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April 24, 2014

VIA EMAIL

Mail Stop Comments - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: James Engel, Senior Legal Advisor

Re: Docket No: PTO-P-2013-0040

Dear Mr. Engel,

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America (“PhRMA”) to convey the views of PhRMA’s members in response to the Notice of Proposed Rulemaking on Changes to Require Identification of Attributable Owner.

PhRMA’s members are leading pharmaceutical research and biotechnology companies devoted to researching and developing new medicines to allow patients to live longer, healthier and more productive lives. PhRMA’s members lead the way in finding cures and new treatments as well as in developing critically important improvements in existing therapies. Patent protection is an important incentive to promote the innovative research necessary for such advances and to make available to society the benefits of that research.

The enclosed comments include views of PhRMA’s members on the proposed changes discussed in the notice. PhRMA’s members appreciate the PTO seeking comments in this area, and would welcome further dialogue with the PTO on the proposed changes.

Please feel free to contact me if you have any questions.

Sincerely,



David E. Korn

Enclosure

**Comments of the Pharmaceutical Research and Manufacturers of America in Response
to the PTO's Request for Comments on the Changes to Require Identification of
Attributable Owner**

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to submit comments in response to the Patent and Trademark Office's ("PTO" or "Office") Request for Comments on the Changes to Require Identification of Attributable Owner.¹

PhRMA's member companies are leading research-based pharmaceutical innovators devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA's membership ranges in size from small emerging companies to multi-national corporations that employ tens of thousands of Americans, and encompass both research-based pharmaceutical and biotechnology companies. The U.S. biopharmaceutical sector supported a total of 3.4 million jobs throughout the economy, and directly employed more than 810,000 Americans in 2013.² The industry injects almost \$800 billion in economic output on an annual basis.³

The U.S. biopharmaceutical sector accounts for the single largest share of all U.S. business research and development, representing about one in five dollars spent on domestic research and development by U.S. businesses.⁴ PhRMA member investment in discovering and developing new medicines reached over \$51 billion in 2013.⁵ Medicines developed by the sector have produced large improvements in health across a broad range of diseases, with the rapid growth of biological knowledge creating growing opportunities for continued profound advances against our most complex and costly diseases. Developing a new medicine takes between 10 and 15 years of work and costs an average of over \$1 billion of investment in research and

¹ 79 Fed. Reg. 4105-21 (Jan. 24, 2014).

² Pharmaceutical Research and Manufacturers of America, *PhRMA Profile*, 2014 at ii (citing Battelle Technology Partnership Practice, *The Economic Impact of the U.S. Biopharmaceutical Industry*, Battelle Memorial Institute (Columbus, OH), July 2013.).

³ *Id.* at v.

⁴ Battelle Technology Partnership Practice, *The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and the Factors that Will Drive It*, April 2014.

⁵ Pharmaceutical Research and Manufacturers of America, *PhRMA Profile*, 2014 at ii (citing Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 1981–2013.).

Comments of the Pharmaceutical Research and Manufacturers of America
Docket No: PTO-P-2013-0040
April 24, 2014

development.⁶ Like innovators across the spectrum of American industries, pharmaceutical companies make the substantial R&D investments that yield new medicines in reliance on a legal regime that provides protection for any resulting intellectual property. Our companies rely on patents to protect their inventions and provide an opportunity to recover their research investments. But patents are particularly important to pharmaceutical innovation given the research-intensive nature of this sector and the substantial investment required to discover and develop products that meet FDA approval requirements.⁷

Bringing new life-saving and life-improving products to patients is the central role of our member companies. PhRMA members appreciate the efforts of the PTO to consider the issue of abusive patent litigation. However, the PTO must also provide predictable and reliable patent rights. In our view, the PTO's proposed rulemaking is overly broad and would cause undue burden to the overwhelming majority of patentees that are not involved in such abusive practices.

The PTO has requested comments on proposed changes to require the identification of attributable owners. PhRMA respectfully submits that the proposed rules exceed the authority of the PTO, are overbroad given the PTO's stated objectives, are not tailored to address the PTO's stated concerns regarding patent assertion entities and abusive patent litigation, and cause a burden on patentees that outweighs any putative benefits. Further, the proposed definition of an attributable owner lacks clarity, is potentially over-inclusive depending on its interpretation, and requires a substantial amount of investigation and subjective rule interpretation to ensure compliance. Under certain interpretations, PhRMA is concerned that the rules undermine its ability to uphold licensing agreements that require certain information to be kept confidential. To address these concerns, PhRMA suggests alternative proposals that promote patent ownership transparency while minimizing the burden on legitimate, innovative companies. PhRMA urges the PTO to reconsider its approach such that any proposed rules would alter the penalty for failing to comply with the rules and would not cause an undue burden on innovative companies.

