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VIA E-MAIL ONLY

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United States Patent and Trademark Office
Mail Stop Comments-Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: James Engel, Senior Legal Advisor, OPLA

Re: Novartis Comments on Proposed “Changes to Require Identification of Attributable Owner,” Fed. Reg. Vol. 79, No. 16, Jan 24, 2014 pp. 4105-4121

Dear Mr. Engel:

Novartis thanks the United States Patent and Trademark Office (“the Office”) for the opportunity to comment on its recent proposal to change the rules of practice to require identification of the “attributable owner” (“AO”) of patent applications and patents. Novartis is a global healthcare company whose mission is to discover, develop and successfully market innovative products to prevent and cure diseases, to ease suffering and to enhance the quality of life for patients across the world. In pursuit of that mission, Novartis files more than 500 patent applications in the United States every year, and currently maintains over 3000 US patents. Like the Office, Novartis supports and desires a strong and predictable intellectual property system that yields the highest quality patents, minimizes costs and burdens for its users, and provides sufficient certainty to stakeholders to create strong incentives for innovation while ensuring a healthy and competitive marketplace. In this context, Novartis further supports many of the objectives of the proposed AO rules, including the desire to curb abusive patent litigation, and to improve the transparency of patent ownership in cases where patentees may manipulate ownership or the appearance of ownership in furtherance of such abuses. Novartis, however, is concerned that the AO rules as

proposed are far broader than necessary to achieve their stated goals, and will ultimately do more harm than good by creating unreasonable costs and burdens for genuine inventors and good faith users of the patent system (the vast majority), while doing little to thwart the types of abuses by a relatively small number of non-practicing entities that the changes are primarily meant to address. With this in mind, Novartis offers the following remarks, aimed at striking a more equitable balance between the potential benefits of such changes in controlling the abuses of a few, and the costs and burdens that they will create for the many good faith users of the patent system that rely daily on its efficiency and certainty to continue to incentivize innovation.

I. The Proposed AO Rules Are Far Broader Than Necessary to Achieve their Intended Goals, and Should be Substantially Narrowed to Avoid Unduly Burdening Legitimate Users of the Patent System

Novartis appreciates the Office's latest efforts to fashion rules to improve transparency of patent ownership, and understands its renewed mandate to do so in a political climate marked by a series of White-House initiatives aimed at improving the patent system, and more broadly by bipartisan support for a legislative solution to the problem of abusive patent litigation.¹ Novartis also appreciates the unique position that the Office occupies in this regard, with its ability to take measures to improve transparency of ownership at an earlier stage than other government entities, and to do so with an eye to achieving a broader set of goals for overall transparency in the patent system. Precisely because of this unique position, however, the Office through its rules has the ability to impact a vastly larger number and array of patent owners than any of the pending legislative proposals—and with it, the *responsibility* to ensure that the rules are no broader than necessary to achieve their stated goals.

¹ To date, we understand that a total of twelve bills have been introduced in the House and Senate that aim to address one or more perceived aspects of the problem of abusive patent litigation.

Unfortunately, in Novartis' view, the proposed AO disclosure rules fail in this latter regard, incorrectly assuming that *all* patent owners and applicants are contributing to a broad transparency problem that requires a broad "one size fits all" solution covering every patent applicant and owner, for every patent, at every stage of its life cycle, when in fact the majority of the problems are only being driven by a few. Indeed, rather than considering which entities are causing which types of problems at which stage of proceedings, the Office has drafted a single set of rules aimed at addressing *nine* distinct goals at once: four external goals aimed at addressing a variety of perceived public problems and five internal goals aimed at helping the Office facilitate various aspects of patent examination. More specifically, the identified goals (paraphrased for brevity) are:

External Goals

- (1) Enhancing competition and increasing innovation incentives by providing information to help innovators better understand the competitive environment;
- (2) Enhancing technology transfer / reducing transaction costs for patent rights;
- (3) Reducing risk of abusive patent litigation; and
- (4) Leveling the playing field for innovators.

Internal Goals:

- (1) Ensuring current power-of-attorney;
- (2) Avoiding potential conflicts of interest for Office personnel;
- (3) Determining scope of prior art under common ownership exception / illuminating double patenting;
- (4) Verifying that proper parties are making post-issuance proceeding requests;
- (5) Ensuring accuracy of information in published applications/issued patents.

