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From: LSMT (Len Smith) [mailto:LSMT@novonordisk.com]
Sent: Wednesday, May 03, 2006 6:29 PM
To: AB93Comments
Cc: REZG (Reza Green); LAKE (Lars Kellberg); JCSH (Jim Shehan); CPOR (Chris Porter)
Subject: Comments of Novo Nordisk, Inc. (regarding 71FR48 - proposed limitations on continuing application practice)

To Whom It May Concern:

Please accept the attached comments from Novo Nordisk, Inc., in response to 71 FR 48, published on January 3, 2006.

Please contact us if you have questions or concerns associated with this message.

_____

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May 3, 2006

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

Attn: Robert W. Bahr
Senior Patent Attorney
Office of the Deputy Commissioner for Patent Examination Policy

RE: Comments on the *Federal Register* Notice Entitled "Changes To Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims"

Dear Under Secretary Dudas:

Novo Nordisk, Inc. appreciates the opportunity to present our views, on behalf of Novo Nordisk, Inc., Novo Nordisk A/S, and affiliates, on the proposed rule changes published in the Federal Register at 71 Fed. Reg. 48 (January 3, 2006) on behalf of Novo Nordisk A/S and all of its affiliates ("Novo Nordisk").

As detailed below, Novo Nordisk opposes the proposed rules because we believe

(1) the immediate effect of the proposed rules would be an *increased* burden on the United States Patent and Trademark Office ("PTO") and US legal system, resulting in an *increase* in the pendency of many important patent applications (particularly in respect of pharmaceutical and biotechnology-related inventions) and

(2) the larger effect of the proposed rules would be to (a) discourage sharing of scientific information, (b) reduce investment in new technologies, and (c) generally inhibit innovation and, therefore, to negatively impact the US economy, and

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(3) these proposals do not reflect the best possible alternative for achieving PTO's stated goals while upholding the benefits and the Constitutional purpose of the US patent system.

Novo Nordisk is a focused health care company and a world leader in diabetes care, with 22,000 employees stationed in 179 countries, including more than 2,000 employees in the United States currently engaged in the research, development, manufacturing, and marketing of pharmaceutical, biopharmaceutical, and other health care-related products and services.

Novo Nordisk is a significant customer of the PTO, with well over 1,000 currently pending US patent applications and issued US patents in its name. These and other US patents actively support Novo Nordisk's business, providing critical legal protection for the numerous innovations that are at the heart of Novo Nordisk products which, in turn, offer significant health benefits to millions of US citizens and residents. Novo Nordisk is continuously engaged in the licensing and enforcement of US patents. As such, the quality of US patents is of utmost concern to Novo Nordisk.

Novo Nordisk supports the stated goals of these rules proposals; namely, the efforts of the PTO to find ways to reduce patent application pendency, improve the quality of US patents, and to promote certainty in the marketplace. However, Novo Nordisk believes that these proposals will fail to materially advance these goals and that any marginal advances that might be achieved by implementation of these proposals will be far outweighed by serious negative impacts on the functioning of the PTO, the operation of the US legal system, and the level and quality of research and innovation in the US.

The remainder of this letter sets forth (I) possible alternative reform proposals that Novo Nordisk believes would better advance the PTO's stated goals, (II) a more detailed analysis of the negative impacts on the PTO, legal system, and public that Novo Nordisk expects will arise from adoption of the currently proposed rules, and (III) specific comments concerning some of the particular rule proposals set forth in the Federal Register notice.

I. Novo Nordisk's Proposals to Better Advance the PTO's Goals

Novo Nordisk believes that, contrary to the PTO's position, the current practice of allowing patent applicants to freely pursue second and subsequent continuing applications[1], is not a significant impediment to the PTO's attainment of the above-stated goals. As such, Novo Nordisk primarily proposes that the PTO maintain the current system of handling continuing applications while exploring other options for improving patent quality and reducing pendency (such as a suitable variation of the current PTO proposal to primarily limit patent

[1] Unless otherwise stated, "continuing applications" herein include continuation, continuations-in-part, and divisional patent applications, as well as requests for continued examination ("RCEs").

examination to 10 representative independent claims (71 Fed. Reg. 61 (January 3, 2006)[2] or adopting a suitable pre-grant or post-grant opposition procedure).

