of "manufacturing patents" and "manufacturing know-how" to the production of pharmaceutical products (examples are from licenses submitted to the SEC from parties registered under SIC code 2834, which corresponds to NAICS code 325412 (Pharmaceutical Preparation Manufacturing)):

- Celgene Corporation entered into a License Agreement with Pharmion GmbH in which "CELGENE TECHNOLOGY" shall mean data, manufacturing know-how, regulatory submissions and other intellectual property."[58]
- Alkermes, Inc. entered into a License and Collaboration Agreement with Cephalon, Inc. in which "Manufacturing Know-How" is specified.[59]

[57] Exhibit 10.18, http://www.sec.gov/Archives/edgar/data/1001425/0000950135-97-003389.txt
[58] Exhibit 10.36, http://sec.gov/Archives/edgar/data/816284/000093041306002083/c41166ex_10-36.txt.
[59] Exhibit 10.5(a), http://www.sec.gov/Archives/edgar/data/873364/000110465905037892/a05-12700_1ex10d5a.htm.

- DURECT Corporation entered into a Development and License Agreement with Pain Therapeutics, Inc. in which "manufacturing know-how" is specified.[60]
- Arrow Therapeutics Limited entered into a Collaboration and License Agreement with Triangle Pharmaceuticals, Inc. in which "manufacturing know-how" is specified.[61]
- Boehringer Ingelheim International GmbH entered into a License Agreement with BioMedicines, Inc. in which "Manufacturing Know-How" is specified.[62]
- Novartis International Pharmaceutical Ltd. entered into a License Agreement with NexMed, Inc. in which "Manufacturing Know-How" is specified.[63]

28. Furthermore, the proposed rules' definition of the "pharmaceutical industry" includes "biological products"[64] in which manufacturing processes play an especially important role. The FDA defines therapeutic biological products as "generally derived from living material—human, animal, or microorganism—[that] are complex in structure, and thus are usually not fully characterized."[65] In describing the manufacturing processes of biological products the FDA states, "In some cases, manufacturing changes could result in changes to the biological molecule that might not be detected by standard chemical and molecular biology characterization techniques yet could profoundly alter the safety or efficacy profile. Therefore,

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[60] Exhibit 10.34, http://www.sec.gov/Archives/edgar/data/1082038/000101287003001183/dex1034.htm.
[61] Exhibit 10.3, http://www.sec.gov/Archives/edgar/data/1022622/000100547700007851/0001005477-00-007851-0004.txt.
[62] Exhibit 10.6, http://www.sec.gov/Archives/edgar/data/1086688/000091205700047085/a2027448zex-10_6.txt.
[63] Exhibit 99.1, http://www.sec.gov/Archives/edgar/data/1017491/000114420405028876/v025708_ex99-1.htm.
[64] Federal Register, Vol. 77, No. 161, 8/20/12, Proposed Rules, p. 50061. NAICS Industry Group 3254 includes 325414 Biological Product (except Diagnostic) Manufacturing.
[65] http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm113522.htm. "As mentioned above, biologics are subject to provisions of both the FD&C Act and the PHS Act. Because of the complexity of manufacturing and characterizing a biologic, the PHS Act emphasizes the importance of appropriate manufacturing control for products. The PHS Act provides for a system of controls over all aspects of the manufacturing process. In some cases, manufacturing changes could result in changes to the biological molecule that might not be detected by standard chemical and molecular biology characterization techniques yet could profoundly alter the safety or efficacy profile. Therefore, changes in the manufacturing process, equipment or facilities may require additional clinical studies to demonstrate the product's continued safety, identity, purity and potency." For this reason, the industry frequently refers to "small molecule" drugs (more conventional pharmaceutical preparations) as distinct from "large molecule" drugs (biological preparations).

changes in the manufacturing process, equipment or facilities may require additional clinical studies to demonstrate the product's continued safety, identity, purity and potency."[66]

29. The FDA even highlights the importance of manufacturing process in its review and approval for biosimilar products, that is, third-party, follow-on versions of therapeutic biological products: "The implementation of an abbreviated licensure pathway for biological products can present challenges given the scientific and technical complexities that may be associated with the larger and typically more complex structure of biological products, as well as the processes by which such products are manufactured."[67] Thus, manufacturing processes play an especially important role in this sector of the pharmaceutical industry.