(Fed. Reg. 79(16), Jan 24, 2014 at p. 4106).

Evidently aiming to achieve all nine goals efficiently, the Office has developed a single framework for all patent owners and applicants built on the type of aggressive disclosure requirements that are only necessary to achieve the broadest goal (avoiding abusive patent litigation), while adding requirements to repeat AO disclosures frequently enough (at least five times during the life of a normal patent, and in many cases more)² to simultaneously address the remaining goals. Novartis understands that, from a rule-drafting perspective, it may be convenient to concurrently address nine goals through a broad set of universal rules that apply to all. In practice, however, this approach penalizes the majority for the abuses of a few, by melding together an array of fundamentally different problems, the most serious of which do not arise in the overwhelming majority of cases before the Office, and the rest of which can be adequately addressed through far narrower and less burdensome rules. The result is a system of rules that, in our view, will create undue costs and burdens for all applicants and for the patent system as a whole, undermining innovation and some of the very goals that the rules are intended to achieve.

As discussed below, we respectfully urge the Office to reconsider this approach, by separating the most serious and pressing transparency problem—that of abusive patent litigation—from the other problems that the Office hopes to address, designing rules specifically aimed at the cause of that problem, and narrowing the remaining rules to a level and scope that strikes a more appropriate balance between the other eight cited goals and the burdens and costs on the patent system. To assist the Office in this reassessment, we make several concrete suggestions which, in Novartis' view, would result in a stronger set of tailored rules that would be equally, and in some cases, more effective than the currently-proposed AO rules, while lowering the burden on legitimate patentees and applicants.

²This includes (1) when a patent application is filed; (2) in the event of any change to any AO; (3) when the patent is allowed; and (4) every time a maintenance fee is paid.

A. The Goal of Reducing Risk of Abusive Patent Litigation Should Be Addressed Separately, Through a Set of Rules that Targets the Source of That Problem

While Novartis again appreciates the ambitious breadth of goals that the Office has set out to achieve through the AO disclosure rules, it seems clear from the current legislative climate that the external goal of reducing the risk of abusive patent litigation is the initiative's strongest driver. Due to the nature of this problem, and the intentionally opaque patent ownership structures constructed by abusive patent litigants, it is also the issue that requires the most stringent set of corrective rules. The Office's proposed rules seem to have been drafted with precisely this problem in mind, broadly requiring the disclosure of at least: (1) the owner/assignee, (2) any entity necessary to be joined in a lawsuit for purposes of standing to assert a granted patent (or one resulting from an application), which, under Federal Circuit case law, includes exclusive licensees in many circumstances; (3) the ultimate parent entity of either party 1 or 2; and (4) any other entity that through a variety of contractual mechanisms impacts the attributable ownership of a patent. While rules of this breadth might be understandable if abusive patent litigation were a systemic problem in the USPTO, statistics tell a *staggeringly* different story.

By definition, abusive patent litigation can only arise when a patent is actually granted and asserted, either through litigation or the threat of litigation. While estimates vary, the proportion of patents that are actually asserted is thought to be less than 2% of all granted patents. (Attributable Owner Public Hearing, March 13, 2014, Alexandria, VA, Transcript at p. 41). This statistic alone means that a minimum of 98% of granted patents are completely detached from the problem of abusive patent litigation. In practice, that number is even higher, since patent owners like Novartis who are engaged in the legitimate enforcement of patent rights against infringers are also included in the 2%. Putting these figures further into the perspective of the much larger pool of patent applications that do not result in granted patents, the scope of the

problem of abusive patent litigation as a factor of the Office's area of activity (i.e., examination, processing and issuance of patents) is incredibly limited, affecting only a tiny fraction of the applications that the Office handles.

Given this reality, in Novartis' view, there is no justification for a broad set of rules that require all patent applicants to disclose such a wide array of related and potentially related parties for each and every application and patent at so many points during a patent's life cycle. If such a wide breadth of AO disclosure is required to address abusive patent litigation in situations where there is risk, then a rule requiring this level of disclosure should be narrowly tailored to circumstances in which the risk of such abuse is probable, or at the very least, in which it is *possible*.