Novo Nordisk also believes that despite PTO's projections, much of the back-log and pendency problems currently facing the PTO can be overcome by maintaining PTO's recently adopted hiring and training initiatives. In this respect, Novo Nordisk agrees that management, training, and hiring in the PTO is the most important component of achieving the PTO's goals.

Novo Nordisk furthermore believes that in many, if not most, instances the practice of pursuing a second or even subsequent (e.g., third) continuing application is based on legitimate business and legal considerations, including concerns about quality of examination afforded an application in view of complex legal issues, technology, or an inexperienced examiner; the need of the applicant to pursue patent protection for certain aspects of an invention at different times in view of unforeseen events in product development; or the need to delay examination in order to avoid commitment of limited scientific and legal resources to a patent that may or may not be relevant to business interests in the future,[3] etc. Novo Nordisk is concerned that the PTO has not provided any analysis of the continuing applications that would be impacted by the proposed rule. As such, the PTO currently has no basis for concluding that quality of examination is diminished in such second or subsequent continuing applications or that such applications are being used for non-legitimate purposes. For this reason alone, Novo Nordisk believes that adoption of the proposed limits on continuing application practice, without such further study, would be premature.

To the extent that changes in respect of PTO examination of continuing applications are deemed necessary to achieve the PTO's goals, Novo Nordisk believes that other changes are better suited to achieve such goals and to avoid the negative impacts that will likely arise from the adoption of the currently proposed rules. Two such alternatives are set forth here.

a. Adoption of a Deferred/Flexible Examination System

Novo Nordisk believes that PTO adoption of an examination system that includes deferred examination as its cornerstone[4] would be far better suited to the achieving PTO's goals than, and would avoid many of the negative impacts that will likely arise from, the currently proposed rules. Specifically, Novo Nordisk envisions the PTO could adopt an examination system wherein many, most, or all applications are not substantively examined until the applicant requests

[2] Novo Nordisk believes that changes to the fee structure for the few applications that contain an unusually large number of claims be a better approach than the proposed rule. If PTO nonetheless decides to adopt a rule similar to the proposed rule, Novo Nordisk believes PTO should require examination support documents only where there is a demonstrated clear burden on the PTO to examine the additional claims at issue in any application.

[3] Suspension of examination under current PTO rules is significantly limited in time and availability, particularly when compared with other major patent systems (UNITED STATES PATENT AND TRADEMARK OFFICE MANUAL OF PATENT EXAMINING PROCEDURE, 8th Ed., Rev. 4, §709).

[4] Novo Nordisk believes that inclusion of provisions for accelerated examination of applications as part of such a system also would be of benefit to applicants and the general public.

examination (and presumably pays a fee associated with such PTO services) as an effective way for PTO to better focus examination resources without having to limit the rights of applicants, thereby reducing PTO application pendency and back-log.[5] Novo Nordisk believes that many, if not most, of the PTO's current "customers," would not opt for immediate examination under such a system and that, consequently, the total application workload of the PTO would be significantly reduced. Thus, the PTO could afford greater time to the examination of individual applications, thereby increasing quality. Moreover, as the number of applications under active examination in such a system would be significantly less in such a system, there would be no need to limit the number of continuing applications available to an applicant based on pendency, back-log, or quality concerns.

Novo Nordisk believes that the current PTO examination system, which calls for immediate substantive examination for all patent applications, is not consistent with the reality of the different ways in which US patents are used. Academic research in the field has repeatedly shown that only a very small fraction of patents ever become licensed or are associated with a marketed product, and an even significantly smaller fraction of such patents are ever litigated[6]. In view of these facts, Novo Nordisk believes that PTO resources would be best used on examination of patent applications where a rigorous, substantive examination is of most benefit to applicants and society, regardless of the number of continuing applications required for the patent applicant and PTO to reach resolution as to the patentability of the applicant's claims. Indeed, Novo Nordisk believes that such patent applications frequently embody the type of invention that requires two or more continuing applications for the PTO and the applicant reach an acceptable resolution regarding patentability. In fact, analysis of continuing application practice has revealed correlation between the use of continuing application practice and such "high value" patents.[7]

Novo Nordisk understands that the PTO is already actively considering adoption of a deferred examination system (or at least a pilot study of such a system). Novo Nordisk believes that until such matters are fully considered (and ideally discussed with the public), adoption of the current rule proposals would be, at a minimum, premature.

