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VIA E-MAIL ONLY
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U.S. Patent and Trademark Office
Mail Stop Comments—Patents
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: Novartis's AIA Implementation Comments on First Inventor To File, Inventor's Oath or Declaration, Post Grant Review Proceedings, Supplemental Examination, Study on Genetic Testing (Section 27 of the Act), and Human Organism Prohibition

Dear Sir or Madam:

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 the Implementation of the America Invents Act. Novartis believes that the Office's interest in soliciting comments on the appropriate implementation of the America Invents Act is a meritorious and worthwhile endeavor, and wishes to assist it in developing its implementation rules and guidance. Our specific comments at this time are as follows:

Section 3 of the Leahy-Smith America Invents Act: First Inventor To File

When the Leahy-Smith America Invents Act takes effect, patent applicants will, at times, need to establish that a public disclosure citable against a pending patent application was made by the inventor or obtained from the inventor. It will be important for the Office to provide guidance on both the level of public disclosure that is required in order for an Inventor to benefit from the exclusion of an earlier

disclosure as prior art under §102(b), and on the level of evidence and mechanism for establishing that publicly-disclosed subject matter was either disclosed by the inventor(s) or obtained from the inventor(s).

A. Publicly-Available Art

Under the current version of 35 U.S.C. § 102, the scope of disclosures that can be used to anticipate or invalidate a claim requires an element of public availability. In addition, there is a vast array of well-settled jurisprudence that makes clear that public accessibility to the prior art is fundamental to the ability of such art to anticipate or invalidate a claimed invention.

A review of the House Judiciary Committee Report reveals that it was the intent of Congress that the new statutory definition of prior art not upset the established expectations of the patent community with respect to the public availability of prior art. Thus, we recommend that the Office draft rules that maintain the current standards and criteria for deeming prior art "publicly available."

Clarification of public availability is particularly important in the context of the language of § 102(a)(1) that creates a category of prior art that is "otherwise available to the public." We suggest that the Office provide guidance as to the scope and meaning of this phrase. We propose that the Office provide interpretive guidance to clarify that the term "otherwise" can encompass modes of information flow consistent with current and future technology (e.g., digital and social media, web pages, etc.), provided that current notions of public availability (e.g., indexed, searchable, inherent, etc.) are maintained. Moreover, we recommend that the Office

issue rules that require Office Examiners to at least appropriately document how the cited art was "otherwise available to the public".

B. Parallel Scope of §§ 102(a) and 102(b): What Is a "Disclosure?"

New 35 U.S.C. § 102(a)(1) provides that novelty will be forfeited if the claimed invention was "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public." The exceptions to prior art under new section § 102(b) however, are largely focused on "disclosures" made by an inventor or others who obtained the "disclosed" subject matter from the inventor. What is unclear in the current language of the statute, however, is whether the scope of exempted "disclosure" under § 102(b) is coterminous with the circumstances that create prior art under § 102(a). For example, would an offer for sale by the inventor that would otherwise be prior art against a claimed invention under § 102(a) be exempted as prior art under §102(b), if the offer for sale occurred less than 1 year before the effective filing date of the claimed invention?

We believe that identity in scope between § 102(a) prior art and § 102(b) exceptions is the correct interpretation of the new section § 102. Accordingly, we recommend that the Office issue rules and guidance that make it clear that the scope of prior art under § 102(a) and the excepted disclosures under § 102(b) is the same.

C. Showing that a public disclosure was made by an Inventor or by another who obtained the subject matter from Inventor(s) under § 102(b)(1)(A)

The new § 102(b)(1)(A) makes clear that a "disclosure" will not operate as prior art if the disclosure was made by the inventor or by another who obtained the

subject matter from the inventor or a joint inventor. The new statute places the burden for examination on the Office (note the use of "...shall be entitled to a patent unless..." in the new § 102), consistent with existing practice under MPEP § 716.10. The Office thus is responsible to establish that a reference at least appears to be available as prior art. Novartis submits that, where a public disclosure appears on its face to be published or disclosed by the same inventive entity as appears on the application, or by fewer than all of the inventors of the application when inventorship is joint, the Office should not make a rejection, unless there is a *prima facie* basis to doubt that the entire public disclosure originated from the named inventor(s). Thus, Novartis proposes that, in agreement with current practice, the Office should not require evidence that subject matter in a public disclosure was disclosed by or obtained from the person claiming inventorship if the source of the public disclosure is identifiable and the authorship corresponds credibly to one or more of the named inventors and no other person. In such a situation, the Office should simply not cite the disclosure against the application.