To correct the undue breadth of the current rule, Novartis proposes two solutions: First, the requirement to disclose AO should be limited to the 2% of patents that are actually asserted, and/or to specific events that are traditionally linked to patent assertion, rather than events associated with obtaining and maintaining patents. In Novartis' view, such activities at most include PTAB proceedings, reissue correction (particularly broadening reissue), supplemental examination, reexamination, the sending of patent demand/notice letters, and patent lawsuits. This could be achieved by limiting the application of the proposed AO rules to the above-referenced Office proceedings, and adding additional disclosure events such as the assertion of a patent in a demand letter, and the filing of a complaint for patent infringement.³ For the reasons discussed, events that occur prior to patent grant, as well as the payment of maintenance fees, should be removed from any AO rules, since there is no possibility that these events alone will lead to abusive patent litigation—which, again, is the case for at least 98% of granted patents, and the thousands of applications filed annually that do not even result in a granted patent.

³ Several of the pending legislative proposals would operate this way, requiring disclosure of various entities to the adverse party, the Court and the Office when a complaint is filed.

Second, to further limit the burdens and costs that such a broad AO disclosure requirement will impose on legitimate users of the patent system, we urge the Office to consider a narrower rule for bona fide innovators and practicing entities, whose interests and business models generally do not involve intentional obfuscation of patent ownership. In cases where these types of entities assert their patents or participate in post-grant activities linked to assertion, a simple rule requiring disclosure of the owner/assignee and the ultimate parent entity should suffice to inform the public of the patentee's identity.⁴ There is close precedent for aligning the far lower risk of litigation abuse from such entities with the stringency of the disclosure requirement. The Goodlatte Innovation Act (H.R. 3309), for instance, would exempt parties engaged in Hatch-Waxman patent litigation from its "Transparency of Patent Ownership" provisions altogether, an acknowledgment that adequate protections against litigation abuse already exist for parties engaged in this type of litigation. H.R. 3309, Sec. 4. A previously proposed bill, the "Saving High-Tech Innovators from Egregious Legal Disputes Act of 2013" (SHIELD Act), which would award costs and attorneys' fees to prevailing defendants in most patent cases, more broadly exempts any party who is the original inventor or assignee, or who can provide documentation of substantial investment in the exploitation of the patent through production or sale of an item covered by the patent. H.R. 845, Sec. 2.

A narrower AO disclosure rule for certain low risk entities, modeled perhaps after the SHIELD Act's, combined with our first suggestion to limit the events that trigger a disclosure obligation, would help to tailor the Office's proposed rules to the main problem they are designed to address, while minimizing the costs and burdens

⁴ As discussed elsewhere in these comments, the definition of AO in the current rules is highly problematic on other levels, and should be amended across the board to **exclude** those parties necessary to perfect standing to sue (§ 1.271(a)(2)), and the "catch-all" category of any entity to any agreement or arrangement that has the "purpose or effect" of temporarily removing the party from a category of attributable owners (§ 1.271(c)). If this is done, the need for a narrower rule for certain entities would be greatly reduced.

for legitimate users of the patent system. Specifically, we propose that AO disclosure be limited to the owner/assignee and the ultimate parent entity for applicants and patent owners who are able to attest that they or their internal corporate affiliates (1) are the original inventors or assignees of the invention, (2) have substantially invested in the commercial development or exploitation of the patent, or (3) have a regular and established record of engaging in innovative research, or of commercially developing or exploiting patented technologies. This narrower approach for low-risk entities would greatly allay many of the concerns that Novartis (and no doubt other heavy users of the patent system) has over the practical impact of litigation-related disclosure rules on our business, and in our view, would better serve the aims that the Administration, the Office, and Congress are attempting to achieve.⁵

B. The Remaining External Goals and All Internal Goals Can be Achieved Through the Adoption of a Mandatory Patent Assignment Database

As discussed above, while the proposed AO disclosure rules may be designed to improve transparency of ownership to achieve nine different goals, it seems clear that their breadth and the required frequency of compliance is largely, if not entirely, aimed at the abusive patent litigation problem. Once this problem is separated from the other eight goals and dealt with individually (e.g. through one or more of the alternative approaches suggested above), it becomes evident that the remaining goals can be met by adopting a significantly more streamlined mechanism. More specifically, what remains to be achieved are transparency goals relating to enhancing