V. CONCLUSION

30. In my opinion, the explanations provided in the NPR for the proposed HSR rules' application to only the pharmaceutical industry are not supported by evidence. In fact, based upon my experience, the NPR's rationales for focusing solely on the pharmaceutical industry are contrary to the realities of patent licensing incentives and practices across industries. For these reasons, as discussed in more detail above, I do not believe there is a good factual basis for distinguishing the pharmaceutical industry in the manner suggested by the NPR.

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66 http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm113522.htm.

67 http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm113522.htm.

I hereby declare under the penalty of perjury that the foregoing declaration is true and correct to the best of my personal knowledge.

_____ 10/25/12

Thomas R. Varner, Ph.D. Date

Exhibit 1

THOMAS R. VARNER, Ph.D.

Office Address

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Education

1992 – 1997 **Stanford University,** Stanford, CA
Ph.D., *Engineering-Economic Systems & Operations Research*

1980, 1987 **University of California, Berkeley,** Berkeley, CA
M.S. *Civil Engineering,* ***MBA***

1975 – 1979 **California Polytechnic State University,** San Luis Obispo, CA
B.S. *Architecture, with Honors*

Work Experience

Vice President, Economists Incorporated, San Francisco, CA
April 2010 – Present

Principal, Cornerstone Research, Inc., San Francisco, CA
January 2002 – April 2010

Lecturer (Economics and Finance), Economics Department, University of California, Davis, CA
January 2004 – March 2005

Manager (Financial Advisory Services), PricewaterhouseCoopers LLP, San Francisco, CA
April 2001 – November 2001

Managing Director Investment & Risk Analytics, Inc.,Lafa yette, CA
September 1997 – April 2001

Work Experience (continued)

Consulting Researcher (Valuation of Financial Instruments), Prof. Darrell Duffie, Graduate School of Business, Stanford University, Palo Alto, CA
September 1994 – September 1997

Teaching Assistant and Research Assistant,De partment of Engineering-Economic Systems, Stanford University, Stanford, CA
September 1993 – September 1997

Engineering Manager, Dames & Moore, San Francisco, CA
June 1989 – September 1993

Project Manager, Forell/Elsesser, Rutherford & Chekene and Paul F. Fratessa & Assoc., San Francisco, CA
June 1980 – June 1989

Expert/Testimony

2012: *Intellectual Ventures I LLC v. Check Point Software Technologies Ltd., et al.*, U.S. District Court, Delaware, 1:10-cv-01067-LPS. Durie Tangri, San Francisco, CA.Economi cs and damages expert in patent infringement suit involving Internet technology.

2012: *TransUnion Intelligence LLC, et al. v. Search America, Inc.*, U.S. District Court, District of Minnesota, 0:11-cv-01075-PJS-LFN. Baker Hostetler, Costa Mesa, CA. Economics expert in patent infringement suit involving software technology.

2012: *Light Guard Systems, Inc vs Spot Devices, Inc.*, U.S. District Court, District of Nevada, 3:10-cv-00737-LRH –WGC. Alston & Bird LLP, Menlo Park, CA. Economics expert in patent infringement suit involving transportation technology.

2011-2012: *Arkema Inc., et al. v. Honeywell International, Inc.*, U.S. District Court, Eastern District of Pennsylvania , 2:10-cv-02886-WY. Kirkland & Ellis LLP, Washington, DC. Economics expert in patent suit (declaratory judgment and counterclaim patent infringement suit) involving chemical product.

2009-2010: *Angela Bates, et al. v. KB Home,* Superior Court of California, County of Alameda, RG-08- 384954. K&L Gates LLP, San Francisco, CA. Provided declaration addressing the validity of sampling and statistical analysis of escrow instructions performed by plaintiffs related to class certification of a set of home buyers in California.

Expert/Testimony (continued)

2009: *In re Patent of Hee Young Yun, et al.,* U.S. Patent and Trademark Office, 90/008, 143, 145, 146, and 150. McKenna Long & Aldridge LLP, Washington, DC. Provided declaration addressing economic issues related to claimed commercial success of patents for liquid crystal display (LCD) modules as part of patent reexamination process.