However, where the source of a public disclosure is not apparent, or the source of a public disclosure appears on its face to include any person other than one or more named inventors, Novartis proposes that the Office may cite this disclosure against the application and allow the Inventors to submit evidence tending to show entitlement to an exception provided in § 102(b)(1)(A). When required, establishing entitlement to an exception under new § 102(b)(1)(A) will involve either showing that the relevant portions of the public disclosure directed to a claimed invention were

disclosed by one or more of the named inventors or were obtained from one or more of the named inventors. Once the new laws take effect, an added section of 37 C.F.R. § 1.131 could be inserted to provide a mechanism for demonstrating entitlement to the exemptions of new § 102(b)(1)(A). Declaration practice under 37 C.F.R. § 1.131 seems to be an appropriate mechanism for this, since this showing would be analogous to showing prior invention under existing practice. Alternatively, a section could be added to 37 C.F.R. § 1.132. Indeed, as per current MPEP § 716.10, attribution and derivation can be addressed during prosecution using a simple "Katz"-type declaration under 37 C.F.R. § 1.132, which need only provide an unequivocal statement from the Inventors that the relevant portions of a reference originated with or were obtained from the Inventors. Novartis proposes that, under the new laws, an uncontradicted and unequivocal statement from the inventor(s) regarding the subject matter disclosed in cited prior art (e.g., an article, patent, or published application) should similarly be accepted by the Office as establishing that the subject matter was obtained from the inventor(s). As a general practice, the Office should not require a statement by the authors of the actual public disclosure.

If following the submission of, e.g., a Katz-type declaration, the Office nevertheless still finds the appearance of an independent origin for the public disclosure, the Office may require more evidence to show that the public disclosure was made by the inventor(s) or obtained from the inventor(s). For example, the Inventors may provide the Office with a signed statement by each author of the public disclosure who was *not* named as an inventor, stating that said author did not invent

the claimed subject matter or that said author learned about the claimed subject matter from one or more named inventors. Alternatively, if a public disclosure appears to be made by another person or entity (not solely by one or more of the named inventors), and the Inventors cannot provide statements from each of the non-inventors associated with or responsible for the public disclosure, then the named Inventors can provide a further declaration and/or evidence stating that the public disclosure represents the work of one or more of the named inventor(s) (at least to the extent that it discloses the claimed invention) and explaining the role of any non-inventors to whom the public disclosure appears to be attributed.

D. Double Patenting / Obviousness-Type Double Patenting

New § 102(b)(2)(C) and § 102(C) provide that a previously-filed patent application that would previously have been citable under § 102(e) will no longer be prior art to a pending application when it is owned by the same person or subject to an obligation of assignment to the same person, or when the claimed invention in a pending application and the subject matter disclosed was made by (or on behalf of) parties to a joint research agreement. Therefore, establishing common ownership will preclude citing a previously-filed patent application for both anticipation and obviousness rejections.

The new statute does not expressly address the basis for either statutory double patenting or obviousness-type double patenting rejections when the previously-filed patent application is not citable as prior art. Novartis believes that the underlying policy reasons for both statutory double patenting (historically based on

35 USC § 101) and judicially-created obviousness-type double patenting rejections are not affected by the change in 35 USC §§ 102 and 103. Therefore, the Office should clarify that those doctrines remain intact and do not require a 'prior-art-based' rejection under 35 USC §§ 102 or 103.

Section 4 of the Leahy-Smith America Invents Act: Inventor's Oath or Declaration

A. 35 U.S.C. §115 (Inventor's Oath or Declaration)

Revised 35 U.S.C. §115, subpart (e) provides:

> An individual who is under an obligation of assignment of an application for patent may include the required statements under subsection (b) and (c) in the assignment executed by the individual, in lieu of filing such statements separately.
>
> 35 U.S.C. §115(e).