⁵ Novartis again appreciates that the rules are also directed to other external goals, such as facilitating technology transfer and reducing the costs of transactions for patent rights by making ownership information more readily available. These other goals, however, can be met by the mandatory assignment recordation system that we propose in the following section (IB).

competition and enhancing technology transfer, and the five internal goals aimed at facilitating patent examination.⁶

We respectfully submit that these remaining goals can be achieved by converting the Office's existing voluntary assignment recordation system to a mandatory system that encompasses all granted patents and pending applications. The resulting mandatory patent assignment database would be well-suited to achieve the remaining external goals, providing the public with ample ownership and contact information to better understand the competitive environment, and allowing parties to easily locate the current assignee of all patents and applications of interest in order to facilitate technology transfer. The same assignment information in a comprehensive database is also sufficient to enable the Office to meet each of its five internal goals. To keep the system up-to-date, the Office could use the rule-making process to require all assignments to be recorded shortly after execution (e.g., within 6 months), whether pre-issuance or post-grant. For assignments of applications executed prior to filing, the Office could require recordation upon filing the application, shortly thereafter, or in response to a Notice to File Missing Parts.

Critically, in contrast to the proposed AO disclosure rules, a move to a mandatory recordation system would come with minimal burdens to the vast majority of patentees, since, according to the Office, 92% of patent applications *already* have recorded assignments at the time of grant (and changes during application pendency, as well as over the lifetime of a patent, are rare). (Fed. Reg. 79(16), Jan 24, 2014 at p. 4115). Put another way, transition to a mandatory assignment database would impact only 8% of patents and applications, which in and of itself means significantly less

⁶ The fourth external goal, "levelling the playing field for innovators," is not sufficiently clear in the Federal Register Notice to allow Novartis to respond to it specifically. The Office has provided little explanation of this goal, or how it would be achieved by increasing transparency of ownership in the manner proposed by the AO rules. We assume, therefore, that this goal is similar to or partially redundant of the other stated goals, and address it collectively through our discussions of those goals.

burden on the system than the currently-proposed AO rules. For those patentees and applicants that would need to begin recording assignments, the cost would almost certainly be less than the USPTO's estimated 43.5 million-dollar annual burden on USPTO customers (Fed. Reg. 79(16), Jan 24, 2014 at p. 4119). The cost to the Office and taxpayers would also be minimal, as the Office already has an assignment recordation database in place that could be modified to handle additional mandatory assignment information.

This alternative would also strike a better balance between the need for patent ownership information in furtherance of the Office's stated goals, and the defined need for similar information in a variety of other public contexts that already exist, which the Office may not have considered in its analysis. For instance, parties filing Declaratory Judgment actions for declarations of non-infringement or invalidity must be able to identify and notify the correct patent owner/assignee in order to initiate suit, a task that could be complicated, or at least be made more burdensome or costly, by a system that resulted in the over-compilation of information about other related (but not pertinent) parties. Likewise, in Hatch-Waxman litigation, generic drug manufacturers that are statutorily required to send Paragraph IV Notice Letters to NDA holders and all patent owners within strict time limits could be substantially burdened by a system whose overabundance of information unnecessarily expands the universe of "attributable owners" that a company must consider for notification, and could even endanger the confidentiality of a Letter's contents (e.g. if sent to the wrong party or address), or jeopardize a generic's "first-filer" exclusivity status.⁷

⁷ A single day can sometimes mean the difference between "first-filer" status (entitling that generic to 180-day generic exclusivity) and all other generic filers. Delays in identifying patent owners could impact when a generic is able to file its generic drug application, or interfere with its ability to timely comply with the strict 20-day notice period that follows. *See* 21 USC § 355 (j)(2)(B)(ii).

For all of these reasons, we respectfully submit that a simple system that requires the recordation of assignments would better achieve the Office’s remaining eight goals, while minimizing the burdens on patentees and applicants.

