-----Original Message-----
From: Thomas, Nicole On Behalf Of Ryberg, Betty
Sent: Friday, March 15, 2013 1:37 PM
To: QualityApplications_Comments
Subject: Novartis Comments on Preparation of Patents

Ms. Haines:

Please see attached comments on the preparation of patent applications. Thank you.

Best Regards,

Betty Ryberg
Novartis Corporation
212-830-2475

NOVARTIS

Betty Ryberg
Vice President

Novartis Corporation
230 Park Avenue
New York, NY 10169

T: 212-830-2475
F: 212-830-2495
betty.ryberg@novartis.com

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VIA E-MAIL ONLY
(QualityApplications_Comments@uspto.gov)

U.S. Patent and Trademark Office
Mail Stop Comments—Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Attn: Nicole D. Haines

Re: Novartis's Comments on Preparation of Patent Applications

Dear Ms. Haines:

Novartis Corporation ("Novartis") respectfully requests that the United States Patent and Trademark Office ("Office") consider the following comments in response to its Request for Comments on Preparation of Patent Applications, which was published in the Federal Register on January 15, 2013. Our specific comments at this time are as follows:

Novartis appreciates the Office's desire to enhance the quality of issued patents and increase the efficiency of patent prosecution, and understands that the need for improvement may be especially great in the software field. Some of the practices the Office proposes could improve the quality of some patent applications if implemented on a voluntary basis, and perhaps limited to the software field. For the reasons set forth below, Novartis believes other proposed practices should not be implemented, and none of them should be required.

First, the proposals appear to be largely intended to improve perceived issues with software or technology patents. It is unclear from the Notice whether the proposed practices would be recommended or mandatory: if the

Office intends to impose burdensome practices on all applicants, Novartis believes the proposed practices would be counterproductive. The patenting process in other fields should not be drastically altered simply to reduce issues in a particular area of technology.

Second, applications prepared by competent patent practitioners in most fields will typically provide the clarity desired by the Office, without the proposed practices, and the enablement, written description, and definiteness requirements of 35 USC §112 already provide vehicles for the Office to reject patent claims lacking in clarity. Skilled patent practitioners have the information and awareness to avoid ambiguity, and know that, if they fail to do so, they risk having their claims rejected by the Office or invalidated by a court. Some of the proposed practices might be beneficial to an inexperienced drafter or *pro se* applicant, but they should not be imposed on the skilled drafters who are aware of the standards for clarity and claim construction and make informed decisions about how to comply with them. For all applicants, the proposed steps would significantly increase costs and time for preparing a patent application: preparing a chart showing every limitation of each claim, and pointing out support in the application for every limitation, would involve significant work, for example.

Third, these practices, if implemented, would be unique to the United States – no other country requires them. Imposition of these practices would move the U.S. patent system *away* from the goal of international patent harmonization that the Office otherwise seems to embrace. Some of these practices, as discussed in more detail below, would injure non-U.S. inventors, whose patent applications may be drafted in other languages and not crafted by experts in U.S. law and practice. Moreover, if the U.S. imposes such requirements, other countries may follow suit, placing the U.S. inventors at a

disadvantage, and further complicating the patent system and undermining incentives for innovation.

Fourth, courts have long dealt with issues such as determining whether a patent claim invokes 'means-plus-function' construction; thus, court decisions provide guidance to the Office and practitioners. In most cases, any ambiguity can be resolved by relying upon those standards, which is what practitioners currently expect. Imposing new rules would do more to increase uncertainty than to remove it, at least until such time as courts have the opportunity to analyze and address patents issued under the various proposed new practices.

Finally, imposition of these requirements by the Office complicates the role of patent prosecution as it relates to litigation and, to some degree, disadvantages patentees during litigation. How the courts would interpret an applicant's required statements to the Office is unknown. It is unclear whether the courts would honor all of the applicant's positions with respect to definitions, dictionary sources, glossaries, limiting nature of the preamble and examples, etc. It seems likely that at least some such statements to the Office would create estoppel during later litigation that could place sharp boundaries on claim scope and deny applicants any benefit from the doctrine of equivalents. The doctrine of equivalents was created by the courts to ensure that a copyist cannot escape liability for infringement by making insubstantial changes to a claimed invention, thus, in the words of Judge Learned Hand, "stealing the benefit of the invention." *Royal Typewriter Co. v. Remington Rand, Inc.*, 168 F.2d 691, 692 (2d Cir. 1948). Eviscerating the doctrine of equivalents would reduce the value of each affected U.S. patent. While some might consider that an 'improvement,' to the extent it reduces the scope of patent protection, it would discourage innovation, which is contrary

to the Office's constitutional mandate to "promote the progress of science and useful arts."

As long as patent practitioners meet the statutory requirements for clarity, they should be able to draft claims so that the claim language speaks for itself: they should not have to artificially define terms before those terms can be used in a claim, or align the entire vocabulary of an application with a particular dictionary. The claims define the invention; not the specification or dictionaries. True, the specification must support the claims and may, in some cases, be the "single best guide" to their meaning. But, as the *Phillips v. AWH Corp.* and *Vitronics Corp. v. Conceptronic, Inc.* courts made clear, "the claims themselves provide substantial guidance as to the meaning of particular claim terms." Applicants, and ultimately the Courts, ought to be able to decide for themselves whether, and in what way, to provide further definition to or support for a claim limitation. To mandate otherwise, may conflict with the law that the claims alone ultimately define the invention.