Thus, under this new section of the law, an Applicant for patent may file a single document that serves the dual function of assignment and oath/declaration.

One of the formal requirements for a valid patent remains the provision of an oath or declaration having the statements set forth in 35 U.S.C. §115(b). A common starting point to assess the validity of a patent, or the likely validity of a patent issuing from a pending patent application, is devising whether the patent holder properly complied with the requirements of 35 U.S.C. §115. Under new 35 U.S.C. §115(e), the statements of 35 U.S.C. §115(b) may be provided as part of an assignment. However, under 37 C.F.R. §1.12(b), certain assignment documents, i.e., those found in pending or abandoned applications that are not open to the public pursuant to 37 CFR §1.11

or for which copies or access may not be supplied pursuant to 37 CFR §1.14, are not available to the public absent a showing under 37 C.F.R. §1.12(c) and in accordance with M.P.E.P. 301.01.

If assignment documents with statement under 35 U.S.C. §115(b) are not fully available to the public, then the public will be unable to determine whether the formal requirements of 35 U.S.C. §115(b) have been met for a particular patent application, and consequently, will not be able to determine the likely validity of any patent issuing therefrom. Accordingly, Novartis requests that the Office, in drafting rules related to 35 U.S.C. §115, revise 37 C.F.R. §1.12(b) to clarify that assignment documents that are used to simultaneously satisfy the Oath or Declaration provision of 35 U.S.C. §115(e) will become available to the public. This will allow the public to determine if the requirements of 35 U.S.C. §115(b) have been fulfilled. Novartis also requests that the Office clarify that assignment documents that are **not** used to satisfy the Oath or Declaration provision of 35 U.S.C. §115(e), and which normally would not be available to the public under 37 C.F.R. §1.12(b), will remain unavailable to the public under 37 C.F.R. §1.12(b).

B. 35 U.S.C. §118 (Filing by Other than the Inventor)

Novartis requests that the Office, in drafting rules related to the first sentence of new 35 U.S.C. §118, acknowledge that the term "... *person* ... " is used to mean a human being or a corporate entity. The first sentence of 35 U.S.C. §118 provides:

> A *person* to whom the inventor has *assigned or is under obligation to assign* the invention may make an application for patent. ...
>
> 35 U.S.C. §118 (emphasis added).

It is often the case that an inventor(s) assigns rights in a particular invention to a corporation, frequently an employer, a corporation designated in an agreement (e.g., a clinical trial agreement, a research agreement, etc.), or a corporate purchaser of a particular invention. Part of the intent of the American Invents Act is to harmonize patent law in the United States with the laws of foreign jurisdictions. In most foreign countries, the Applicant for patent is the assignee – and in many cases that is a corporate entity. There is no indication that Congress intended "...*person*..." to be limited to an actual human being, but instead Novartis submits that Congress intended this provision to include corporate entities.

Novartis requests that the Office, in drafting rules related to the first sentence of new 35 U.S.C. §118, acknowledge that an applicant for patent, when filing in lieu of an inventor(s) and using the criteria "... *assigned or is under obligation to assign* ..." need not submit any evidence to establish entitlement to make the application for patent. This interpretation is supported by a comparison of the text of first sentence of new 35 U.S.C. §118 with the text of the second sentence of new 35 U.S.C. §118. While the second sentence of new 35 U.S.C. §118 contemplates "proof of pertinent facts and a showing that such action is appropriate to preserve the rights of the parties", the first sentence of new 35 U.S.C. §118 provides no such mandate. This is

also in accordance with 37 C.F.R. §1.34, which states that a practitioner's signature functions as evidence of the practitioner's right to represent the party on whose behalf he or she acts.

The term "... *person* ..." is used in the second sentence of 35 U.S.C. §118, and, for the reasons set forth above, Novartis requests the Office to acknowledge that the term "...*person* ..." is used similarly in the second sentence of 35 U.S.C. §118, i.e., to mean a human being or a corporate entity.

