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Re: Comments from Novartis on Proposed Rules to Require Disclosure of Patent Ownership Interests

Dear Mr. Vishnubhakat:

Novartis Corporation ("Novartis") thanks the United States Patent and Trademark Office (the Office) for the opportunity to respond to the Office's proposal to promulgate rules requiring patent applicants and patent owners to record and update Real Party in Interest ("RPI") information for U.S. patents throughout application pendency and patent term. Novartis respectfully requests that the United States Patent and Trademark Office ("Office") consider the following comments in response to its Notice of Roundtable on Proposed Requirements for Recordation of Real-Party-in-Interest Information Throughout Application Pendency and Patent Term, published in the Federal Register on November 26, 2012.

Novartis believes that most if not all of the benefits identified in the Office's proposal are already provided for under the Office's current system of assignment recordation, and/or under the Patent Act as amended by the

America Invents Act. As set forth below, Novartis is concerned that the Office's proposal may have unexpected consequences and create unreasonable burdens on patent applicants, patentees, and patent practitioners, ultimately causing more harm than good.

To the extent new regulations on RPI disclosure are ultimately adopted, Novartis urges the Office to carefully balance any anticipated benefits against the burdens such new rules will create—for instance, by adopting a narrow and practical definition of "RPI" that is objective, predictable, and easily applied by patent professionals handling cases for entities large and small. With this in mind, Novartis offers the following remarks in response to the Office's request for comments.

RPI Identification

The benefits of the proposed RPI disclosure requirements set forth in the Federal Register Notice essentially fall into two categories. The first category relates largely to facilitation of patent examination and post-grant patent proceedings. The existing rules concerning assignments and the statutory requirement to identify inventors and/or applicants upon filing already adequately enable the Office and interested parties to determine patent ownership in the vast majority of cases, and disclosure of such information for post-grant proceedings can be mandated for the small percentage of cases for which that information is needed without burdening each applicant and patentee.

The second category of benefits mentioned in the Notice relates to the role of patents in the marketplace. Taken together, such benefits fall generally in the realm of enhancing the ability of companies such as Novartis to make sound, well-reasoned business decisions in the face of third party patent rights.

Many of the corporate entities that spoke at the roundtable held at the USPTO on January 11, 2013, argued that accurate ownership information permits companies to determine whether they have freedom to operate in the marketplace. With respect to this second category of benefits, it is important to note that the claims of a granted patent determine whether one has freedom to operate, not the identity of the patent owner, ultimate parent corporate entity, or licensee. Ownership information may affect whether, how, and perhaps how aggressively some entities choose to proceed once it is determined that third-party patent rights exist, but those are business and strategy decisions that have more to do with private business interests than with helping the public ascertain the state of intellectual property protection in a particular art. We question whether it is the proper role of the Patent Office to involve itself in these types of decisions by third parties at the burden and expense of patentees who, as discussed below, often have legitimate business interests in maintaining confidentiality (including legal obligations to do so at times) that may conflict with the broader proposed definition of RPI, and could face unreasonably heavy compliance burdens and new sources of uncertainty.

In addition, 35 U.S.C. § 261 makes clear that identification of patent ownership (via recordation of an assignment) is optional, and lays out the penalty for not recording: "[a]n assignment, grant, or conveyance shall be void against any subsequent purchaser or mortgagee for a valuable consideration, without notice, unless it is recorded in the Patent and Trademark Office". The risks of failure to record an assignment already deter concealment of ownership interests for most purposes; the rare exceptions to this norm should not dictate blanket new rules that would burden each and every patentee and applicant. Furthermore, the Office should consider whether institution of the suggested

rules relating to mandatory identification of assignees and other parties would be in contravention of the recordation statute.

RPI Definition

The Office specifically invited comments on two possible definitions of the term "Real Party in Interest." One proposed definition for that term includes exclusive licensees having rights to assert the patent as well as assignees. The second definition includes the assignee or title holder and 'ultimate parent entity,' if any. For the reasons discussed below, to the extent the Office believes new regulations are necessary, taking into account the resulting burdens on applicants and patentees, Novartis believes such regulations should at most require disclosure of the assignee.

With regard to the first proposed definition, Novartis strongly opposes any definition of RPI that would require disclosure of exclusive licensees. In Novartis's view, including licensees in the definition of RPIs would inject undesirable uncertainty and ambiguity into the patent rules, creating an unacceptable level of opportunity for good-faith mistakes by practitioners. For example, it is not uncommon for exclusive licenses to be granted to more than one party in limited fields, in specific territories, for varying duration, for multiple patents, for specific claims in a patent, and with the possibility of retained rights. Federal Circuit case law, moreover, makes clear that the Court will look to the explicit language in the agreement to determine whether a license is actually exclusive. Thus, determining which licensees to disclose would be burdensome and risky, particularly for patent owners who rely upon licensing, such as academics. Also, license expirations may be triggered by a variety of events, some of which the patent practitioner will not even be aware of without a detailed analysis of the license terms and of business activities

entirely unrelated to the patent itself. Even for the seasoned corporate or transactional attorney, determining whether a particular patent is currently under an exclusive license, and whether the exclusive licensee qualifies as an RPI under the proposed definition would be, in many instances, extremely challenging, highly burdensome, and rife with pitfalls.