2007-2008: *Quantum Systems Integrators, Inc. v. Sprint Nextel Corp.,* U.S. District Court, Eastern District of Virginia, 1:07-CV-00491. Crowell & Moring LLP, Washington, DC. Provided expert report, deposition testimony, and testified at trial on economic damages arising out of alleged infringement of copyrighted software.

2007: *Alvarado Hospital Medical Center, Inc. v. Alan Wittgrove, M.D.,* Superior Court of California, County of San Diego, GIC 827726. C. Matthew Didaleusky, Esq., Oakland, CA. Provided testimony at arbitration hearing on economic damages arising out of alleged breach of contract.

2007: *SCI California Funeral Services, Inc. v. Five Bridges Foundation,* Superior Court of California, County of San Mateo, CIV 432392. Shartsis Friese LLP, San Francisco, CA.P rovided deposition testimony on economic issues related to valuation of provisions in real estate agreement.

2006-2007: *DVD Copy Control Association, Inc. v. Kaleidescape, Inc.*, Superior Court of California, County of Santa Clara, 104CV031929. White & Case LLP, Palo Alto, CA. Provided deposition testimony on economic damages arising out of alleged breach of contract by licensee of proprietary DVD technology.

2005: *Confidential Real Estate Co. v. Confidential Law Firm*, private arbitration. Nixon Peabody LLP, San Francisco, CA. Provided expert report, deposition testimony, and testified at arbitration on economic damages related to valuation of multiple appraisals for real estate leasehold contract.

2005: *Poway RHF Housing, Inc. v. Irwin Pancake Architects, et al.*, Superior Court of California, County of Orange, 04CC09795. Hinshaw & Culbertson LLP, San Francisco, CA. Designated expert on economic damages arising out of alleged breach of contract and professional negligence against architect, and resulting in delayed opening of senior assisted living facility.

2003: *Eco-Steel Fabrication, Inc. v. Markol Iron, et al.*, Superior Court of California, County of Orange. Miller, Brown & Dannis, San Francisco, CA. Provided expert report and testified at mediation on economic damages resulting from delayed construction of luxury car dealership in southern California.

Selected Matters

2012: *Noven Pharmaceuticals v. Watson Laboratories, et al.* U.S. District Court, District of New Jersey, 2:11-cv-05997-DMC –MF. Brinks Hofer Gilson & Lione, Chicago, IL. Economic analysis of the commercial success of Daytrana methylphenidate transdermal system.

2012: Confidential. McKool Smith, Los Angeles, CA. Analysis of economic damages in patent infringement suit involving Internet technology.

2011-2012: *Thermal Design, Inc. v. American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc.* U.S. District Court, Eastern District of Wisconsin, 07-c-0765-WEC. von Briesen & Roper, s.c., Milwaukee, WI. Economic analysis of competitive issues related to industry standards established for insulation used in non-residential, pre-engineered metal buildings.

2011-2012: *Warner Chilcott Laboratories Ireland, Ltd. et al. v. Mylan Pharmaceuticals Inc. et al.* U.S. District Court, District of New Jersey, 2:09-cv-02073-WJM-MF. Wilson, Sonsini, Goodrich & Rosati, Palo Alto, CA. Analysis of economic issues related to the market for doxycycline hyclate delayed-release tablets and effects of proposed preliminary injunction.

2011-2012: *Abbott Laboratories et al. v. Impax Laboratories, Inc.* U.S. District Court, District of New Jersey, 210-cv-01322-DMC-JAD. Wilson, Sonsini, Goodrich & Rosati, San Diego, CA. Economic analysis of the commercial success of Abbott Laboratories' introduction and sale of TRILIPIX® (branded fenofibric acid delayed-release 45 mg and 135 mg capsules).

2011: Confidential. Hennigan Dorman LLP, Los Angeles, CA. Analyzed economic damages in patent infringement suit involving wireless communication technology.

2010: *Kenneth D. Klaas et al. v. Vestin Mortgage, Inc. et al.*, Eighth Judicial District Court In and For Clark County, State of Nevada, A528385.Gibson, Dunn & Crutcher LLP, Palo Alto, CA. Analyzed economic damages arising from merger of real estate investment funds into real estate investment trusts (REITs).