The second sentence of 35 U.S.C. §118 provides:

> ... A person who otherwise shows *sufficient propriety interest* in the matter may make an application for patent on behalf of and as agent for the inventor on *proof of the pertinent facts and a showing that such action is appropriate to preserve the rights of the parties*. ...
>
> 35 U.S.C. §118 (emphasis added).

Novartis requests that the Office, in drafting rules related to the second sentence of new 35 U.S.C. §118, acknowledge that the criteria "*sufficient proprietary interest*" may be evidenced by a variety of contractual obligations, including, e.g., employment agreements, services agreements, research agreements, etc. This criteria may also be evidenced by written and/or oral agreements by an inventor or entity acknowledging the intention of the inventor or entity to make an assignment, as well as various common law relationships and implied obligations, e.g., an employee or business-to-business relationship in which one is hired to invent or had been given

tasks to which to devote effort to solve a particular problem (*see, e.g., Standard Parts v. Peck*, 264 U.S. 52 (1924); *Teets v. Chromalloy*, 83 F.3d 403, 407 (Fed. Cir. 1996); *Reddi-Wip, Inc. v. Knapp-Monarch Co.*, 104 F. Supp. 204 (E. D. Mo. 1952)).

Given the confidential nature of proofs that may be used to establish compliance with the criteria of the second sentence of 35 U.S.C. §118, Novartis requests that, if any confidential documents are used for this purpose, the Office not include such documents in the public file wrapper. Instead, e.g., the Office may state in the file-wrapper that certain agreements were reviewed by the Office and found to fulfill the criteria set forth in the second sentence of 35 U.S.C. §118.

Novartis requests that the Office, in drafting rules related to the second sentence of new 35 U.S.C. §118, also acknowledge that the requirement "*proof of the pertinent facts and a showing that such action is appropriate to preserve the rights of the parties*" include such proofs as correspondence, declarations, letters or intent, agreements, and any other evidence that a court of law would consider in determining whether an applicant has sufficient proprietary interest in the subject matter of a patent.

Section 6 of the Leahy-Smith America Invents Act: Post Grant Review Proceedings Under 35 USC §321

As an initial consideration, one challenge to filing a proper request for post-grant review (PGR) under the Leahy-Smith America Invents Act stems from the fact that conditions for patentability based on novelty and obviousness are changing under the new 35 USC §§ 102 and 103. If the requirements for what constitutes a "prior disclosure" under the new rules are not clearly delineated, parties will waste tremendous resources arguing whether subject matter qualifies as a prior "disclosure" that would challenge a patent. Thus, clearly defining the boundaries of art and exceptions under the new § 102 will be critical to a successful PGR program.

According to new 35 USC § 324(b),

> The determination required under subsection (a)
> may also be satisfied by a showing that the petition
> raises a novel or unsettled legal question that is
> important to other patents or patent applications.

Novartis submits that clear guidance should be provided to the Director and to parties filing petitions for post-grant review regarding whether a petition raises a novel or unsettled legal question that is important to other patents or patent applications. Such guidance should include: (1) whether the petitioner must assert that the questions raised should be considered a novel or unsettled legal question; (2) the evidence required to establish what is a novel or

unsettled legal question; (3) whether the Director has leeway to determine, without an assertion on the part of the petitioner, that a petition raises a novel or unsettled legal question; (4) what, if any, arguments or evidence may the patentee present to avoid a finding that the petition raises a novel or unsettled legal question; and (5) whether a finding that a petition raises a novel or unsettled legal question is appealable.

Under new 35 USC § 326(a)(9), the patent owner has the ability to propose a reasonable number of substitute claims during the PGR. Novartis proposes that multiple propositions of substitute claims should be allowable in the form of a reasonable number of auxiliary requests, similar to what is available to a patent owner in a European opposition proceeding. Further, it is Novartis' position that a "reasonable number of substitute claims" should be interpreted to mean a reasonable number of claims given the particular case at hand, e.g., taking into consideration the number of auxiliary requests, the number of original patent claims, the complexity of the subject matter, the timing of submission of the auxiliary requests, etc. Novartis does not support a flat number of claims for any particular auxiliary request. Finally, Novartis suggests that, under the new PGR procedure, if the patent owner proposes substitute claims or presents amended claims (e.g., as auxiliary requests), a petitioner should have the opportunity to file written comments addressing the patentability of the proposed claims within a reasonable time period (e.g., three months) as established by the Director.