⁶ *Id.* (citing J.A. DiMasi and H.G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?* Managerial and Decision Economics 2007; 28(4-5): 469-479; J. Mestre-Ferrandiz, J. Sussex, and A. Towse, *The R&D Cost of a New Medicine*, London, UK: Office of Health Economics, 2012; S.M. Paul, *et al*, *How to Improve R&D Productivity: The Pharmaceutical Industry's Grand Challenge*, Nature Reviews Drug Discovery 2010; 9: 203-214.).

⁷ See Claude Barfield & John E. Calfee, *Biotechnology and the Patent System: Balancing Innovation and Property Rights*, at 1-2 (AEI PRESS 2007). ("Without patent protection, investors would see little prospect of profits sufficient to recoup their investments and offset the accompanying financial risk."); see generally Battelle Technology Partnership Practice, *The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and the Factors that Will Drive It*, April 2014; Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. OF INT'L ECONOMIC L. 849 (2002).

I. The PTO Lacks Authority to Promulgate the Proposed Rules

As an initial matter, the proposed attributable owner rules exceed the statutory authority of the PTO. The PTO's alleged basis for these rules is the limited grant of authority in 35 U.S.C. § 2(b)(2), which allows the PTO to "establish regulations, not inconsistent with law, which . . . shall govern the conduct of proceedings in the Office." This narrow grant of procedural rulemaking authority, however, "does NOT grant the Commissioner the authority to issue substantive rules."⁸ "A rule is 'substantive' when it 'effects a change in existing law or policy.'"⁹ In the context of patent prosecution, such a change occurs if the rules, "on their face, 'foreclose effective opportunity' to present patent applications for examination."¹⁰

The proposed rules requiring disclosure of attributable owners depart from existing law and policy. As explained below, disclosure of such information is not required under existing law and represents "more than the incidental inconveniences of complying with an enforcement scheme."¹¹ Moreover, because, in many instances, the proposed rules deem applications that do not comply with the disclosure requirement abandoned, they may foreclose effective opportunity to present patent applications for examination.¹² The proposed rules are therefore substantive and beyond the statutory authority of the PTO.

Also, to the extent the failure to disclose attributable owner information before payment of maintenance fees would result in abandonment or early expiration¹³, this would also exceed

⁸ *Merck & Co. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996) (emphasis in original); *see also Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336 (Fed. Cir. 2008). No court has considered the scope of the PTO's rulemaking authority since the enactment of the Leahy-Smith America Invents Act of 2011 ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (2011). Yet, this principle holds true. Just as Congress's re-enactment of the predecessor of § 2(b) ratified *Merck's* conclusions regarding the scope of the PTO's rulemaking authority, *see Tafas v. Doll*, 559 F.3d 1345, 1352-53 (Fed. Cir. 2009) (Prost, J.), *reh'g en banc granted, opinion vacated*, 328 F.App'x 658 (Fed. Cir. 2009), Congress's amendment of § 2(b) in the AIA with only minimal, unrelated changes ratifies that same holding. *See, e.g., Lorillard v. Pons*, 434 U.S. 575, 580-81 (1978) ("[W]here, as here, Congress adopts a new law incorporating sections of a prior law, Congress normally can be presumed to have had knowledge of the interpretation given to the incorporated law . . .").

⁹ *Cooper Techs.*, 536 F.3d at 1336; *cf. Tafas*, 559 F.3d at

¹⁰ *Tafas*, 559 F.3d at 1356 (Prost, J.).

¹¹ *Id.* at 1374 (Rader, J.) (quoting *Chamber of Commerce of U.S. v. U.S. Dep't of Labor*, 174 F.3d 206, 211 (D.C. Cir. 1999)).

¹² *Id.* at 1356 (Prost, J.).

¹³ As described further below, the proposed rules do not indicate what the repercussion is for failure to identify the attributable owner before maintenance fees are paid. *See* 79 Fed. Reg. 4120 (Jan. 24, 2014).