2010: *In Re: Outsidewall Tire*, U.S. District Court, Eastern District of Virginia, 1:09cv1217. Gilbert LLP, Washington, DC. Analyzed economic issues in misappropriate of trade secret, copyright infringement, and trademark infringement matter involving specialty tires.

2010: Confidential. Morgan, Lewis & Bockius LLP, Washington, DC. Retained on behalf of an international computer design firm to research and analyze Internet encryption technology license agreements.

Selected Matters (continued)

2009-2010: Confidential, ICC International Court of Arbitration Proceeding. Morrison & Foerster LLP, San Francisco, CA.A nalyzed fiduciary duties among co-investors in an Asia-based financial institution in relation to private equity industry customs and practices.

2009: *Jasmine Networks, Inc. v. Marvell Semiconductor, Inc., et al.*, Superior Court of California, County of Santa Clara, No. CV801411.Latham & Watkins LLP, San Francisco, CA.Ana lyzed economic damages arising out of alleged misappropriation of trade secrets, breach of fiduciary duty, and breach of contract.

2009: *Fujitsu Limited et al. v. Netgear, Inc.*, U.S. District Court, Western District of Wisconsin, 3:07-CV- 00710-BBC, O'Melveny & Myers LLP, San Francisco, CA. Provided economic and licensing analysis for patent infringement suit involving wireless Internet products.

2009: Confidential. Carmody & Torrance LLP, New Haven, CT. Retained by manufacturing company in printing industry to examine economic issues and damages arising out of patent infringement suits and antitrust counterclaims.

2009: Confidential. Retained by developer of risk analysis software to analyze damages arising out of alleged breach of contract involving joint development agreement.

2009: *Mosaic Systems, Inc. v. Cisco Systems, et al. & Mosaic Systems, Inc. v. Andreas Bechtolsheim, et al.*, Superior Court of California, County of Santa Clara, Nos. 104CV016867 &106CV072920. Morgan, Lewis & Bockius LLP, San Francisco, CA.Ana lyzed performance of board members' fiduciary duties in relation to customs and practices for board members of high-tech startup companies.

2008: Confidential. Retained by electronics firm to examine industry-wide licensing practices related to fees, royalties, and other licensing terms for discrete electronic components.

2008: *Rambus, Inc. v. Samsung Electronics Co., Ltd., et al.*, U.S. District Court, Northern District of California, No. C0502298 RMW. Munger, Tolles & Olson LLP. Analyzed economic issues related to structure of licensing terms among agreements for semiconductor technology.

2008: *Verizon Services Corp., et al. v. Cox Fibernet Virginia, Inc., et al.*, U.S. District Court, Eastern District of Virginia, No. 2:08 CV20-JBF/TEM. Kilpatrick Stockton LLP, Washington, DC. Analyzed economic damages from alleged infringement of patents related to Voice over Internet Protocol (VoIP) technology.

Selected Matters (continued)

2008: *Beal Bank, S.S.B, et al. v. WestPoint International, Inc.*, Court of Chancery of the State of Delaware in and for New Castle County, Civil Action No. 2617-CC. Hennigan, Bennett & Dorman LLP, Los Angeles, CA. Analyzed financial and economic effects on the bondholders of a series of actions taken by defendants related to issuance of preferred shares and changes in corporate governance.

2008: *Stamps.Com Inc., vs. Endicia Inc. and PSI Systems, Inc.*,U. S. District Court Central District of California, No. CV06-07499 ABC (CTx). Sheppard Mullin Richter & Hampton LLP, Los Angeles, CA. Analyzed economic damages from alleged infringement of patents related to automated postage systems.

2007-2008: *United States ex rel. J. Richard West et al. v. Timex Corp.,* U.S. District Court, District of Connecticut, No. 3:04-CV-212 (JBA). Carmody & Torrance LLP, New Haven, CT. Analyzed price of watch products sold to U.S. Service Exchanges in alleged violation of Civil False Claims Act.

2007-2008: *Ronald A. Katz Technology Licensing LP v. General Electric Capital Corp., et al.*, U.S. District Court, Eastern District of Texas, No. 9:06-CV-197-RHC. Hennigan, Bennett & Dorman LLP, Los Angeles, CA. Analyzed economic damages from alleged infringement of patent portfolio related to interactive call processing technology.

