Novo Nordisk's 0651-0031 Comment

May 18, 2012

VIA E-MAIL: InformationCollection@uspto.gov

Susan K. Fawcett, Records Officer, Office of the Chief Information Officer
U.S. Patent and Trademark Office
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ATTN: Susan K. Fawcett, Records Officer, Office of the Chief Information Officer

RE: 0651 – 0031 Comment by Novo Nordisk Inc. in Response to the PTO's Request for Comments on Revision of a Continuing Information Collection Pursuant to the Paperwork Reduction Act of 1995

Dear Ms. Fawcett:

Novo Nordisk A/S and Novo Nordisk Inc. ("Novo Nordisk") respectfully request that the United States Patent and Trademark Office ("PTO") consider the following comments in response to its request for comment on:

- **Revision of a Continuing Information Collection Pursuant to the Paperwork Reduction Act of 1995**.[1]

Novo Nordisk's Background

Novo Nordisk is a pioneer in biotechnology and a world leader in diabetes care with more than 31,000 employees, with offices in the United States, Denmark and many other areas of the world, including Japan, China, India, Africa, and Brazil. For nearly 90 years Novo Nordisk has combined drug discovery with technology to turn science into solutions for people with diabetes. Novo Nordisk also provides treatments for people with hemophilia and growth hormone deficiency, and for women experiencing symptoms of menopause. Novo Nordisk manufactures and markets pharmaceutical products, including medical devices, that make a significant difference to our patents' lives, the medical profession, and society.

[1] 77 Fed. Reg. 16813-16817 (Mar. 22, 2012).

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The USPTO invites comments on:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(b) The accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection of information on respondents, e.g. the use of automated collection techniques or other forms of information technology.

Novo Nordisk's Comments

The following comments by Novo Nordisk focus on items (b) and (d) as noted above.

(1) Accuracy of Time Estimates

On the whole, OMB Number: 0651-031 underestimates the time needed to prepare and submit some items. The column noted "Estimated time for response" appears to only include the time necessary to complete the actual form or paperwork being submitted, not for any additional investigation to obtain the information needed to complete the form or paperwork being submitted. Thus, OMB Number: 0651-031 is missing at least this component in the calculation of "Estimated time".

For example, the time needed to prepare and submit the at least the following items are underestimated:

(a) **(Terminal) Disclaimers** – 12 minutes.

(i) Novo Nordisk submits that all research, including the propriety of any double patenting rejection, analysis of claim scope between the reference application and any application/patent in the rejection, investigating facts, evaluating options, consulting with client, making the decision, filling out the disclaimer form, and filing, **take much longer than 12 minutes**. Novo Nordisk submits that the estimated time of 12 minutes is substantially underestimated. In the pharmaceutical area, an area were Novo Nordisk practices, each day of patent term is important, and filing a Terminal Disclaimer is not taken cavalierly. Extensive research into an underlying reason that a terminal disclaimer should need to be filed is taken seriously. Accordingly, Novo Nordisk requests

that the estimated time of 12 minutes for a (terminal) disclaimer be revisited.

(b) **Request for Continued Examination** (RCE) – 12 minutes.

(i) As the Office knows, a first-filed RCE filing can negatively impact PTA (and consequently overall patent term) if the patent application has been pending for more than three years. Thus, all research, including responding to of any rejection, analysis of claims in relation to the prior art, investigating facts, evaluating options, consulting with client, making the decision, filling out the RCE form, and filing, in concert with any amendment and/or response should be considered in the estimation of the time the applicant takes to prepare and complete an RCE. With the factors previously noted, it often **takes much longer than 12 minutes** to determine whether to prepare and complete an RCE. Accordingly, Novo Nordisk requests that the estimated time of 12 minutes be revisited.

The above two USPTO estimates, disclaimers and RCE's were most out of line with the reality of typical patent practice.

(2) Unnecessary Burdens Associated with Information Disclosure Statements

The views expressed below have previously been voiced publicly by Courtenay Brinckerhoff on the PharmaPatents blog,[2] and Novo Nordisk agrees with these approaches to paperwork reduction. Accordingly, the views of Ms. Brinckerhoff are substantially reproduced below:

> The USPTO's current IDS rules do not provide an efficient framework for citing information from a co-pending U.S. application that is undergoing parallel examination (McKesson-type IDSs), and require Applicants to submit copies of documents that already are in the USPTO's possession.

[2] *See, e.g.,* http://www.pharmapatentsblog.com/2012/05/01/help-the-uspto-reduce-the-paperwork-burdens-of-patent-prosecution/ (last viewed May 17, 2012).