Comments of the Pharmaceutical Research and Manufacturers of America
Docket No: PTO-P-2013-0040
April 24, 2014

PTO authority. The Supreme Court has long held that once the PTO issues a patent, that patent cannot be canceled unless cancellation is expressly authorized by statute.¹⁴ The proposed rules regarding issued patents starkly contrast with this established law to the extent that they suggest that the PTO may cancel an issued patent unless the attributable owner is identified with each maintenance fee payment.¹⁵ The maintenance fee requirement itself illustrates the PTO's need for statutory authority to promulgate the proposed rule. The collection of maintenance fees, including the specific dollar amounts and the consequence of non-payment (*i.e.*, early expiration), is expressly provided for by statute.¹⁶ The PTO's regulations concerning maintenance fees only establish how the maintenance fees are to be paid and what basic identifying information must be submitted with the fees to enable the PTO to maintain its files.¹⁷

Moreover, the proposed ownership disclosure requirement turns what has long been an *optional* procedure to protect patent *assignments* into a *mandatory* procedure to protect patent *validity*.¹⁸ The proposed rules not only impose a new burden on patentees in the form of ongoing disclosure, but also threaten to impose new means by which a property right may be lost. Because the proposed rules require "more than adherence to existing law,"¹⁹ they are substantive and beyond the PTO's authority.

As an alternative to basing these rules on 35 U.S.C. § 2(b)(2), the PTO suggests that 35 U.S.C. § 2(a) provides the rulemaking authority necessary for it to require disclosure of a patent's and patent application's attributable owner. This position, however, is unsupported by

¹⁴ See, e.g., *McCormick Harvesting Mach. Co. v. C. Aultman & Co.*, 169 U.S. 606, 608-09 (1898); see also 35 U.S.C. § 261.

¹⁵ Compare 79 Fed. Reg. 4107 (Jan. 24, 2014) ("For already-issued patents, the Office proposes to require the reporting of attributable owner or owners when the next maintenance fee is paid . . ."), with *McCormick*, 169 U.S. at 612 ("[U]pon the issue of the original patent, the patent office had no power to revoke, cancel, or annul it. It had lost jurisdiction over it . . .").

¹⁶ See, e.g., 35 U.S.C. § 41(b) ("Unless payment of the applicable maintenance fee under paragraph (1) is received in the Office on or before the date the fee is due or within a grace period of 6 months thereafter, the patent shall expire as of the end of such grace period."); *Figueroa v. United States*, 466 F.3d 1023, 1027 (Fed. Cir. 2006) ("[F]ailure to pay required maintenance fees results in expiration of the patent . . .").

¹⁷ See 37 C.F.R. §§ 1.363 (establishing periods in which maintenance fees may be paid), 1.366 (requiring a maintenance fee submission to include only the patent number, application number, and a statement identifying which of the three maintenance fees is being submitted).

¹⁸ See, e.g., *SiRF Tech., Inc. v. ITC*, 601 F.3d 1319, 1327-28 (Fed. Cir. 2010) (recordation "creates a presumption of validity as to the *assignment*") (emphasis added); cf. *Pitts v. Whitman*, 19 F. Cas. 767, 770 (C.C.D. Me. 1843) (statutory collection of patent assignments is merely directory for the protection of bona fide purchasers without notice and *does not require* the recording of a patent assignment).

¹⁹ See *Chamber of Commerce*, 174 F.3d at 211.

practice, law, and the text of subsection 2(a). Prior to this notice, the PTO has never relied upon subsection 2(a) as a basis for rulemaking authority in a Federal Register notice. PhRMA is not aware of any court ever suggesting that any rulemaking powers resides in this provision. Instead, courts have cited subsection 2(a) to describe the general *duties* of the PTO—*i.e.*, “the task of examining patent applications, 35 U.S.C. § 2(a)(1), and issuing patents if ‘it appears that the applicant is entitled to a patent under the law,’ § 131.”²⁰ This reading is expressly supported by the text and structure of 35 U.S.C. § 2, which is titled “Powers and duties.” Subsection 2(a) lists the activities for which the PTO “shall be responsible,” *i.e.*, its duties; subsection 2(b) describes thirteen “specific powers” of the PTO. To read subsection 2(a) as containing a general grant of rulemaking authority would impermissibly render the specific list of powers in subsection 2(b) superfluous.²¹ Accordingly, 35 U.S.C. § 2(a) cannot provide the legal basis for the PTO to promulgate the proposed rules.