2007-2008: North Shore City Council, Auckland, New Zealand.Consult ing engagement related to economic analysis of allocation between different constituencies of construction costs for capital expansion of public transportation system.

2007-2008: *BP Chemicals Ltd. v. Jiangsu SOPO Corporation (Group) Ltd., et al.*, United States District Court, Eastern District of Missouri, No. 4:99-CV-00323 CDP. Paul, Hastings, Janofsky & Walker LLP, San Francisco, CA. Analyzed economic damages from alleged misappropriation of trade secrets related to acetic acid manufacturing technology.

2007-2009: *Lawrence J. Torango v. Aristocrat Leisure Ltd., et al.*, U.S. District Court, District of Nevada, CV-N-03-0690-HDM-VPC. McDermott Will & Emery, Palo Alto, CA. Analyzed economic damages from alleged breach of contract, misappropriation of trade secrets and infringement of patent related to gaming machine technology.

2006-2007: *Asyst Technologies, Inc. v. Jenoptik AG, et al.*, U.S. District Court, Northern District of California, C98-20451 JF. Fenwick & West LLP, San Francisco, CA.Ana lyzed price erosion damages associated with alleged patent infringement of semiconductor manufacturing products and processes.

Selected Matters (continued)

2006-2007: *In Re Methyl Tertiary Butyl Ether ("MTBE") Products Liability Litigation*, U.S. District Court, Southern District of New York, MDL 1358 (SAS) M21-88. Kirkland & Ellis LLP, Chicago, IL.Ana lyzed economic consequences to oil companies of switching from MTBE-based to Ethanol based oxygenated and reformulated gasoline over the period 1995 to 2003.

2006-2009: *MacSolutions, Inc. v. Apple Computer, Inc.*, Superior Court of California, County of Santa Clara, 1-06-CV-056547.La tham & Watkins LLP,

San Francisco, CA. Analyzed economic damages related to alleged breach of contract and misappropriation of trade secrets, among other claims, between independent resellers of Apple products and Apple Computer.

2006: Fairchild Semiconductor, consulting engagement. Orrick, Herrington & Sutcliffe LLP, Menlo Park, CA. Prepared opinion letter addressing potential damage award from pending patent infringement litigation related to the acquisition of a target company by Fairchild Semiconductor.

2006: *H&R Block Eastern Enterprises, Inc., et al. v. Intuit, Inc.*, U.S. District Court, Western District of Missouri, 06-0039-CV-W-SOW. Quinn Emanuel Urquhart Oliver & Hedges, LLP, Redwood City, CA. Analyzed economic damages in original claim and subsequent counterclaim from alleged trademark infringement, false advertising, and fraudulent and negligent misrepresentations related to tax preparation software advertisements.

2006: *In the Matter of: Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, U.S. International Trade Commission, 337-TA. Paul, Hastings, Janofsky & Walker LLP, Washington, DC. Analyzed existence of domestic market for clear orthodontic products on behalf of claimant under Section 337 of Tariff Act of 1930. Claimant alleged patent infringement and trade secret misappropriation.

2006: *Jinro Industries Co., Ltd., v. Obyan Beach Resorts Associates, L.P.*, Superior Court of California, County of San Mateo, CIV436382. Calvo & Clark LLP, San Francisco, CA.Ana lyzed economic damages from alleged breach of contract between partners in a resort in Saipan, CNMI.

2006: *CollegeNET, Inc. v. Xap Corp.*, U.S. District Court, District of Oregon, 03-1229-BR. Fenwick & West LLP, Mountain View, CA. Analyzed economic damages from alleged infringement of patent related to on-line college application software.

Selected Matters (continued)

2006: *The People of the State of California v. Union Bank of California, N.A., et al.*, Superior Court of California, County of Sacramento, 04AS01296. Heller Ehrman LLP, San Francisco, CA. Analyzed economic damages from alleged submittal of false unclaimed property (escheatment) reports related to municipal bonds funds.

2005: *Trust Created Under the Will of Samuel Mills Damon, Deceased*, P. No. 6664 Equity No. 2816-A.J ohn L. McDermott (attorney for Petitioner), Honolulu, HI. Evaluated strategic alternatives and disposition of California and Hawaii real estate assets of trust.