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[5] Novo Nordisk does not generally support the idea of adopting a "suite of patent products," which might include utility models or other petty patents, as has been discussed by PTO officials at "town hall meetings" regarding the proposed rules. In Novo Nordisk's experience, utility models are often subject to abuse by individuals or organizations that were unable to obtain a patent on particular subject matter (e.g., such rights are used to prevent development or marketing of products that could not be patented). Adoption of utility models also would require the development of new standards of obviousness, exclusivity scope, validity, etc., and, consequently, would introduce significant uncertainty and complexity into the US legal system. Novo Nordisk may support PTO consideration of using different patent products for certain technologies, such as software, where short product life-cycles may render patent protection less suitable than in other industries.

[6] *See, e.g.,* Allison et al., "Valuable Patents," 92 Georgetown Law Journal 435 (2004). Novo Nordisk does not agree with all of the conclusions of the Allison et al. paper.

[7] Allison, et al., *supra.*

Novo Nordisk does not believe that retention of a system in which second or subsequent continuing applications may be pursued detracts from public certainty to a point where limits such as those proposed by the PTO would be justified. Since the adoption of the American Inventor's Protection Act of 1999, the US provides a level of public certainty for most patent applications that is consistent with that found in other major markets. Nearly all US patent applications are now published 18 months from filing. As in other jurisdictions (e.g., Europe and Japan), individuals and organizations are free to examine the contents of such applications (and prosecution histories thereof) and to determine, based on applicable law, the type of subject matter than an applicant may be able to pursue from such an application. Novo Nordisk knows of no reason why the PTO should seek to provide greater public notice of potentially patentable subject matter than that used in other leading industrialized countries.

Novo Nordisk strongly disagrees with the position taken by some academics that the US patent system is "unique" in allowing second and subsequent continuing applications. It is Novo Nordisk's experience that the pursuit of second or subsequent continuing applications in the US is consistent with similar practices in the European Patent Office and Japanese Patent Office practice.[8]

If greater public certainty is actually required in respect of US patent applications, Novo Nordisk believes that the PTO should explore other options that are better suited to provide such certainty without having the wide-ranging negative impacts that the current proposed rules will have. In this respect, Novo Nordisk would support PTO consideration of a suitable pre-grant or post-grant opposition procedure in association with a deferred examination system as a means of providing greater certainty to the public regarding patent rights. Novo Nordisk would also or alternatively support PTO consideration of a provision for third party requests for examination of applications where examination is otherwise deferred as a means of providing greater and faster public certainty regarding the types of rights that might arise from a patent application.

b. Implementation of a limited applicant self-examination procedure

In addition, or as an alternative, to adoption of a system in which most or all patent applications are subject to deferred examination, but not limited in terms of continuing applications, Novo Nordisk believes that implementation of a patent system in which patent applicants submit the results of self-performed art searches along with patentability statements or other form of self-examination, under at least certain circumstances (e.g., where the number of references cited by an applicant in an information disclosure statement exceeds a certain number), would far better achieve the PTO's goals and avoid at least many of the negative consequences Novo Nordisk believes would arise from adoption of the currently proposed rules.

[8] Novo Nordisk also believes that the comparisons between patent examination and legal proceedings, such as litigation, made by some academics as a rationale for limiting continuing application practice, are misplaced, given the significant differences in the nature of these processes.

In this respect, Novo Nordisk notes that the PTO's various "town hall" presentations relating to possible patent reform proposals reflect that the adoption of this type of limited self-search and examination procedure would have, by far, *the greatest impact* on reducing pendency and the current PTO back-log than any other currently considered PTO rule proposal, including the present proposal to limit continuing applications. As such, Novo Nordisk believes that the PTO should make a proposed rule change relating to such a procedure before any further consideration of limiting the number of continuing applications is undertaken.

II. Novo Nordisk's Reasons for Opposing the Proposed Rules

Novo Nordisk has several reasons for opposing the current rules in addition to the belief that the above-described alternatives are better adapted to meeting the PTO's goals.

a. The Proposed Rules Will Not Materially Advance the Stated Goals of the PTO

Novo Nordisk believes that the proposed rules will not materially advance the PTO's goals for reducing pendency and the current back-log of applications, increasing patent quality, or promoting public certainty in respect of patents.

