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Nicholas A. Fraser
Desk Officer for USPTO
Office of Information and Regulatory Affairs
Office of Management and Budget

Via Email: [Nicholas A. Fraser@omb.eop.gov](mailto:Nicholas.A.Fraser@omb.eop.gov)

Re: ICR Ref. No. 200809-0651-003
Board of Patent Appeals and Interferences (BPAI) Actions

Dear Mr. Fraser:

Wyeth appreciates the opportunity to provide comments on the U.S. Patent and Trademark Office ("PTO") proposed rules directed to changes to rules of practice before the Board of Patent Appeals and Interferences in Ex Parte Appeals published at 73 Fed. Reg. 32938 (June 10, 2008). For the following reasons, Wyeth asks the Office of Management and Budget not to approve these rules.

Wyeth is one of the world's largest research based pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing and marketing of pharmaceuticals, biotechnology products, vaccines and non-prescription medicines that improve the quality of life for people worldwide. Wyeth's major divisions include Wyeth Pharmaceuticals, Wyeth Consumer Healthcare and Fort Dodge Animal Health.

Wyeth understands the critical importance of discovering and developing valuable new therapies and vaccines to help millions of people around the world. Cutting-edge pharmaceutical research and development is more challenging, more complex and more critical than ever. At the same time, the need for treatments for unmet medical needs is expanding greatly, even as regulatory hurdles increase and costs grow. Novel candidates and new mechanisms of action are central to Wyeth's pipeline, which includes small molecules, biopharmaceuticals and vaccines. The cost of developing a new drug is more than \$800 million, on average, and can take up to 15 years. The patents granted on Wyeth's inventions enable Wyeth to continue to invest in developing the therapies and vaccines of the future to improve the lives of people and lead the way to a healthier world.

The PTO has proposed major changes to the rules of practice before the Board of Patent Appeals and Interferences in Ex Parte Appeals. The stated rationale of the PTO is to permit the Board to handle an increasing number of appeals in a timely manner; the stated intention of the proposed rules is to provide Examiners and Office reviewers with a clear and complete statement of an appellant's position at the time of filing an appeal brief so as to enhance the likelihood that appealed claims will be allowed without the

necessity of further proceeding with the appeal, minimize the pendency of appeals before the office, minimize the need for lengthy patent term adjustments in cases where claims become allowable by the Board in an appeal, provide uniform treatment of requests for an extension of time filed after an appeal brief is filed, and make the decision making process more efficient.

Wyeth supports the PTO's goals stated above, and particularly the goals of handling appeals in a timely manner, enhancing the likelihood that appealed claims will be allowed without the necessity of further proceeding with the appeal, minimizing the pendency of appeals before the office, and making the decision making process more efficient.

However, Wyeth believes that the changes being proposed will not enhance the likelihood that appealed claims will be allowed without the necessity of further proceeding with the appeal, or make the decision making process more efficient. Rather, the proposed rules will burden Appellants with having to supply unnecessary information, and will prejudice Appellants ability to fully discuss the issues on appeal.

I. The Proposed Rules Will Increase The Length And Complexity Of Appellants' Briefs

The PTO has based most of its estimates of burden on statistics for current appeals. However, these estimates are unreliable because the proposed rules will significantly increase the burden. One important reason for this is that the length and complexity of appeal briefs and reply briefs will increase under these proposed rules. Some of the factors leading to longer, more complex briefs are the requirements to include:

- a statement of facts, in which each factual statement is accompanied by a reference to the page in the record which supports the statement;

- a claim support and drawing analysis section, in which each element of a claim must be annotated to show the page and line or paragraph number in the specification describing it and to show where it is illustrated in a drawing or sequence;

- a means or step plus function analysis section in which each means or step plus function element of a claim must be annotated to show the page and line or paragraph in the specification which describes the function and the location in a drawing which corresponds to the function;

- a table of contents;

- a table of authorities; and

- a jurisdictional statement.