2005-2006: *TiVo, Inc. v. EchoStar Communications Corp., et al.*, U.S. District Court, Eastern District of Texas, 2-04cv01 (DF).Morrison & Foerster LLP, San Francisco, CA.Ana lyzed economic damages from alleged infringement of patent related to digital video recorders.

2005-2006: *James and Lisa Camenson, et al., v. Milgard Manufacturing, Inc., et al.*, Superior Court of California, County of Solano, FCS-021177. Sedgwick, Detert, Moran & Arnold LLP, and Heller Ehrman LLP, San Francisco, CA. Supported economics and marketing experts in opposition to class certification in alleged defective aluminum window litigation.

2005-2006: *LG.Philips LCD Co., Ltd. v. Tatung Co. of America, et al.*, U.S. District Court, Central District of California, 02-6775 CBM LTLx. Morgan, Lewis & Bockius LLP, Philadelphia, PA. Analyzed economic damages from alleged infringement of patents related to liquid crystal display panels.

2005: Consulting assignment for Perkins Coie LLP. Performed statistical analysis of patent case terminations in U.S. District Court, Eastern District of Texas.

2004-2005: *Medtronic Vascular, Inc., et al. v. Advanced Cardiovascular Systems, Inc., et al.*, U.S. District Court, District of Delaware, CIV 98-80-SLR. McDermott, Will & Emery, Irvine, CA. Analyzed economic damages from alleged theft of trade secrets and infringement of patents related to cardiovascular and peripheral stents.

2004-2005: *United States v. Arnold Bengis, et al.*, U.S. District Court, Southern District of New York, 03 Crim. 308 (LAK). Morvillo, Abramowitz, Grand, Iason & Silberberg, P.C., New York, NY. Analyzed restitution damages to South African Government arising out of overcatches of South Coast and West Coast rock lobsters.

Selected Matters (continued)

2004-2005: *Liveworld, Inc. v. SocialNet, Inc. and MatchNet PLC, et al.*, Superior Court of California, County of Santa Clara.Lev y, Small & Lallas, Los Angeles, CA. Performed database valuation, domain name valuation, alter ego analysis, and lost profits analysis associated with breach of contract between two Internet dating companies.

2004: *Big West Oil Company, Travel Plaza LLC, and Flying J, Inc., v. ConocoPhillips Company, et al.*, American Arbitration Association, 77-198-00303-03 VSS. Gibson, Dunn & Crutcher LLP, Denver, CO. Analyzed retail diesel fuel pricing strategies of truck plaza operators for company valuation.

2004: *United States v. Intangible Property Rights in 958 Acres (Yuma Mesa Irrigation and Drainage District)*, U.S. District Court, District of Arizona, CIV-02-0560-PHX (SRB), U.S. Department of Justice, Washington, DC. Analyzed lost revenue from the federal government's acquisition of an irrigation district's land in Arizona.

2004: *Network Caching Technology, LLC v. Novell, Inc., et al.*, U.S. District Court, Northern District of California, CV-01-2079 (VRW). Jones Day, Los Angeles, CA. Analyzed economic damages due to alleged infringement of patent related to Internet caching network technology.

2004: *Software AG, et al. v. BEA Systems, Inc.*, U.S. District Court, District of Delaware. Morrison & Foerster LLP, San Francisco, CA. Analyzed economic damages due to alleged infringement of patent related to business integration software.

2003-2004: *MediaTek, Inc. v. Via Technologies, Inc., et al.*, U.S. District Court, Central District of California, 02-05016 DSF (RNBx). Fenwick & West LLP, Mountain View, CA. Analyzed economic damages due to alleged patent and copyright infringement, and misappropriation of trade secrets of technology related to optical disk drives.

2003-2004: *In re Cardizem CD Antitrust Litigation*, U.S. District Court, 6th Circuit. Berman, DeValerio, Pease, Tabacco, Burt & Pucillo, San Francisco, CA. Analyzed economic damages due to alleged delayed market entry of generic pharmaceutical products.

2003: *Retail Services, Inc. and Freebie, Inc. v. Freebies Publishing, et al.*, U.S. District Court, Eastern District of Virginia, Civ. 02-1111-A. Gibson, Dunn & Crutcher LLP. Analyzed economic damages due to alleged infringement of trademark related to on-line and promotional literature.