1. Application Pendency, the Back-Log, and Burden on the PTO

The PTO proposes that implementation of the proposed rules will decrease patent application pendency and the back-log of applications at the PTO by decreasing the burden on the Office. Novo Nordisk disagrees.

The PTO's own analysis of its back-log and the significance of the "re-work" issue (i.e., the number of continuing applications under examination) undermines the PTO's position. For example, USPTO data shows that both first office action pendency and overall pendency do *not* correlate with the percentage of re-work in the applicable technology centers or art units.[9] For example, "re-work" in PTO Technology Center ("TC") 2100 (Computer Architecture, Software, and Information Security) (28.2%) is reportedly significantly lower than in TC 1600 (Biotechnology and Organic Chemistry) (42.4%), but first action pendency and total application pendency for applications in TC 2100 is *significantly greater* than that for applications in TC 1600 (32.7 vs. 23.0 months and 43.5 months vs. 32.3 months, respectively).[10] The same pattern of facts applies in the case of TC 2600 (Communications), which has a re-work rate that is significantly *lower* than that of TC 1600 (25.4%), but which has first action and total application pendency rates that are significantly *higher* than TC 1600 (30.5 moths and 42.3 months, respectively). These facts reflect that "re-work" is *not* the cause of "back-log" or long application pendency within the PTO.

[9] Commissioner John Doll, PowerPoint presentation, "Pendency vs. the Backlog", presented at town hall meetings in support of the proposed rules.

[10] PTO FY 2005 4th quarter pendency statistics, reported at http://www1.uspto.gov/web/patents/opstats/patentpendency.htm.

Second, in the Federal Register notice for the current rules proposals the PTO acknowledges that the current rules will impact less than about 10% of currently pending patent applications (other USPTO data suggests that the impact may be significantly less). Thus, any impact on total back-log and pendency that might be achieved by implementation of the proposed rules will be insignificant in respect of the entire inventory of patent applications at the PTO.

Novo Nordisk believes that, more importantly, the PTO proposal also fails to consider that the "practical pendency" of patent applications may very well *increase* under the proposed rules. "Practical pendency" is the time it requires for an applicant to have reasonable clarity as to patentability of an invention embodied in a US patent application.

Novo Nordisk believes that the factors that cause applicants to pursue multiple continuing applications under the current rules,[11] will *not* simply disappear because the PTO enacts the proposed rules. Applicants will continue to face the same pressures to obtain the best protection for their inventions in an economy that is increasingly driven by intellectual property. As such, Novo Nordisk believes adoption of the proposed rules will very likely lead to the filing of a significantly greater number of appeals within the PTO, and the filing of significantly more appeals to the US Court of Appeal for the Federal Circuit from such PTO decisions due to the lack of further opportunities for examination. In essence, decisions of patentability that could have been decided more quickly and effectively by permitting the ongoing discussion and negotiation between applicants and examiners to continue, would be increasingly handled by the PTO Board of Patent Appeals and Interferences (BPAI) and the Federal Circuit. The impact of such a shift in the burden for patentability determinations will be a significant increase in the actual time it takes for applicants to obtain clarity as to their rights in such inventions, and a significant increased burden on these other areas of the US legal system.

Novo Nordisk also believes that restriction practice in the PTO would, under the proposed rules, increasingly become the subject of petition and possibly even law suits. Though there is significant dissatisfaction with PTO restriction practice among applicants, applicants currently "tolerate" such practice view of the ability to freely pursue divisional and other continuing applications in series. The currently proposed rules would so limit such opportunities that applicants would be forced to increasingly challenge the PTO's restriction requirement practices. PTO will also need to provide greater clarity in any final rules as to how such rules will pertain to restriction practice, particularly in respect of requirements for election of species.[12]

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[11] Such factors may include, e.g., the existence of complicated technical or legal issues that are not amenable to resolution in 3-4 typical office actions or the need to obtain protection for several aspects of an invention (e.g., forms of a chemical compound), some of which may embody a product (e.g., a drug) that still is in the process of clinical or commercial development after filing.

[12] For example, PTO should clarify what types of claims can be appropriately pursued in divisional applications under the proposed rules in cases in which an election of species requirement is treated as a restriction for purposes of examination in a first-filed application.