II. The Attributable Owner Requirements are Overbroad and Burdensome

PhRMA recognizes that the PTO’s proposed rules regarding attributable owners are a response to an executive action from the White House seeking updated ownership information when an applicant or patent owner is involved in a proceeding at the PTO.²² The PTO explains that the proposed rules are intended to target patent assertion entities (*i.e.*, “patent trolls”) who often have “complex structures...to hide their true identities from the public.”²³ While this may be a laudable goal, the scope of the proposed rules are overbroad, and they place a burden on all patentees, including innovative companies that have legitimate business intentions and are not trying to hide their true identities from the public.

A. The Proposed Rules are Overbroad in view of the PTO’s Stated Objectives

To increase transparency of patent ownership, the proposed rules characterize five objectives as facilitating examination and internal PTO processes,²⁴ and four objectives as benefiting the public.²⁵ However, as summarized below, the proposed rules are overbroad and are not tailored to meet the PTO’s stated objectives.

²⁰ *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2242 (2011).

²¹ *Cf. Lowe v. SEC*, 472 U.S. 181, 207 n.53 (1985) (“[W]e must give effect to every word that Congress used in the statute.”).

²² 79 Fed. Reg. 4106 (Jan. 24, 2014).

²³ 79 Fed. Reg. 4109 (Jan. 24, 2014).

²⁴ 79 Fed. Reg. 4106 (Jan. 24, 2014).

²⁵ 79 Fed. Reg. 4108-09 (Jan. 24, 2014).

PTO Internal Benefits

1. **“Ensure that a “power of attorney” is current in each application or proceeding before the Office.”** Although the PTO may have an interest in ensuring that an applicant or patent owner authorizes representation,²⁶ nothing in the proposed rules requires an applicant or patent owner to change the power of attorney on record. The PTO has already implemented new rules under the America Invents Act for powers of attorney and practitioners have a duty of candor to the PTO and cannot make false statements regarding their authority.²⁷

2. **“[A]void potential conflicts of interest for Office personnel.”** The current PTO rules already address conflicts of interest. In actions before the Patent Trial and Appeal Board (“PTAB”), applicants and patent owners must identify the real party in interest in their appeal brief.²⁸ Although the PTO may have an additional interest in identifying conflicts of interest during prosecution, the proposed rules are overbroad because they require disclosure even after prosecution has ended.

3. **“[D]etermine the scope of prior art under the common ownership exception under 35 USC 102(b)(2)(C) and uncover instances of double-patenting.”** The burden of avoiding prior art or double patenting is placed on the applicant, not on the PTO. The applicant or patent owner facing a prior art rejection has the duty to establish that the reference is not prior art under the common ownership exception.

4. **“[V]erify that the party making a request for a post-issuance proceeding is a proper party for the proceeding.”** The attributable owner rules do not address this. Any post-issuance proceedings that allow a third party to challenge a patent are not impacted by the proposed rules because the proposed rules focus on the patent owner, not on the third party requester. The rules for *inter partes* review and post grant review proceedings specify that a petition cannot be filed by a patent owner, and any filing by a patent owner would be a violation of the rules.²⁹ Further, none of the post-issuance proceedings that can be brought by a patent owner are impacted by the proposed rules. For example, *ex parte* reexamination proceedings may be brought by any party,³⁰ and a request for supplemental examination requires an identification of the patent owner.³¹

²⁶ 79 Fed. Reg. 4107 (Jan. 24, 2014).

²⁷ 37 C.F.R. § 11.303.

²⁸ 37 C.F.R. §§ 42.37, 42.8.

²⁹ 37 C.F.R. §§ 42.101, 42.201.

³⁰ 37 C.F.R. § 1.510.

³¹ 37 C.F.R. § 1.610.

5. “[E]nsure that the information the Office provides to the public concerning published applications and issued patents is accurate and not misleading.” As a threshold issue, it is not clear at what rate the information the Office provides is actually inaccurate. If the information is largely accurate as to the patent owner, it is questionable what cost is appropriate to conform the small amount of remaining information. The rules clearly will create a cost for both the PTO and all patent owners. Before enacting the rules, the cost-benefit ratio should be studied and the decisions should be data driven. Thus, as discussed throughout these comments, the proposed rules are of a much greater scope than necessary to address this goal.