Comments on Individual Proposed Practices

Certain of the proposed practices may be helpful to some applicants if offered as guidelines, such as stating whether a claim invokes "means-plus-function" or "step-plus-function" construction, and using standardized text and graphic notations for algorithms in computer-implemented claim limitations. However, other practices may impose undue burdens and uncertainty for years to come. For example, use of a standardized template to identify the parts of a claim would have limited benefit for a patent examiner or drafter in most cases, but would substantially burden every single application. The location and nature of words within a claim identify the function and purpose of the words: there is little if any ambiguity about the identity of those terms in most claims. Would an error by an applicant in charting a claim to comply

with this proposal be harmful to the applicant? Would the chart be used by the Office to construe a claim, instead of the claim itself? By a court? If so, such a rule could be viewed as modifying the statutory requirements for a patent, without Congressional authorization to do so.

A requirement to identify support in the specification for the claim limitations may be acceptable if applicants are asked only to identify representative support, provided it is clear that failure to point to other supporting description does not prejudice the applicant's right to rely upon the other description for claim support in later prosecution or litigation. In the U.S., support for a claim limitation may be found directly in the specification, but may also be implied or inherent. Therefore, it should be made very clear that support in the specification is not required to be literal, otherwise this proposal could prejudice the applicant's substantive right to rely upon the specification to support claims based on all it discloses to the person of ordinary skill, and undermine the time-honored U.S. tradition and practice of making the claims clear and meaningful, rather than reducing them to literal repetition of language from the specification. In addition to the risk that such a requirement might have unintended consequences, it would also be a significant burden on all applicants, and it is not clear that it would actually do anything to address any supposed problem with either examination of claims by the Office or interpretation of patents by the public. Thus, this proposal does not appear to be, on its face, commensurate with the desired outcome.

Other proposed practices are equally troubling. For example, asking an applicant to indicate whether examples are "limiting or merely illustrative." Realistically, it is difficult to imagine what circumstances would lead an experienced practitioner to state that the examples are limiting: if the proposed practices are intended to benefit inexperienced practitioners, this seems instead to invite them to err. Similarly, requiring the applicant to state

whether claim preambles are intended as claim limitations seems potentially problematic. Should an applicant state that the preamble is not limiting, the Examiner may honor that statement, but it is unclear whether a court, bound by precedent, would agree. Also, requiring an applicant to indicate whether terms of degree in the specification (e.g., 'substantially') have a lay or technical meaning and explaining the scope of those terms would invite more uncertainty than it would remove in many cases. If the specification does not meet the requirement, would the Examiner reject it, depriving the applicant of rights to his invention on a technicality? Would a court uphold the Office's decision on that question?

Likewise, requiring an applicant to put a glossary of 'potentially ambiguous, distinctive and specialized terms' in the specification seems to handcuff an applicant to using terms that are actually defined, limiting the language that could be used in the claims. Again, would the absence of an express definition for a term an Examiner deemed 'potentially ambiguous'— a term which is itself highly subjective — prevent use of that term in an otherwise patentable claim?

Finally, requiring an applicant to designate a default dictionary for claim interpretation seems unfair: it forces the drafter to adopt a single source for defining a great many words, and exalts dictionary definitions over the ordinary usage of terms in often-specialized fields. Where an examiner and applicant both understand a term in the claims, the patentee in later litigation may nonetheless be held to a dictionary definition of that term (or other terms) that neither the Office nor the applicant relied upon, merely because the Office required a dictionary to be identified. Moreover, by the very nature of patentable technologies, applicants may have few choices of dictionaries when using a technical term that happens not to be found in many dictionaries, and the need to translate applications drafted in other languages

further complicates compliance. All of these practices may also raise questions about the validity of a priority claim if the priority document, which may have been drafted in another country, fails to comply.

Examiners can already rely upon of 35 USC §112 to reject claims that lack reasonable clarity, taking into account the level of skill in the relevant art and just how revolutionary the claimed invention happens to be. Any experienced practitioner is aware of the need for clarity, of methods to achieve it, and of the risks of failing to achieve it. They should be allowed to draft based on their expertise and the language and limitations of the technology they seek to describe.

To the extent the proposed changes may be offered as voluntary guidance, some of them may be useful to the inexperienced drafter or *pro se* inventor. To assist such applicants, software is available to help with claim drafting, identifying support for claim limitations, making claim amendments, etc. For example, ClaimMaster and Brux Software Solutions™ iCLAIM® provide assistance to those who want it, and the Office can guide users toward such aids or even make similar software available for voluntary use. In addition, the Office can encourage inexperienced drafters or *pro se* inventors to enroll in seminars, courses, or webinars designed to teach claim drafting, or to obtain and read various books and treatises regarding the same. If aspects of the proposal are adopted as guidance for those who need assistance rather than as mandated practices, the voluntary status of the guidance should be made clear to both practitioners and Examiners, as should the risk an applicant takes when relying upon the limitations of such guidance.

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Conclusion

Novartis is opposed to implementation of many of the patent application preparation practices proposed by the Office. While some of the proposed practices could be acceptable, none of them should be mandatory. Instead, they should be optional and directed toward practitioners who are most in need of guidance, e.g., *pro se* inventors and registered attorneys who may be inexperienced in the software field. In addition, any implemented practices should be limited to the software arts if issues with that field are the primary concern these proposals address: Novartis does not believe the perceived problems with lack of clarity or quality attributed to software patents are sufficiently widespread in other art fields to justify the added burdens, costs and uncertainties that requiring these practices would impose. Mandating the proposed practices would be prejudicial to the substantive rights of patent applicants, encroach on the domain of the courts, and increase both costs and uncertainty in the patent system, thus ultimately deterring innovation.

Respectfully submitted,

Betty Ryberg

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