One of the reasons that Novo Nordisk believes the proposed rules have met with significant opposition from intellectual property organizations (such as the American Intellectual Property Law Association and Intellectual Property Owners Association) is the fact that there is a general distrust in industry that adequate examination of at least a subset of applications can be consistently obtained in the PTO in the course of only 3-4 office actions.

Additionally, Novo Nordisk believes the proposed rules will cause many applicants to (1) file *more* and narrower patent applications in order to maximize their ability to obtain patent protection for aspects of innovations that might currently be filed under a single application and (2) to pursue many more divisional applications (which the new rules essentially require to be pursued *simultaneously*). Thus, Novo Nordisk expects the actual burden on the PTO in terms of the number of *total* applications may very well *increase*, thereby increasing the back-log and pendency in the examining corps, as well as in other parts of the legal system.

2. Patent Quality

The PTO also states that adoption of the proposed rules will increase patent quality. Novo Nordisk disagrees and believes that the PTO's own data undermines such a view. For example, the patent allowance error rate as measured by the PTO for TC 1600 (which, as indicated above, has a re-work rate of 42.4%) is significantly lower than, e.g., the allowance error rate for TC 1700 (Chemical and Materials Engineering) and TC 3700 (Mechanical Engineering, Manufacturing, and Products), each of which has significantly less "re-work" than TC 1600.[13] This data demonstrates that re-work is not correlated with low patent quality. Novo Nordisk believes that patent quality may actually be *enhanced* in several cases where examination has extended into two or more continuing applications, inasmuch as applicants and the Office have been given sufficient time to explore important and complex legal and technical issues (which often are the motivating factor for pursuing such continuing applications). Novo Nordisk furthermore believes that patent quality could be more improved by other means, which may include adoption of a pre-grant or post-grant opposition system in the US, a matter that is under active consideration by Congress (with the support of the PTO).

3. Public Certainty

The PTO also asserts that the proposed rules should be enacted to provide the public with greater certainty. As noted above, Novo Nordisk disagrees.

In the vast majority of major patent systems of the world, the same amount of certainty is provided to the public as is now afforded in the US for nearly all patent applications - i.e., applications are published after 18-months and no additional subject matter may be added to such applications without the loss of

[13] TC 1700 had a FY2005 allowance error rate of 6.46% with 28% "re-work"; TC 3700 had a FY2005 allowance error rate of 6.43% with 28.1% "re-work"; TC 1600 had an allowance error rate of only 4.88% with 42.4% "re-work."

priority right for such additional subject matter. This system of providing public notice has worked very well in such other countries for decades. The public can readily review the body of a patent application and understand what can and cannot be claimed from it or continuations or divisionals of that application.

4. Alleged Diminishing Returns in Examination Process

The other major reason cited by the PTO in support of the proposed rules, that there are "diminishing returns" in the exchange between applicants and the Office in second and subsequent continuing applications, is not supported by any factual findings or data presented by the PTO. The Office has not cited, conducted, or provided any studies or surveys that demonstrate this alleged effect of continued patent examination. While Novo Nordisk appreciates the Office's expertise in respect of examination procedure, it is Novo Nordisk's experience that such continued dialogue can often materially improve the examination process. Moreover, at least informally, several PTO examiners and officials have stated in industry meetings and in internet postings that such so-called "re-work" actually is beneficial in properly examining applications. Therefore, without an adequate study to refute such views, Novo Nordisk also finds this rationale for adopting the proposed rules to be lacking.

b. The Proposed Rules Would Hinder Innovation in the United States and Negatively Impact the US Economy

Novo Nordisk believes that in addition to not fulfilling the PTO's stated goals, the proposed rules would actually hinder innovation in the US and negatively impact the US economy in many respects including the following:

1. Discouraging the Dissemination of Scientific Information

Novo Nordisk believes that one impact of the proposed rules is that organizations would be motivated to file narrower patent applications in order to maximize their ability to protect important aspects of inventions during product development. As such, one very likely consequence of the proposed rules would be less disclosure in patent applications (individually and collectively). Organizations would therefore be motivated retain new innovations and technical data as proprietary and secret for even longer periods than under the current system, thereby stifling the dissemination of scientific communication regarding such new technologies. For example, in technologies such as biotechnology and pharmaceuticals, where product development is a long-term investment subject to significant risks, applicants will be motivated to withhold the sharing of pre-clinical and clinical data until much later in the product development process than is currently the norm based on the significant loss in flexibility under the proposed rules. Novo Nordisk believes, in these respects, that the proposed rules actually contravene the Constitutional purpose of the US patent system - i.e., to "promote the progress of science and the useful arts."[14]

2. Reducing Investment in New Technologies

[14] U.S. CONST. art. 1, §8, cl. 8.