II. The Proposed AO Disclosure Rules Have the Potential to Harm Innovators and Licensees, Undermining Many of the Rules’ Stated Goals

As discussed above, Novartis believes that the proposed AO rules can be substantially narrowed while still achieving all of the stated goals. Lowering the costs and burdens of new rules on the patent system is reason enough for the Office to consider revising its proposal to create a better balance. The unintended harms that the proposed AO rules could inflict on both innovators and their licensees are another.

Fundamentally, the current proposal creates a host of problems by including exclusive licensees in the list of parties that qualify as “attributable owners” and that must be disclosed throughout the life of a patent and at various times during pendency. One problem, as the rule itself seems to acknowledge, is that identifying exclusive licensees is not straightforward. Indeed, rather than refer to “exclusive licensees” by name as past Office proposals did, the currently-proposed AO rules put the burden on the patentee or applicant to determine in a given case whether a licensee is exclusive by deciding whether it is either an effective “assignee” with standing to enforce a patent in litigation on its own, or an “entity necessary to be joined in a lawsuit in order to have standing to enforce the patent.” (Proposed 37 CFR §1.271(a)(1) and (2)). Answering this question, however, involves a complex multijurisdictional legal analysis that is *highly* fact-intensive, the result of which—as the ample body of Federal Circuit case law on the topic shows—is often difficult and unclear even at the time of litigation.⁸ To conduct this analysis at the application and

⁸ An exclusive licensee with “all substantial rights” under the patent is effectively an assignee with standing to enforce the patent on its own. An exclusive licensee who lacks all such rights does not

maintenance stages (as the AO rules currently propose) may not even be possible, and would almost certainly require the time, expertise, and expense of an experienced patent attorney or litigator at each and every stage of the proposed disclosure process, a task that may be incompatible with the patent maintenance processes of corporations, which rely heavily on service providers to manage the administrative side of their portfolios.

A second problem with including licensees in the proposed AO disclosure requirements is the negative impact that the rules could have on the confidentiality of legitimate license agreements, potentially destroying the value of existing transactions, and leading to a chilling effect on future transactions, all in contravention of the proposed rules' goals. In many cases, license agreements contain provisions requiring the parties to keep not only the terms, but the very existence of a license confidential. License confidentiality is often critical in industries with long R&D timelines like pharmaceuticals, because the very existence of a license agreement can reveal information about an otherwise confidential business plan or research direction that could be unfairly exploited by competitors (e.g., R&D priorities, disease type or area, state of development, commercialization strategy). The identity of the parties to the transaction can also reveal this type of

have standing to sue alone, but may nevertheless be a “necessary party” that must be joined under Rule 19 of the Federal Rules of Civil Procedure. See *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 875 (Fed.Cir.1991). To determine whether an exclusive license is effectively an assignment, however, one “must ascertain the intention of the parties [to the license agreement] and examine the substance of what was granted,” which in turn is a question of state law. *Aspex Eyewear, Inc. v. Miracle Optics, Inc.*, 434 F.3d 1336 (Fed. Cir. 2006); *Alfred E. Mann Foundation v. Cochlear Corp.*, 604 F.3d 1354 (Fed. Cir. 2010). There is no simple way to conduct this inquiry, and no complete list of the rights that must be examined. *Id.* To complicate matters further, if, under the applicable state law, the licensee is *not* an effective assignee, the question of joinder is determined under the law of the *regional* circuit, which in the case of the proposed AO rules, would often be impossible, since the venue in most cases is not yet known. *A123 Systems, Inc. v. Hydro-Quebec* (626 F.3d 1213, 1220 (Fed. Cir. 2010)). The situation only worsens where patent rights are divided amongst various parties, in which case whether an exclusive licensee is “necessary” can only be determined once an accused product is identified.

information, undermining incentives for one side or both to enter into such transactions. For existing licenses that contain these clauses, compliance with the proposed AO rules could at minimum conflict with these terms, interfering with the assumptions and business conditions on which the parties relied. Worse, however, is the very real risk that complying with the AO rules would actually reveal the type of information just described. The structure of the current AO rule again exacerbates this risk, since it hinges disclosure on whether a licensee has standing to sue. Since, as discussed, this in turn depends on the scope of the rights transferred in the license, complying with the AO rule could well have the unintended consequence of revealing a substantial amount of proprietary information, which in turn may destroy much of the value of the transaction, and much of the incentive to collaborate on innovation.