Selected Matters (continued)

2003: *MEIE Syndicate Analysis*, Australia Taxation Office and Owens Dixon, Sydney, NSW, Australia. Analyzed economic basis for series of licensing and funding agreements between investors of distributed multimedia computing technology.

2003: *In re Timex Industries, Inc., et al.* U.S. Bankruptcy Court, Central District of California, 03- 16833-MJ, Chapter 11 Proceeding. Levy, Small & Lallas (attorney for creditor), Los Angeles, CA. Analyzed financial viability of building products company in bankruptcy proceeding.

2003: *Dan Gill, et al. v. ExxonMobil Corporation, Inc., et al.*, County Court 4 of Nueces County Texas, 03-60079-4. ExxonMobil in-house counsel, Houston, TX. Analyzed wholesale, DTT, and retail gasoline prices in selected Texas cities in response to alleged breach of contract regarding dealer price rebates.

2003: *Sun Life Assurance Company of Canada v. Golden Eagle Insurance Corporation, et al.*, Private arbitration. Milbank, Tweed, Hadley & McCoy LLP, Los Angeles, CA. Analyzed statistical sampling methodology employed in review of reinsurance treaties associated with a portfolio of Workers' Compensation insurance claims.

2002-2003: *Lawrence J. Knapp and Nicer Technologies, L.P. v. Raymond M. Galas so and Thompson & Knight LLP*, District Court of Tarrant County, Texas, 153-191270-02. Shannon, Grace, Ratliff & Miller LLP, Fort Worth, TX. Analyzed economic damages due to alleged negligence in prosecution of a patent related to testing equipment used to calibrate semiconductor manufacturing devices.

2002: *Macpherson's Inc., et al. v. Windermere Real Estate Services Company, et al.*, U.S. District Court, Western District of Washington, C01-1885P. Deco Law Firm, P.S., Seattle, WA. Assessed validity of plaintiffs' antitrust claims against a franchisor of residential real estate brokerage businesses.

2002: *Raman Froze d.b.a. Wizen Software v. EarthLink Network, Inc., et al.*, Superior Court of the State of California, City and County of San Francisco, 11889-01. Quinn, Emanuel, Urquhart, Oliver & Hedges, LLP, San Francisco, CA. Analyzed economic damages due to alleged breach of contract and misappropriation of software programming code.

2001-2002: *Business Objects, S.A. v. Congas, Inc., et al.*, U.S. District Court, Northern District of California, C 20503. Fenwick & West LLP, Mountain View, CA. Analyzed economic damages due to alleged infringement of patent related to relational database software.

Publications

Varner, Thomas R., "Empirical Data on 'Comparable Licenses' in Patent Infringement Suits," *The Economists Ink*, Fall 2012.

Varner, Thomas R., "An Economic Perspective on Patent Licensing Structure and Provisions," *Business Economics*, Vol. 46 (4), October 2011.

Varner, Thomas R., "Uniloc and the Demise of the 25 Percent Rule," *The Economists Ink*, Spring 2011.

Varner, Thomas R., "Technology Royalty Rates in SEC Filings," *les Nouvelles*, Journal of the Licensing Executives Society International, Vol. XLV, No. 3, September 2010, pp. 120-127.

Varner, Thomas R., "Reasonable Royalties and 'Comparable Licenses': Three Recent Court Rulings," *The Economists Ink*, Spring 2010.

Professional Affiliations

Member, American Economics Association

Member, National Association of Business Economists

Member, American Society of Civil Engineers

Associate Member, American Bar Association (Litigation Section, Real Property Section and Construction Industry Forum)

Other

Speaker on economics, damages and technology licensing issues at Licensing Executives Society (LES), American Law Institute/American Bar Association (ALI/ABA) and Law Seminars International (LSI) seminars and conferences.

Licensed Civil Engineer and Licensed Structural Engineer (Inactive), State of California

Certificate in Hazardous Materials Management, University of California, Davis, 1990

Ph.D. Dissertation: *Strategic Investment Analysis: A Study of Indirect Effects in Optimal Portfolio Selection*, 1997