In addition, a third party's desire to know ownership details for a patent is strictly a business consideration, and should not outweigh the equally compelling business interests of the licensees and patentees/licensors, who value confidentiality for certain negotiations and business ventures. In a great many patent licenses, confidentiality is expressly required by the agreement between the parties: this demonstrates that the patentees and licensees often value confidentiality, and it is not clear whether savings clauses in existing licenses that allow disclosure 'when require by a court or law' would authorize disclosure based on a rule from the Office. Thus, the parties to a patent license have business interests that often favor confidentiality, and the competing business interests of third parties desiring disclosure of exclusive licensees should not outweigh those of the patentees whose research and licensing efforts drive innovation. In view of the attendant burdens and uncertainties involved, Novartis firmly believes that the definition of RPI should not include exclusive licensees.

The second proposed definition of the term RPI includes the assignee or title holder and the 'ultimate parent entity,' if any. There does not appear to be a reason why identification of the ultimate parent would be necessary. Only the assignee is legally relevant to patent examination. If conflict of interest concerns in post-grant proceedings arise, the Office can gather additional information when it is needed, limiting the burdens to the small percentage of patents subject to post-grant proceedings, rather than imposing a requirement

applicable to ALL patents and applications, regardless of relevance to Office proceedings.

Also, the requirement to disclose the parent entity introduces new layers of uncertainty and opportunities for inadvertent non-compliance, which risks becoming a source of litigation and a possible basis for challenging the patent. For example, requiring identification of the 'ultimate parent entity' of the assignee imposes undue burdens on patent agents, who may not be legally qualified to determine which level of corporate structure represents "an entity which is not controlled by any other entity." Accordingly, Novartis believes the term 'RPI' should refer to the actual title holder or assignee of the patent or application.

When to Provide RPI Information

To the extent the Office proceeds with rulemaking in this area despite the above concerns, Novartis believes that any requirement to identify the RPI for a patent application or patent should be structured to occur once, such as upon payment of the Issue Fee, and updating of RPI information should not be required except in connection with an actual change to the RPI. The current proposal would require submitting RPI information upon filing, updating of RPI information whenever it changes, and affirming that RPI information has *not* changed at numerous milestones. Novartis strongly discourages the Patent Office from enacting rules that would require confirmation of RPI status during examination or after patent grant.

Requiring the patentee to periodically update the RPI disclosure for every patent and every application would necessitate repeated practitioner involvement, and perhaps a duty to re-investigate each time, just to confirm the *status quo*. The Patent Office has asserted that such confirmatory RPI

disclosure is proposed to take place at times when the patent practitioner would have contact with the Office anyway (such as upon publication, or payment of the issue fee), thus minimizing the burden on the practitioner or patentee. What this argument misses, however, is that the acts needed to confirm RPI status at prescribed times go well beyond the scope of activities that would normally take place at those times. The requirement as currently outlined in the Federal Register would change each maintenance fee payment, for example, from the simple and automated process that is currently handled by an external service for many patentees, to a docketed item requiring practitioner investigation and analysis *just to state that nothing has changed.* Moreover, particularly if the broader definition of RPI were adopted, each confirmation would force a patent practitioner to review the terms of any relevant licenses to determine their current status. This is a grossly disproportionate burden relative to the benefit of updating information about the small fraction of situations where a change of ownership has occurred, particularly when added on top of a requirement to report any changes that actually *do* occur.

Burdening all patents and applications with a recurring obligation to verify that the RPI is unchanged is excessive and entirely unnecessary. If updating of RPI information is required, the trigger for updating should be the occurrence of some relevant change in the RPI, not a patent prosecution or maintenance event that is unrelated to any change of ownership. Indeed, the existing rules and statute are sufficient, and Novartis respectfully requests that the Office forego any effort to change or add to those requirements.

Consequences of Non-compliance

The proposal for RPI disclosure says little about consequences for failure to fully comply: this could potentially introduce a new source of uncertainty into the patent system. The Office's stated goals of enhancing transparency by requiring submission of current ownership information should not be pursued by means that increase uncertainty about the enforceability of a patent or increase the already exorbitant cost of patent prosecution and litigation: rules having such effects would undermine the very purpose of the Patent Office, which is promoting the progress of science and the useful arts. Accordingly, it is critical that any rules promulgated to require RPI disclosure must not create new questions about the validity or enforceability of patents issued by the Office—surely new rules having that effect should be avoided unless mandated by statute. The Office should clearly spell out what consequences arise in the event of non-compliance with any new disclosure rules, and should provide a method to correct any failure to fully or accurately comply.

As one option, the Office could provide a mechanism to correct the RPI information on file at any time, subject to payment of fees for untimely compliance. For example, at any time when RPI information is required for post-grant proceedings or litigation, if the RPI information provided is not consistent with information already on file with the Office, the Office could require a correction to be made. If the correction comprises a change that should have been submitted more than, e.g., three months earlier, the fee for the correction could be substantial enough to promote timely reporting of the correct RPI or of any change in RPI. No 'unintentional or unavoidable' standard would be needed, only one of timeliness: this would create incentive for compliance and penalty for non-compliance, without raising questions of patent validity based on the proposed new rule. The Office could also state

that the RPI disclosure requirement promotes transparency but is not so material to examination that it creates a basis for invalidation or revocation, in an effort to preempt attempts to use imperfect compliance or even non-compliance to challenge patent validity. Moreover, RPI disclosure requirements should not give rise to allegations of inequitable conduct. Given the justifications set forth for the proposed rule, and the lack of express statutory basis for it, Novartis believes the means employed by the Patent Office to encourage compliance with any new RPI disclosure requirement should not be as large as potential invalidation or unenforceability of a patent, or abandonment of a pending application, under any circumstances.

Novartis appreciates the opportunity to be heard on the proposed new rules and for consideration of the comments provided herein.

Respectfully submitted,

Betty Ryberg