Novo Nordisk also believes that the new rules will lead to a reduction of investment in new technologies because the value of the potential protection afforded now for a US patent application will be seen by investors and organizations as significantly diminished. Without sufficient ability to obtain protection for innovations, investors will simply not be motivated to support the development of such inventions.

3. Inhibiting Innovation Due to Increased Legal Costs

Novo Nordisk also believes that the increased legal costs that will arise should the proposed rules be adopted will inhibit innovation in the US. Such increased legal costs will arise due to, e.g., the perceived need to file more and narrower patent applications and to appeal a significant number of patent applications under final rejection by the Office. Moreover, Novo Nordisk expects there will be an increased legal burden to applicants in terms of determining whether applications that have an "overlapping disclosure" and common inventor are patentably distinct, and in disputing such issues with the PTO. Furthermore, there will be an increased legal burden on applicants that lack satisfaction with examination in any two related patent applications in demonstrating to the PTO why an additional continuation is justified. All of the new procedures attendant the rule proposal will also provide fertile new ground for allegations of inequitable conduct, which will require additional legal scrutiny and create greater legal risks for patent applicants (as well as greater burden for the US legal system). These and other significant increased legal costs associated with adoption of the proposed rules will undoubtedly take away from resources that could have been better applied to developing new technologies that could benefit the public.

4. Negatively Impacting the US Economy

Novo Nordisk believes that the aggregate effect of these and other consequences that would arise from adoption of the proposed rules will lead to a negative impact on the US economy, which increasingly relies on strong intellectual property protections to fuel investment in innovations. The reduction in investment in new technologies will mean that US consumers will not obtain the benefit of new products that may improve the quality of their life (e.g., new life-saving drugs). The inability of small companies and individuals to as effectively obtain legal protections for their inventions will mean that this vital sector of our economy may significantly suffer.

Novo Nordisk is aware that the PTO asserts that applicants will *retain* the ability to pursue two or more continuations. However, this ability is limited to the arbitrary discretion of the PTO, and the PTO would not have made the current rule proposal if it did not believe it could exercise its discretion to significantly limit the ability of applicants to pursue such additional continuations. The great uncertainty most applicants would face in view of such standards in respect of pursuing second or subsequent continuing applications will mean that most applicants view the proposed rules as ending any likelihood of pursuing a second or subsequent continuing application.

III. Comments Regarding Specific Rule Proposals

The several reasons Novo Nordisk believes the PTO should not adopt the proposed rules (or any other limitation on the ability of applicants to freely pursue second and additional continuations), as a general matter, are set forth above as are our proposals for better alternatives should the PTO persist in its attempts to reform the current examination system. In the event that the PTO intends to adopt these rules, despite the several shortcomings associated therewith, we offer the following comments concerning the specifically proposed regulations.

Rule 1.78(d)(1)(i): The PTO should limit the proposed rule as it pertains to filing continuations of PCT applications. Specifically, the PTO should ensure that a PCT application designating the US is counted as an examination filing only if it enters the US national stage. In other words, the PCT application should not be "counted" as an application where an applicant files a continuation of the PCT *in lieu* of entering national phase proceedings in the PTO from the PCT application. As the proposed rule currently stands, applicants that prefer to use this so-called "bypass" route of filing a continuation from a PCT application, as opposed to entering national phase in the US, would only have the right to pursue a single continuation of the "PCT continuation." Without such a provision, the proposed rule creates an undue burden on organizations that prefer to use the bypass route.