The potential negative effect of the proposed rules on *future* transactions is of even greater concern. If the AO disclosure rules make the confidentiality of licenses uncertain, they may well have a direct chilling effect on the future pursuit of such agreements. As Robert Hardy, Director of the Council on Governmental Relations, testified at the Office's recent Round Table, if this occurs, one of the biggest losers will be universities, a common industry licensing partner, since from an industry perspective, confidentiality is often what makes a deal for a University's patents attractive. (Attributable Owner Public Hearing, March 13, 2014, Alexandria, VA, Transcript at p. 64).

Another potential unintended consequence of including licensees in the AO definition is harm to those licensees, including loss of the licensed patent, due to the licensee's inability to ensure compliance with the rules. As currently proposed, the AO rules indicate that the provider of the required AO information about exclusive licensees (37 CFR §1.271) must be either the applicant or patent owner. (37 CFR §§1.273, 1.275, 1.277 and §§1.383, 1.385, respectively). A licensee has no clear ability itself to provide this information, or to even monitor an applicant's compliance

in many cases (since several of the disclosures are expected to occur before the file history becomes publically available on PAIR). Nor is a licensee likely to have contractual means to compel the applicant/patentee's compliance, at least for licenses executed before the rules would take effect.⁹ These risks are exacerbated by the strict penalty for non-compliance that the Office has proposed. Should a patent application become abandoned for non-compliance, an exclusive licensee cannot itself revive the abandoned application, a result which seems fundamentally unfair (Proposed 37 CFR §1.273 or 1.277). Furthermore, with abandonment as a penalty, an applicant/patentee's non-compliance with the AO rules could later result in a finding of inequitable conduct rendering an exclusively-licensed patent unenforceable, again depriving the licensee of the value of its transaction through no fault of its own. See *Therasense v. Becton, Dickinson and Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc).¹⁰

Given the above concerns, Novartis urges the Office to consider removing exclusive licensees (an "entity necessary to be joined in a lawsuit in order to have standing to enforce the patent," §1.271(a)(2)) from the AO definition. Should the Office, despite these concerns, decide to maintain the current definition, we request that it at least consider limiting the application of this definition to disclosures related to the filing of a complaint, or at most, to the sending of a demand letter, as proposed in Section IA of these comments. If the Office does not agree with either of these proposals, we further ask that it consider implementing these rules only prospectively, limiting the AO disclosure requirement to patent applications filed after the effective date of any final

⁹ Another unintended consequence of the proposed rules may therefore be that exclusive licensees are forced to incur the risk and expense of renegotiating their current license agreements to include AO disclosure compliance provisions.

¹⁰ This same concern could lead more generally to a new "plague" of inequitable conduct charges in patent cases based on allegations of non-compliance by an applicant/patentee. Such inequitable conduct suits could add to patent litigation, clog the already over-burdened court system, and add further uncertainty by reviving the abuses that the Federal Circuit sought to curb in *Therasense*. Such effects are wholly at odds with the Office's goals of curbing litigation abuses, increasing incentives for innovation, enhancing technology transfer and reducing transaction costs for patent rights.

rules, and patents and applications exclusively licensed after that date. This would at least eliminate the risks relating to current license agreements that lack provisions to adequately address AO disclosure requirements, and provide licensing parties with fair notice of the risks that the rules pose to the confidentiality of their agreements.¹¹

III. The “Purpose or Effect” Catch-All of §1.271(c) Could Harm Innocent Third Parties

Novartis is also concerned that the category of AO defined in 37 CFR §1.271(c)—which includes any entity that “directly or indirectly” uses any agreement, arrangement or device with the “purpose or effect” of temporarily divesting that entity of attributable ownership, or of preventing the vesting of attributable ownership—is confusing and vague, and could harm innocent parties that have nothing to do with the problems that the AO disclosure rules are aimed at addressing. As one example, a manufacturer who contracts for an exclusive *option* to license or purchase a patent for the purpose of attracting a funding partner would not qualify as a patent “owner,” or confer standing to sue for infringement. Nevertheless, such an option agreement could be construed as having the direct or indirect “effect” of rendering the manufacturer a non-AO for the time-being, or of preventing AO from vesting in either himself or the patentee, since exercising the option at some later point in time could result in a change of ownership or licensee status.