Public Benefits

The PTO also lists what it asserts to be four public benefits from the disclosure of attributable owner information, but the actual benefits are speculative at best:³²

1. “Enhance competition and increase incentives to innovate by providing innovators with information that will allow them to better understand the competitive environment in which they operate.”
2. “[E]nhance technology transfer and reduce the costs of transactions for patent rights since patent ownership information will be more readily and easily accessible.”
3. “[R]educe risk of abusive patent litigation by helping the public defend itself against such abusive assertions by providing more information about all the parties that have an interest in patent or patent applications.”
4. “[L]evel the playing field for innovators.”

These are varied and far-reaching goals that are likely not best addressed by one set of rules. Further, the notice does not provide adequate support to demonstrate a connection between the proposed rules and how they will achieve the listed objectives. With respect to the PTO’s asserted objective of reducing abusive patent litigation, such litigation can only arise when a patent has been asserted. Despite the fact that the number of patents that are actually asserted is thought to be approximately 2% of all granted patents,³³ the rules apply to all patents and patent applications. Therefore, the proposed rules are not narrowly tailored to address these collective objectives. Further, the rules lack clarity and create an unnecessary administrative burden that outweighs any public benefit.

³² 79 Fed. Reg. 4108 (Jan. 24, 2014).

³³ Attributable Ownership Public Hearing, March 13, 2014, *Comments by Mr. Wamsley of IPO* at 41.

B. The Proposed Rules Lack Clarity and Create an Administrative Burden that Outweighs Any Stated Benefit

The proposed rules place an administrative burden on all patentees, including innovative companies that have legitimate business goals and are not patent assertion entities. The PTO suggests that implementation of the proposed rules would impose a \$43 million administrative burden on companies based on the PTO's estimate that it will take about six minutes per patent to identify an attributable owner and one hour to correct a good faith failure to notify the Office of a change.³⁴ Elsewhere, the office notes a transaction cost of \$100.³⁵ Even if the PTO's numbers are correct, if a company owns a large patent portfolio, this could still impose a very large cost burden. For example, one member company has a total U.S. patent portfolio of more than 2,000 patents and pays maintenance fees on about 370 patents per year. If this company were required to identify the attributable owner for these patents at the time of maintenance fee payments, it would incur an additional annual cost of around \$37,000 (using the PTO's \$100 per transaction cost estimate). This company also had 276 patents issue in 2012 so the additional annual cost for identifying attributable owners at the time of allowance would be around \$27,600. These numbers do not even factor in the costs of identifying attributable owners at other time periods required by the PTO, such as during prosecution.

We note that Richard Neifeld, a patent attorney unaffiliated with PhRMA, recognized in his comments³⁶ that the PTO grossly underestimates the transaction costs for filing attributable owner information.³⁷ The PTO estimates that identifying an attributable owner will only cost \$38.90 (\$389/hr * 0.1 hrs).³⁸ Mr. Neifeld points out that this estimate is low by comparing it to the cost of filing maintenance fees. The AIPLA 2013 Economic Survey states that the mean charge for paying maintenance fees was \$355 for all locations (Table I-112)³⁹, and maintenance fee payments are automated and thus much more straightforward than attributable ownership

³⁴ 79 Fed. Reg. 4119 (Jan. 24, 2014).

³⁵ 79 Fed. Reg. 4116 (Jan. 24, 2014).

³⁶ Richard Neifeld comments dated Jan. 30, 2014 at 6-7 (available at http://www.uspto.gov/patents/law/comments/attributable_ownership_comments.jsp, last accessed 4/15/14).

³⁷ The PTO is under an obligation to conduct a cost and benefit analysis of any proposed rules, (*e.g.* Executive Order No. 12866 (Sept. 30, 1993); 44 U.S.C. § 3501 *et seq.*) but failed to do so in a reasonable manner here, which is most evident in its cost analysis. The PTO's conclusory analysis provides no reasonable basis for its finding that the identification of an attributable owner will take only 6 minutes.

³⁸ 79 Fed. Reg. 4119 (Jan. 24, 2014).