New 35 USC § 325(c) permits the Director to consolidate multiple petitions for PGRs against a single patent into a single PGR. Novartis believes that, as experienced with the similar process in the European Patent Office, consolidation is the ideal way to proceed in these instances. Accordingly, Novartis suggests that the Director promulgate rules that require consolidation of multiple petitions into a single PGR unless specific extenuating circumstances exist that militate against consolidation. A Proprietor may, e.g., petition the Director to maintain separate PGRs, by showing extenuating circumstances.

New 35 USC § 321(c) requires any petition for PGR to be filed not later than nine months after the date of issue of the patent or reissue patent. New 35 USC § 323 permits the Director to set the time period for the patent owner to file a preliminary response to such a petition (setting forth reasons why the patent owner believes no PGR should be instituted). Finally, new 35 USC § 324(c) requires the Director to determine whether to institute a PGR within three months after the patent owner files its preliminary response under 35 USC § 323, or, if no such response is filed, the last day on which such response may be filed.

In order to (a) promote consolidation of multiple petitions, (b) minimize effort on the part of the patent owner, and (c) permit the Director and all parties to comply with the statutory provisions cited above, Novartis suggests that the Director promulgate a rule under 35 USC § 323 that:

(i) permits a patent owner to file a single preliminary response to multiple PGR petitions, and

(ii) requires such response to be filed no earlier than nine months after the date of issue of the patent, and no later than twelve months after said date.

In this manner, the patent owner can wait until all petitions are filed before filing a consolidated response, and have at least three months after the last petition is filed to prepare that response. Also, the Director does not have to institute the PGR until after all petitions have been filed. Furthermore, in the event that multiple PGR petitions are filed and all such PGRs are consolidated into a single PGR, the Director should consider mandating that the proprietor shall file a single consolidated response that answers all arguments set forth in all PGR petitions. This will facilitate an expedient PGR proceeding.

Section 12 of the Leahy-Smith America Invents Act: Supplemental Examination

A. 35 U.S.C. §257 (Supplemental examination to consider, reconsider, or correct information) – "*Information*" and "*Relevant to the Patent*"

35 U.S.C. §257, subparts (a)-(c)(2)(A) provide:

> (a) Request for Supplemental Examination.--A patent owner may request supplemental examination of a patent in the Office to consider, reconsider, or correct *information* believed to be *relevant to the patent*, in accordance with such requirements as the Director may establish. Within 3 months after the date a request for supplemental examination meeting the requirements of this section is received, the Director shall conduct the supplemental examination and shall conclude such examination by issuing a certificate indicating whether the *information* presented in the request raises a substantial new question of patentability.
>
> (b) Reexamination Ordered.--If the certificate issued under subsection (a) indicates that *a substantial new question of patentability* is raised by 1 or more items of *information* in the request, the Director shall order reexamination of the patent. The reexamination shall be conducted according to procedures established by chapter 30, except that the patent owner shall not have the right to file a statement pursuant to section 304. During the reexamination, the Director shall address each substantial new question of patentability identified during the supplemental examination, notwithstanding the limitations in

chapter 30 relating to patents and printed publication or any other provision of such chapter.

(c) Effect.--

(1) In general.-- A patent shall not be held unenforceable on the basis of conduct relating to *information* that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the *information* was considered, reconsidered, or corrected during a supplemental examination of the patent. The making of a request under subsection (a), or the absence thereof, shall not be relevant to enforceability of the patent under section 282.

(2) Exceptions.----

(A) Prior allegations.--Paragraph (1) shall not apply to an allegation pled with particularity in a civil action, or set forth with particularity in a notice received by the patent owner under section 505(j)(2)(B)(iv)(II) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(B)(iv)(II)), before the date of a supplemental examination request under subsection (a) to consider, reconsider, or correct *information* forming the basis for the allegation.