Rule 1.78(d)(1)(ii): The PTO should consider removing the requirement that divisional applications can only claim priority to a single nonprovisional application under the rule. The effect of such a rule is that all divisional applications must be filed during the pendency of the parent application. This places a significant burden on both the PTO and applicants in terms of filing fees and legal costs for preparing and filing such applications. The pursuit of all divisionals at one time is also likely to be wasteful in the instance where product development is ongoing concurrently with prosecution. The PTO should also clearly allow claims that are dependent on independent or broader dependent claims that were identified in a requirement for restriction or requirement for unity of invention to be pursued in divisionals.

Rule 1.78(d)(1)(iv): The PTO should provide clearer and more objective guidelines as to situations/facts that would satisfy the Director that an "amendment, argument, or evidence" submitted in association with a request for a second or subsequent continuing application "could not have been submitted during the prosecution of the prior-filed application." As it currently stands, Novo Nordisk believes this standard is arbitrary and will create a great deal of uncertainty for applicants as to what types of facts would justify the belief that a petition permitting the pursuit of such a second or subsequent continuing application will be approved by the PTO.

Rule 1.78(d)(3): The PTO should not require applicants to identify which claims in a continuation-in-part are supported under 35 USC § 112 by the prior-filed application as an initial matter, but rather should presume that all claims

are supported by the prior-filed application until the Office identifies a reference in which such a determination becomes critical to patentability. In the alternative, such a requirement, in the first instance, places an unnecessary burden on applicants.

Rule 1.78(f)(1): The PTO should not require applicants to identify applications involving a common inventor and common owner that are filed within two months of each other if the subject matter of such applications is clearly unrelated.

Rules 1.78(f)(2)(ii) and 1.78(f)(3): The PTO should not require the filing of a terminal disclaimer if it also retains a right to eliminate claims that are not demonstrated to be patentability distinct absent a "good and sufficient reason" for having two applications including such claims. The PTO also should clarify what is a "good and sufficient reason" for maintaining two such separate applications as the current standard is vague and arbitrary.

Effective Date of Proposed Rules: The PTO should limit the proposed rules to applications claiming the benefit of applications filed on or after the effective date of the new rules, rather than to applying the rules to any applications filed after the effective date. The retroactive effect of the proposed rules is not in accordance with traditional notions of due process.

IV. Conclusion

Novo Nordisk appreciates the opportunity to provide comments on these proposed rules. Novo Nordisk welcomes the opportunity to work with the PTO to achieve its goals by finding workable solutions that meet the needs of innovative companies and individuals, the PTO, and the general public.

For the reasons set forth above, Novo Nordisk believes the PTO should not adopt the proposed rules, or other similar rules, limiting the ability of applicants to pursue second or subsequent continuation patent applications. Should the PTO determine that change in its handling of patent applications is necessary to achieve its goals, Novo Nordisk encourages the PTO to consider adopting new proposals along the lines of our above-described suggestions. Given the lack of information concerning the PTO's proposed rules, rationale for adoption thereof, and likely impacts thereof, Novo Nordisk believes the PTO should conduct additional study in such areas before moving forward with such drastic limits on continuing application practice. Should the PTO decide to move forward with such rules, without conducting such study of the likely effects of such rules, perceived pendency and quality problems, and/or other alternative such as those discussed herein, Novo Nordisk asks the PTO to consider modifying the currently proposed rules in view of the rule-specific comments we have provided here.

Novo Nordisk's comments provided here do not constitute an acknowledgement that the PTO has the authority to make such rule changes. At this time, Novo Nordisk has not fully examined whether the PTO does or does not have such authority under Title 35, United States Code, or other provisions of US law (e.g.,

Title 5, United States Code). We note that serious questions about the PTO's authority to make such rules have been raised by relevant organizations (e.g., the American Intellectual Property Law Association and the Biotechnology Industry Organization).

Novo Nordisk believes that the United States has a leading patent system, which has served the US very well (as reflected by the robust US economy and the leadership of the US in many areas of technology). As such, Novo Nordisk believes that changes of the magnitude proposed by the PTO in respect of continuing applications are almost certainly best left to Congress, which is actively considering a number of reforms to the US patent system at this time.

Moreover, as indicated, Novo Nordisk is also concerned that adoption of these or similar rules would contravene the Constitutional purpose of the US patent system, and we encourage the PTO to consider this purpose carefully in respect of such rule proposals.

Sincerely,

Reza Green, Ph.D., J.D.
Chief Patent Counsel
Novo Nordisk, Inc.