The parties to a legitimate agreement like this might never recognize the possibility that it could fall into this “catch-all” requirement, which, given the abandonment penalty for non-compliance with the rules, could jeopardize the patent. While we understand that such innocent errors may be correctable under the rules, the theoretical ability to correct will not prevent the confusion resulting from such a vaguely worded provision, or prevent these types of situations from becoming the

¹¹ If the current AO definition is indeed adopted despite the above concerns, the Office should also amend the rules to allow exclusive licensees to disclose the requisite AO information to the Office.

bases for challenges by competitors in patent litigation. The latter result will only benefit parties who make no contributions to innovation, in direct conflict with the stated goals of the rules.

We respectfully submit that no AO definition should contain such a vague and uncertain catch-all category that includes subjective standards like “purpose or effect.” If the Office insists that such a category is necessary—for example, to achieve the goal of reducing the risk of abusive patent litigation—then it should be narrowly tailored to those arrangements that are *intended* to mask a party from being identified or named in a legal action.¹² As discussed in Section IA of these comments, it should also be narrowly applied to only those circumstances and entities where such litigation abuses are probable.

IV. The Rules as Proposed Are Unnecessarily Burdensome and Costly, and The Proposed Penalty is Unduly Severe

As set forth earlier in these Comments, the proposed rules require AO reporting or updating *at least* five times during the life of a normal patent—at filing, at payment of the issue fee, and with each of the three maintenance fee payments—and in many cases more (e.g. post-grant proceedings, change of AO). Reporting is required at each of these events *even if there is no change to report*. For the reasons previously discussed, even where a change of AO *has* occurred, we urge the Office to reconsider whether so many reporting events are truly necessary, where, as explained and proposed, narrower rules can achieve the same goals while reducing the burdens on patentees and applicants.¹³ Whether or not the Office maintains these reporting

¹² The proposed AO rules could additionally be amended to except from the reporting requirement parties to option contracts and similar agreements, or those where one party is a manufacturer or producer.

¹³ To the extent that the Office proceeds with implementing these or modified AO rules, we suggest that the Office first establish an electronic reporting system that provides user-friendly standard forms that patentees and practitioners can employ to comply with rules. Particularly if the rules are to be

events for situations where the AO has changed, however, we see *no* justification for requiring reporting when all attributable owners have remained the same. Since the rules, as stated, already require additional reporting any time AO information has changed, a simple requirement that a patentee or applicant report its AO information *once* should suffice, with any further reporting triggered by that existing change requirement. We again appreciate the political climate in which these rules are being proposed, with calls on many fronts to rein in abusive patent litigation. Given, however, as previously discussed, that significantly less than 2% of applications are even in a position to contribute to this problem, we question what legitimate aims can be served by a redundant rule that seems only to create unnecessary burdens.¹⁴

More generally, the Office's estimate of the cost of complying with the AO rules (\$100 or less per transaction) is, in our view, unrealistic, because that estimate relies on a series of incorrect assumptions that do not hold true for a great many patentees and applicants. The Office suggests that the required AO analysis and reporting can be undertaken by a patent attorney or a general practice attorney. It seems to assume, however, that such professionals would be employed by the reporting entity, and that only one entity would be involved. While this may be true in some cases, not all companies have the capacity to manage their patent portfolios

retroactive, a simple system which allows bulk uploading and updating will be necessary to reduce the costs and burdens of compliance. Such a system should also be designed to accommodate large updates that may occur as a result of mergers, acquisitions, and licensing ventures.