³⁹ REPORT OF THE ECONOMIC SURVEY (AIPLA July 2013).

information.⁴⁰ Mr. Neifeld provided a rough estimate “that compliance costs will run several hundreds of millions of dollars, such as \$350 times roughly 700,000 compliance requirements annually.”⁴¹

Additionally, several of the rules are ambiguous, as described in more detail below, requiring companies to expend additional in-house resources or hire outside counsel to interpret the rules for compliance with the attributable owner disclosures.⁴² For example, one of our members whose collective portfolio exceeds 10,000 U.S. patents estimates that substantial ownership questions will arise requiring more than 10 attorney hours to resolve for at least 1 in every 50 of its patents. For 1 in every 500 of its patents, the required investigation would likely take more than 50 attorney hours. Using the estimate of \$389 per attorney hour cited in the notice of proposed rulemaking (“NPRM”),⁴³ this member estimates that one compliance cycle alone will cost more than an additional \$1 million over the costs of basic administrative compliance, while yielding no corresponding public benefit, as its patents are not involved in the kinds of assertions that have spawned this PTO initiative. This analysis is important because the repercussions of failing to report the proper attributable owners is severe—abandonment of the patent.

1. The Definition of “Attributable Owner” is Unclear, which Creates a Burden for Compliance

The proposed rules represent a shift from the current scheme that permits voluntary reporting of ownership information to a system that requires reporting of attributable owner information at various time periods during patent prosecution and after patent issuance. Proposed rule § 1.271 defines an attributable owner in a multi-prong definition that appears duplicative, uses language that melds different legal concepts, and is overbroad in view of the PTO’s stated objectives. Because the rules lack clarity, they create a challenge for companies attempting to comply with them. Under the proposed rule § 1.271, an attributable owner includes: (a)(1) an assignee; (a)(2) an entity necessary to be joined for standing; (b) the ultimate parent entity; and (c) any entity that directly or indirectly temporarily divests or prevents divesting of attributable ownership (“the catchall”). This multi-prong definition of an attributable owner creates confusion, as described below, and the definition would be simplified if it only required disclosure of the assignee and ultimate parent entity.

⁴⁰ Richard Neifeld comments dated Jan. 30, 2014 at 7 (available at http://www.uspto.gov/patents/law/comments/attributable_ownership_comments.jsp, last accessed 4/15/14).

⁴¹ *Id.*

⁴² 79 Fed. Reg. 4119 (Jan. 24, 2014) (citing proposed 37 C.F.R. § 1.271).

⁴³ 79 Fed. Reg. 4119 (Jan. 24, 2014) (citing AIPLA 2013 Economic Survey).

Comments of the Pharmaceutical Research and Manufacturers of America
Docket No: PTO-P-2013-0040
April 24, 2014

The proposed rules make inconsistent references to the real party in interest as the standard for determining the attributable owner, which creates confusion as to the definition of an attributable owner. The NPRM explains that it uses the term “attributable owner” rather than “real party in interest” to avoid confusion given that the term “real party in interest” is used elsewhere in title 35 (e.g., 35 U.S.C. §§ 118, 315, 317, 325, 327).⁴⁴ Despite this supposed different use in terminology, the NPRM alludes to the fact that real parties in interest will be disclosed and § 1.271 includes the term “real-parties-in-interest” in the title. The real party in interest standard appears different than that in the proposed rules, so this is confusing and unclear.

Additionally, § 1.271(a)(1) and (2) appear to be duplicative, which creates ambiguity as to how the provisions should be interpreted. The only party necessary to provide standing in a lawsuit as required by (a)(2) is the patentee,⁴⁵ which is already covered in section (a)(1), or in certain circumstances an exclusive licensee where the license has risen to the level of an assignment, which the PTO suggests may also be covered by section (a)(1).⁴⁶ Thus, one could interpret (a)(2) as being duplicative and without meaning.

Further, the PTO’s explanation of an attributable owner under (a)(2) seems to meld the concepts of standing and a necessary party under Fed. R. Civ. Pr. 19, which are different legal issues.⁴⁷ A necessary party under Fed. R. Civ. Pr. 19 is not required to create standing as recited in section (a)(2) of the proposed rule. However, the rules are unclear as to how the PTO and a future defendant would react if a company filed a lawsuit naming more plaintiffs than were identified as attributable owners in the PTO. At the very least, this could unnecessarily subject patentees to inequitable conduct challenges. Further, to determine whether an exclusive licensee has “all substantial rights” or whether a party is a necessary party, a fact-specific analysis must

⁴⁴ 79 Fed. Reg. 4106 (Jan. 24, 2014).

⁴⁵ See 35 U.S.C. § 281.