35 U.S.C. § 257(a)-(c)(2)(A) (emphasis added).

The term "*information*" has not been defined by the Leahy-Smith America Invents Act (AIA) or in other parts of Title 35 of the United States Code ("Section 35"). New 35 USC § 257 appears to use the term "*information*" broadly, to encompass anything, in any form, that is "*relevant to the patent*", e.g., anything that could conceivably raise a substantial new question of patentability and/or eventually form the basis of an allegation of invalidity or unenforceability. Novartis submits that this should include information related to all sections of Title 35 that are "*relevant to the patent*", i.e., 35 USC §§ 101,102, 103 and 112. Previously, an *ex parte* and *inter partes* reexamination at the Office was limited to a substantial new question of patentability arising from prior art consisting of patents or printed publications. However, the term "*information*" as used in new 35 USC § 257 is clearly much broader. Indeed, the broad use of any document or evidence of any form or type that is "relevant to the patent" is without precedent in reexamination procedures under Title 35. Accordingly, Novartis requests that the Office clarify that "*information*" that is "*relevant to the patent*" includes any document or evidence, of any form or type, that may be relevant to a substantial new question of patentability or could eventually form the basis of an allegation of invalidity or unenforceability, under any relevant part of Title 35.

B. **35 U.S.C. §257 (Supplemental examination to consider, reconsider, or correct information) – "*Material Fraud on the Office*"**

The first sentence of 35 U.S.C. §257, subpart (e) provides:

> If the Director becomes aware during the course of a supplemental examination or reexamination proceeding ordered under this section, that a *material fraud on the Office* may have been committed in connection with the patent that is the subject of the supplemental examination, then in addition to any other actions the Director is authorized to take, including the cancellation of any claims found to be invalid under section 307 as a result of a reexamination ordered under this section, the Director shall also refer the matter to the Attorney General for such further action as the Attorney General may deem appropriate.
>
> 35 U.S.C. § 257(e) (emphasis added).

Novartis requests that the Office, in drafting rules related to 35 U.S.C. § 257(e), provide guidance as to what would constitute a "material fraud on the Office," such as those actions involving deceit, gross misconduct, dishonesty, , etc., in order to aid in identifying those activities which may not be reasonably addressed by this process. In other words, during rule making, the Office should distinguish 'material fraud on the Office' from inequitable conduct or what was previously referred to as 'fraud on the office'. The AIA clearly distinguishes between cases of "material fraud" in 35 U.S.C. § 257(e) and the type of lesser omissions and misstatements that might have formed the basis of an inequitable conduct allegation

under pre-AIA and pre-*Therasense* case law, which the supplemental examination process was in large measure designed to address. Novartis submits that clear Rules defining a higher standard for "material fraud" under 35 U.S.C. § 257(e) are necessary in order to give effect to the new process and the Congressional intent of curbing abuse of the inequitable conduct doctrine. For example, the Office may consider using language from a civil fraud statute in formulating their Rules.

Additionally, Novartis requests that the Office provide guidance as to the process and authority given to the Director to investigate potential occurrences of "material fraud" under 35 U.S.C. § 257(e) in order to determine if action under 35 U.S.C. § 307 or referral of the matter to the Attorney General is required. Further, Novartis requests that the Office provide the patent owner with an opportunity to respond during any the investigation of an alleged "material fraud on the Office" under 35 U.S.C. § 257(e).

Novartis also requests that the Office provide guidance with regard to whether the Office will institute disciplinary investigations of practitioners based on material submitted during the Supplemental Examination and Reexamination.

Section 27 of the Leahy-Smith America Invents Act: Study on Genetic Testing

Section 27 of the America Invents Act requires the Office to conduct a study on effective ways to provide "independent confirming genetic diagnostic test activity" where patents and exclusive licenses cover primary genetic diagnostic tests. In particular, the study is required to analyze (1) the impact that a putative lack of independent second opinion testing has had on patient and test recipient medical care; (2) the impact of same on innovation in the field of genetic diagnostic tests; (3) the effect that providing independent second opinion genetic diagnostic testing would have on existing patentees and exclusive licensees in the field; (4) The impact that current exclusive licensing and patents in the field has had on the practice of medicine; and (5) The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests. In addition to the study results, within 9 months of the Act's enactment, the Office is expected to provide the House and Senate Judiciary Committees with recommendations for establishing the availability of independent confirming genetic diagnostic test activity.