II. The PTO Has Failed To Provide A Reliable And Objective Estimate Of The Added Burden The Proposed Rules Will Create

The PTO has estimated the time it will take to prepare an appeal brief under the proposed rules by calculating the median time taken to prepare appeal briefs under the current rules, and then arbitrarily increasing this number to 30 hours. (Supporting Statement OMB Control Number 0651-00xx, p. 16) However, the PTO has no basis for determining how much longer appeal briefs will take under the proposed rules - it has not done a study or run a pilot program to obtain the necessary information.

The PTO has stated that currently the "better briefs" contain some of the information that will be required under the proposed rules (Supp. Stmt., p. 11). However, the PTO does not provide any information about the time it took to prepare these "better briefs", which would be pertinent to estimating at least a portion of the burden under the proposed rules.

The need to make a request to increase the page limit is completely new, and a direct result of the PTO's arbitrary page limit. The PTO has provided no rational basis for its estimate of the time it will take to prepare this information. Given that this request will be made by those who believe that additional pages are necessary to a full and proper consideration of their case, and hence, that the approval of the request is crucial, a great deal of effort and time is likely to go into these requests. The PTO's estimate is entirely arbitrary.

Furthermore, the PTO estimated the number of requests to increase the page limit by using the number of briefs that currently exceed the proposed limit. This estimate is unreliable, since the proposed rules will affect brief length. The PTO has not made an objectively-based estimate of the number of briefs drafted under the proposed rules that may require additional pages.

Additionally, the PTO has provided no guidance and made no estimate regarding the number of requests for an increase in page limit that will be rejected. If a request is rejected, appellant may seek to appeal this rejection. The PTO has provided no estimate of the burden associated with such appeals.

The PTO has also made no attempt to estimate the added time that appellants will need to condense complex arguments to fit into the significantly curtailed page limits. For example, if 40 pages of argument must be cogently condensed to 30 pages of 14-point typeface due to the proposed requirements, appellants will need to spend much more time on editing and strategy (indeed, good arguments may need to be omitted entirely). It is clearly debatable whether the PTO is correct when it argues that this will lead to better briefs, but it is certain to increase the appellants' burden, and the PTO has provided no estimate of this increased burden.

III. Many Proposed Rules Require The Submission of Unnecessarily Duplicative Information

The proposed requirements for a statement of facts, a claim support and drawing analysis section, and a means or step plus function analysis section all require appellants to submit information that is already in the record and available to the PTO. This information is unnecessarily duplicative.

In addition to being unnecessarily duplicative, these sections will be extremely burdensome, due to the requirement to locate in the record support for every factual statement and every claim element.

The PTO has argued that this duplicative information is not unnecessary because it saves resources that would be needed to hunt for the information in the record (Supp. Stmt. pp. 13-14). However, this is generally not the case.

For a case to be on appeal, the examiner must have made a rejection of the claims, supported by facts and reasons, in the final office action. The appellant must then provide well-supported arguments in the appeal brief to refute the examiner's position. The examiner then files an answer to the brief. These documents generally contain all the cogent facts related to the appeal, and any material misstatements by the appellant should be corrected in the examiner's answer. It is, therefore, not necessary for the Board of Appeals and Interferences to go through the record to ascertain the facts of the case. For these reasons, the proposed requirements for a statement of facts, a claim support and drawing analysis section, and a means or step plus function analysis section all require appellants to submit unnecessarily duplicative information.

Furthermore, it is unnecessary to require appellant to identify the support for each claim element if the examiner has not rejected the claim on the basis that it lacks support; for example, where the rejection is based on the existence of prior art and support for the claim elements in the specification is not at issue. Such duplication of information in the specification is clearly unnecessary. It is likewise unnecessary to require appellants to identify support for a fact that is not at issue in the appeal. Yet the proposed rules burden appellants with the requirement to support each fact in the statement of facts and each element in the claim support and drawing analysis section, and the means or step plus function analysis section.

IV. Conclusion

The rules proposed by the PTO impose significant new burdens on patent applicants, and the PTO has failed to provide an objectively-based estimate of all the burdens created by these rules. Additionally, the proposed rules require the submission of much unnecessarily duplicative information. For these reasons, Wyeth asks the Office of Management and Budget to deny approval of these rules.

Very truly yours,

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