⁴⁶ 79 Fed. Reg. 4110 (Jan. 24, 2014) (“Reporting of exclusive licensees might be required in the limited circumstances where the exclusive license transfers so many rights that it is effectively an assignment, but the Office expects that exclusive licensee information would more routinely be reported under the second type of ownership information the Office proposes to collect (entities that have standing to enforce).”)

⁴⁷ The NPRM explains that §1.271(a)(2) concerns “those parties that would be necessary and sufficient to bring a legal infringement action” and cites *Vaupel Textilmaschinen KG v. Meccanica EuroItalia SPA*, 944 F.2d 870, 875-76 (Fed. Cir. 1991). 79 Fed. Reg. 4110 (Jan. 24, 2014). However, this citation only adds to the confusion. The *Vaupel* case, while stated to be a standing case, also cites to Fed. R. Civ. P. 19 regarding necessary parties. Thus, it is unclear whether the proposed rule requires disclosure of the parties necessary for standing, or the necessary parties under Fed. R. Civ. P. 19. This lack of clarity creates an administrative burden on companies trying to comply with the rules.

Comments of the Pharmaceutical Research and Manufacturers of America
Docket No: PTO-P-2013-0040
April 24, 2014

be undertaken (potentially by a court). Such analysis may include state law concepts and contract interpretation. Additionally, this analysis would be difficult, if not impossible, to conduct during the reporting times outlined in the proposed rules and would be more appropriate after a lawsuit has been filed.

The proposed requirement for disclosing licensee information is also overly burdensome. Companies often enter into agreements where this information is confidential for business purposes, and it is unclear how they could respect their agreements while also complying with the proposed rules. Further, the PTO has not provided adequate justification for supplying this confidential information to the public.

Similarly, it is also unclear whether licenses between commonly-owned companies would have to be disclosed under section (a)(2) as necessary parties. It is quite common for corporations to transfer rights by assignment or exclusive license to other wholly owned subsidiaries. It is also not uncommon for serial exclusive licenses to be granted to multiple entities over the course of a patent's lifetime. A company's patent department may not even be aware of these licenses because the agreements are entered as part of routine commercial activity, and are only individually evaluated, if ever, for tax purposes or as a part of litigation diligence. Thus, to the extent the rules would require such reporting, it would constitute an ongoing administrative burden to track down and follow this changing information.

The lack of clarity also extends to the definition of "entity" in § 1.271(d).⁴⁸ Specifically, the definition of "entity" provided under § 1.271(d)(4) ("any other organization or corporate form not specifically listed in paragraphs (d)(1), (d)(2), or (d)(3) of this section that holds an interest in an application or patent") is broad and does not specify whether the entity must hold a financial or ownership interest in the application or patent. Depending on the meaning of "interest," it is difficult to understand how the definition applies to the use of the term "entity" in § 1.271(a)-(c). For example, the proposed definition of "entity" in 37 C.F.R. § 1.271 could be construed to require biopharmaceutical corporations to reveal the existence of potentially confidential and sensitive licensing relationships with other parties.

Thus, the lack of clarity in the definition of the attributable owner creates a burden in attempting to interpret the definition to ensure compliance with the rules, and an ongoing burden if the rules are interpreted as liberally as the PTO's definitions would seem to intend.

⁴⁸ It is also not clear why government agencies and other governmental bodies are excluded from the definition of "entity" at proposed 37 C.F.R. § 1.271(e).

2. The Proposed Rules Lack Clarity because they Do Not Consistently Describe the Repercussions of Non-Compliance

The proposed rules do not consistently describe the repercussions of not filing the required disclosures. For example, § 1.273 governs the disclosure of an attributable owner in an application.⁴⁹ The proposed rule § 1.273 indicates that if the attributable owner is not identified within a certain time period after filing, then the application will be abandoned.⁵⁰ In contrast, § 1.381 governs the disclosure of an attributable owner with the maintenance fee payment.⁵¹ The proposed rule § 1.381 requires disclosure when the maintenance fee is paid, but it does not indicate what happens if no disclosure is made.⁵²

3. The Reporting Requirement before the Payment of Maintenance Fees is Burdensome

Proposed rule § 1.381 requires disclosure of the current attributable owner prior to the date the maintenance fee is paid, even if there has been no change.⁵³ This requirement is burdensome because third party services often make these maintenance fee payments. Under the proposed rules, in-house legal counsel or an external law firm would be required to conduct an analysis of the attributable owner, and then coordinate with the third party service to ensure that the proper information was disclosed before the fee was paid. This additional step complicates the maintenance fee payment system and requires additional cost to determine and/or verify the attributable owner.