Novartis believes that the key to providing Congress with the balanced study and results that this Section requires in the relatively short period prescribed (i.e. by June 16, 2012) is to provide all stakeholders with the opportunity to participate. To that end, we understand that the Office intends to solicit public input through a Request for Comments and/or Public Hearings , similar to the process that the Office is presently using for the required studies on the scope of prior user rights and international patent protection for small businesses. Novartis fully supports this

approach, , but further suggests that it would be most effective to bifurcate the Requests for Comment/Hearings into two phases: (1) a first phase for comment and submission of data/evidence on the areas of concern that Congress identified, and (2) a second phase to submit recommendations for improving access to confirming genetic diagnostic tests, based on the information submitted in the first phase. Separating the data/evidence gathering phase from the recommendations phase will give all stakeholders an opportunity to study, process and respond to the data and evidence, which should result in an overall stronger and more practical set of recommendations that balances the interests of all.

Regarding the scope of Requests for Comment and Hearings, Section 27's definition of "confirming genetic diagnostic test activity" makes clear that the study is not intended to assess or address access to *primary* or *initial* genetic diagnostic tests that are protected by patents.[1] Nevertheless, Novartis believes that Office guidance clearly setting forth the bounds of the study will help to keep the focus on the issues and subject matter that Congress specified—namely, "second opinion" or confirming genetic diagnostic tests—resulting, again, in a more effective study and recommendations.

[1] The Section defines "confirming genetic diagnostic test activity" as the "performance of a genetic diagnostic test, by a genetic diagnostic test provider, on an individual solely for the purpose of providing the individual with an independent confirmation of results obtained from another test provider's prior performance of the test on the individual."

Section 33 of the Leahy-Smith America Invents Act: Human Organism Prohibition

Section 33(a) of the America Invents Act provides:

> (a) LIMITATION.— Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.

On September 20, 2011, the Office issued a Memorandum to the Patent Examining Corps stating that this provision codifies existing Office policy that "human organisms are not patent-eligible subject matter," and "does not change existing law or longstanding Office policy that a claim encompassing a human being is not patentable." *See* Office Memorandum from Robert W. Bahr to Patent Examining Corps, September 20, 2011 (Citing MPEP § 2105's existing policy that "If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. §101 must be made indicating that the claimed invention is directed to nonstatutory subject matter.")

Novartis agrees with the Office that §33(a) of the AIA does not change existing law or longstanding policy with regard to the patentability of human beings, and nothing in the Act indicates a legislative intent to broaden the limitation. Nevertheless, Novartis is concerned that the undefined terms "*directed to or encompassing* a human organism" (emphasis added) could lead to uncertainty regarding the scope of the restriction without further guidance to examiners, in the form of formal Rules, a supplemental memorandum, or otherwise. While the new Section clearly forbids patents on human beings themselves—in line with existing law

and policy, as the Office Memorandum states—the "directed to or encompassing" language could, without further guidance, be interpreted to extend, for example, to non-naturally-occurring human components, such as human cells and cell lines (arguably "human" organisms, even though plainly not human beings themselves), or even to methods of treating human beings, since such claims are arguably "directed to" human beings. There is, again, no indication in the America Invents Act that Congress intended to restrict the patentability of any subject matter other than human beings themselves, but Novartis believes that further guidance on this point would add valuable certainty to the examination of life sciences patents, particularly given the new opportunities now available to third parties to challenge patents in the Office (e.g., the new post-grant review process). In sum, for the avoidance of doubt, such guidance should instruct examiners that while §33 indeed codifies the existing restriction on patenting human beings themselves, it does not broaden the scope beyond this subject matter.

Respectfully submitted,

/s/

Betty Ryberg