¹⁴ The Office suggests that these burdens would be minimal, since confirmatory disclosures would be required at times when the patentee or applicant already has some contact with the Office (e.g. upon payment of maintenance fees). This is not correct, however, because traditional activities and communications like payment of maintenance fees are largely automated and, for many patentees, are undertaken by external service providers. In contrast, due to the nature of the parties currently defined in the rules as "AOs," the process of assessing and updating AO information would likely be conducted by a different entity, which would probably include in-house or external lawyers with the training and expertise to conduct the analysis. Even in cases where nothing has changed, this would entail extra communications between such personnel and those who pay the fees, or those personnel and the Office directly.

in-house, and many—especially smaller ones—would have to rely on external patent agents or law firms to perform this work. Universities are another entity that commonly would not fit the Office’s assumption, since they often out-license their patents, and the licensed patents are typically managed by law firms. In each of these cases, the patentees or applicants will have to pay the high costs of an external law firm to handle their AO disclosure compliance, while also expending internal resources to communicate with such firms. In fact, speaking more broadly, in the case of any licensed patent—which, as discussed, the proposed rules may frequently cover—at least two parties would be involved in the analysis, and often at least one law firm as well. Every interaction will result in a transaction cost, at least a temporal one if not financial. For these reasons, the Office’s suggestion that the AO verification can be accomplished at a cost of \$100 or less per transaction is highly unlikely in a great many cases.¹⁵

Last, in addition to the cost burdens, in Novartis’ view the rules’ proposed consequences for non-compliance are unduly severe in a variety of situations. The proposed consequence for failing to comply with either the filing or allowance reporting requirements is abandonment. For supplemental examinations and reexaminations, the consequence is failure to obtain a filing date. The Office has offered no explanation or justification for these penalties in either case. In any event, in our view, the severity of the penalties is in no way consistent with the rules’ stated aims. As discussed throughout these comments, the only goal that in any way implicates an entity’s intentional conduct is the goal of reducing abusive patent litigation. That goal, however, as previously discussed, is not relevant before a patent

¹⁵ As a benchmark, the mean cost for an outside law firm to pay a maintenance fee in 2013 was around \$250 (2013 AIPLA Report of the Economic Survey). Given that identifying or verifying AO would, under the currently proposed rules, be much more complex, one would expect the average cost of compliance to be significantly higher than \$250.

application is granted, and in 98% of cases, never becomes relevant for granted patents. Given this reality, other less extreme consequences would be much more appropriate and more consistent with the rules' aims of helping, in various ways, to encourage innovation through the patent system.¹⁶

While the proposed rules make some effort to ameliorate the severity of these penalties by extending the reporting deadline for one event and allowing for corrections of certain errors or omissions that occur for others, both of these provisions are, in our view, problematic. For the deadline extension, if the rules are to include penalties as severe as abandonment, we believe that the extension should be available for all reporting events, coupled perhaps by payment of a late fee, ideally without a requirement to file a petition, which seems unnecessary in most circumstances. Regarding the proposed correction procedure for other events, this procedure seems to apply only to cases where a “good faith effort” was made to comply with the rule, and it is not clear what this standard entails. Given the rules' requirement to report AOs at least five times for a typical granted patent, and the difficulties and uncertainties in determining whether a party is in fact an AO (e.g. in the case of exclusive licensees), occasional clerical oversights and judgmental errors are bound to occur. Particularly since external service providers or attorneys may be used to comply with the rules and process AO reports, the “good faith effort” standard is too uncertain and too narrow to protect honest applicants against inadvertent errors in all circumstances, as the rules should. In our view, given the context and aims of this rule, correction should be permitted under most circumstances without requiring a particular standard. In that regard, we note that even 35 U.S.C. § 256, which formerly required a showing of a “lack of deceptive intent” to correct inventorship errors, was amended to remove that requirement in the

¹⁶ These might include payment of a fee, loss of patent term adjustment for non-compliance within a given time frame, etc.

America Invents Act. Requiring “good faith effort” statements as a pre-requisite for correction (as currently-proposed 37 CFR §§1.279 and 1.387 suggest) could also lead to abuses of the inequitable conduct doctrine under the *Therasense* standard, a risk that again does not help innovation and that does not seem justifiable given the rules’ aim of *curbing* abusive litigation. If a standard for correction is required at all, we propose that the standard at least be consistent with that of 35 U.S.C. § 255, requiring only that the *error* be one made in good faith, rather than requiring a showing that “good faith efforts” were made to comply with the rules.

CONCLUSION

Novartis again thanks the Office for the opportunity to be heard on the proposed new rules, and for considering the comments provided above. We are confident that the changes proposed will result in a significantly more targeted and less burdensome set of rules that will nevertheless achieve the Office’s stated goals.

Respectfully submitted,

_____/s/ Corey Salsberg_____

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