The current IDS rules impose unnecessary burdens on both Applicants and the USPTO. For example, in the context of McKesson-type IDSs, the current IDS rules require the same documents to be processed at least ***three times:***

1. First, when the USPTO issues the first Office Action and provides copies of non-patent references.

2. Second, when the applicant copies the Office Action and references for the IDS in the co-pending application.

3. Third, when the USPTO scans/uploads the Office Action and references from the IDS for the electronic file of the co-pending application

There is no legitimate justification for these wasteful and duplicative requirements, particularly where there are straight-forward regulatory fixes that would go far to alleviate these burdens:

(1) Extend MPEP 2001.06(b) to Co-Pending U.S. Applications

MPEP 2001.06(b) provides that if an application is filed as a CON, DIV or CIP of an earlier application, the examiner will consider the prior art cited in the earlier application without the applicant having to cite to same art in the later application. The USPTO should extend this provision to co-pending U.S. applications that are identified by the applicant. For example, once an Applicant has identified a co-pending U.S. application (such as in an initial IDS), the examiner could periodically check the co-pending application file for new information that may be material to patentability, such as prior to issuing each Office Action or Notice of Allowance. Alternatively, the applications could be linked electronically, such that new information in one application automatically would be added to the electronic file wrapper of the other application.

(2) Extend 37 CFR 1.97 to Co-Pending Applications

The timing requirements of the current IDS rules include several exceptions for information first cited in a counterpart foreign application. The USPTO should extend these provisions to co-pending U.S. patent applications. There is no reason the USPTO should make it more difficult for applicants to obtain consideration of information originating from a co-pending U.S. application as compared to a foreign application.

(3) Extend 37 CFR 1.98 to Co-Pending U.S. Applications

The documentation requirements of the current IDS rules require applicants to submit copies of all references (other than U.S. patent documents) unless the references already were cited in an earlier U.S. parent application. The USPTO should extend this exception to references that already were cited in co-pending U.S. applications. An examiner can access information of record in the co-pending application electronically, and nearly as easily as information of record in the application at hand. Alternatively, the applications could be linked electronically, such that new information in one application automatically would be added to the electronic file wrapper of the other application. Thus, there is no justification for imposing this burden on applicants. Indeed, this rule stems from the days of paper patent files, and now is obsolete in view of the USPTO's electronic file system.

The USPTO should more effectively integrate the new Common Citation Document Application (CCD) tool to reduce the burdens associated with submitting copies of documents cited in co-pending EPO or JPO applications. The CCD tool "enables patent examiners as well as innovators to search for and view, in a single screen, the prior art cited by the [EPO, JPO and USPTO] patent offices for the family members of a patent application." Now that this tool is available the USPTO should tweak these IDS rules:

(4) Extend MPEP 2001.06(b) to Foreign Applications encompassed by the CCD

As noted above, MPEP 2001.06(b) provides that if an application is filed as a CON, DIV or CIP of an earlier application, the examiner will consider the prior art cited in the earlier application without the applicant having to cite to same art in the later application. The USPTO should extend this provision to related foreign applications encompassed by the CCD (e.g., at least corresponding EPO and JPO applications), such that the examiner would use the CCD tool to determine if any potentially relevant references are cited in co-pending EPO or JPO applications. Alternatively, the applications could be linked electronically, such that new information in a EPO or JPO CCD application automatically would be added to the electronic file wrapper of the U.S. application.

(5) Extend 37 CFR 1.98 to References available on the CCD

As noted above, the documentation requirements of the current IDS rules require applicants to submit copies of all references other than U.S. patent documents unless the references already were cited in an earlier U.S. parent application. The USPTO should extend this exception to include references available on the CCD.

The USPTO also should take advantage of free patent databases and should not require Applicants to submit copies of documents that it has ready access to, such as published PCT applications and other foreign patent documents that are freely available on-line. Now that that WIPO maintains a database with over 10.5 million patent documents including over 2 million published PCT applications, the USPTO should tweak this IDS rule:

(6) Extend 37 CFR 1.98 to Freely Available PCT and Foreign Patent Documents

In addition to expanding the exception in 37 CFR 1.98 to include references available on the CCD, the USPTO should extend the exception to include freely available PCT and foreign patent documents, such as those freely available through the WIPO Patentscope website.

For the above reasons, Novo Nordisk respectfully submits that the calculation of the time it takes to complete certain responses, and the burdens associated with Information Disclosure Statements, should be revisited.

Respectfully Submitted,

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Vice President, Chief Intellectual Property Counsel
Novo Nordisk Inc.