III. Proposed Modifications to the Proposed Rules to Provide Clarity and Minimize the Burden on Compliance

To address concerns addressed above, PhRMA suggests modifications to the proposed rules. These modifications are an effort to clarify the reporting requirements and minimize the burdens on innovative companies.

A. The PTO Should Wait for Congress to Act on this Issue

Congress is considering several pending bills concerning patent reform that have provisions directly related to the PTO's proposed rules on attributable owners.⁵⁴ PhRMA

⁴⁹ 79 Fed. Reg. 4120 (Jan. 24, 2014) (citing proposed 37 C.F.R. § 1.273).

⁵⁰ 79 Fed. Reg. 4120 (Jan. 24, 2014) (citing proposed 37 C.F.R. § 1.273).

⁵¹ 79 Fed. Reg. 4120 (Jan. 24, 2014) (citing proposed 37 C.F.R. § 1.381)..

⁵² 79 Fed. Reg. 4120, 4113 (Jan. 24, 2014) (citing proposed 37 C.F.R. § 1.381)..

⁵³ 79 Fed. Reg. 4120 (Jan. 24, 2014) (citing proposed 37 C.F.R. § 1.381)..

⁵⁴ *See, e.g.*, the Patent Transparency and Improvements Act of 2013 (S. 1720); the Innovation Act (H.R. 3309).

recommends that the PTO not adopt any proposed rules while Congress is considering the pending patent legislation. This avoids a situation where companies are forced to report certain ownership information to comply with the PTO rules and other ownership information to comply with a new statute. Potentially duplicative reporting requirements would create an unnecessary burden that could be avoided by waiting for the approval of any legislation in Congress, and proposing rules that are consistent with any new statutory requirements. If Congress does not pass any legislation, then the PTO can propose its rules at that time.

B. The PTO Should Change the Definition of an Attributable Owner

An attributable owner should be limited to all assignees of full legal title and their ultimate parent entity. This would provide the public with the benefit of understanding the ownership of applications and patents, reduce the burden on companies to determine complicated factual and legal questions based on other parties who may or may not hold an interest, and retain the confidentiality of certain strategic licensing agreements.

To the extent the PTO retains the multi-prong definition of an attributable owner, the rules should explicitly carve out from the definition of “entity” two general groups: (1) licensees, both exclusive and non-exclusive, and (2) an affiliate, direct subsidiary, or indirect subsidiary of an assignee of a patent or patent application. The proposed rules already require disclosure of the ultimate parent entity and the PTO has not explained why the identification of these additional groups is necessary. Additionally, § 1.271(a)(2) should be drafted to clarify that it only pertains to parties necessary for standing.

C. The PTO Should Amend the Repercussions for Failure to Report Attributable Owner Information

The devastating result of abandonment for failing to report attributable owner information seems misaligned with the PTO’s objectives for reporting the information. Practitioners, applicants, and patent owners are already under a duty of candor and good faith to report information to the PTO,⁵⁵ and this obligation is sufficient to ensure compliance. PhRMA recommends removing all references to patent abandonment for failing to report attributable owner information.

PhRMA suggests that failure to report attributable owner information is more appropriately a matter for consideration by Congress. Both the Patent Transparency and Improvements Act of 2013 (S. 1720) and the Innovation Act (H.R. 3309) state that if a party asserting infringement fails to comply with the disclosure requirements, then it is not able to recover increased damages under § 284 or attorney fees under § 285 with respect to infringing

⁵⁵ 37 C.F.R. § 1.56.

activities taking place during any period of noncompliance and the court shall award a prevailing accused infringer reasonable attorney fees and expenses incurred in discovering any previously undisclosed ultimate parent entities.⁵⁶ The bills thus propose a different approach to the consequences for failing to comply with the reporting rules by creating an incentive for companies to comply with the rules by linking compliance to damages recovery.

IV. Conclusion

PhRMA appreciates the PTO's efforts to consider ways to address the issue of abusive patent litigation. However, given the burden of the proposed rules relative to their benefit, PhRMA urges the PTO to reconsider the scope and necessity of these rules. PhRMA is committed to helping the PTO find solutions to the many challenges it faces today and in the years to come.

⁵⁶ S. 1720, § 263(d); H.R. 3309, sec. 4.