IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Control Nos.: **90/007,542** Group Art Unit: 3991

90/007,859

Confirmation Nos.: 7585 ('542) Examiner: P. Ponnaluri

6447 ('859)

Filed: 13 May 2005 ('542)

23 December 2005 ('859)

Patent Owner: Genentech, Inc. and

City of Hope

For: Merged Reexaminations of U.S. Patent No. 6,331,415 (Cabilly et al.)

Mail Stop Ex Parte Reexam Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION and/or PETITION UNDER 37 C.F.R. § 1.183

Sir:

This petition is directed to the "DECISION DENYING PETITION TO EXPUNGE INFORMATION (37 CFR 1.59(b) AND 182) AND PETITION TO WAIVE SERVICE RULE" mailed in the merged reexamination proceeding identified above on 5 May 2009.

On a final review of the reexamination file, Owners have discovered that one of the documents filed with the submission under M.P.E.P. § 724.02 on 6 June 2008 was not the version that Owners intended to present to the Office. In particular, as discussed below, Owners inadvertently and erroneously provided an expert report from a then-pending litigation that included an appendix containing highly confidential information, whereas it had been intended to submit the expert report without that appendix.

Owners renew their petition to expunge information specifically with respect to the inadvertently submitted appendix. As an alternative basis for providing the requested relief, Owners petition the Director under § 1.183 to suspend the rules to substitute the attached copy of the expert report, without the appendix in question, for inclusion in the record.

This petition requires the fee specified in § 1.17(f) (\$ 400). The Director is requested to debit that amount, as well as any other fees which may be required in connection with this petition, from our **Deposit Account No. 18-1260.**

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Background

- 1. Genentech, Inc. and City of Hope are co-owners of the patent that is the subject of the captioned merged reexamination proceeding.
- 2. On 6 June 2008, Owners filed certain materials from a then-pending litigation involving the patent under reexamination under the provisions of M.P.E.P. § 724.02. Owners' submission included a petition under 37 C.F.R. §§ 1.59(b) and 1.182 to expunge the cited information from the file, and a petition under § 1.183 to waive the service requirement of § 1.550(f).
- 3. In an advisory action mailed on 19 July 2008, the examiner acknowledged the submission of information under M.P.E.P. § 724.02 and stated:
 Pursuant to MPEP § 724.04 the submitted information is found to be material to the patentability and/or confirmation of the instant reexamination claims.
- 4. There has been no further discussion of the information submitted under M.P.E.P. § 724.02 on 6 June 2008 by the examiner in this reexamination proceeding.
- 5. A Notice of Intent to Issue a Reexamination Certificate (NIRC) was mailed in this proceeding on 23 February 2009. A Certificate has not yet been granted.
- 6. An interview summary dated 30 April 2009 states that Owners' representative indicated to the Office that petitions to expunge filed on 13 September and 24 October 2007 would not be renewed. The interview summary does not record any representation concerning the petition to expunge associated with the 6 June 2008 submission.
- 7. In a decision mailed on 5 May 2009, the Office denied both of the petitions related to the submission under M.P.E.P. § 724.02 filed on 6 June 2008.

Discussion

One of the two items of information cited in the submission under M.P.E.P. § 724.02 filed on 6 June 2008 was the expert report of a licensing expert, Dr. E. Fintan Walton, that was submitted in *MedImmune, Inc. v. Genentech, Inc.*, No. CV-03-2567 (C.D. Cal.). One component of Dr. Walton's report, specifically Appendix 3, contains highly sensitive proprietary information. The public disclosure of the proprietary information in Appendix 3

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would severely prejudice the interests of not only the patent owners, but of third parties as well. Because of the inclusion of that information, Dr. Walton's report is marked "Restricted Confidential – Attorney's Eyes Only."

The body of Dr. Walton's expert report sets forth his analysis of how the biotechnology industry's licensing of the Cabilly patents is probative of the commercial success of the invention claimed in the '415 patent. This was the information that Owners intended to present for review by the Office.

Appendix 3 of Dr. Walton's original report provides a table that identifies licenses taken under the Cabilly patent, the licensees, and the nature and essential economic terms of the licenses. Genentech is under contractual obligations to its licensees to protect the confidentiality of the proprietary information in Appendix 3 of Dr. Walton's report.

Owners did not intend to present Appendix 3 for consideration by the Office. Indeed, Owners' attention to the sensitivity of the information is shown in a corresponding declaration under § 1.132 by Dr. Walton, filed by Owners in the public record on 6 June 2008. In that declaration, Dr. Walton stated that "[b]ecause of confidentiality considerations regarding these licenses, I have not provided a detailed table of the companies, products, and terms of the licenses." *See* Walton § 1.132 dec., page 4, footnote 3.

Relief requested

Expungement of proprietary information

Specifically with reference only to the portion of Dr. Walton's expert report identified as Appendix 3, Owners respectfully renew their request that the Office expunge information filed in the submission under M.P.E.P. § 724.02 on 6 June 2008 from the record of this proceeding. Owners reiterate the representations stated in their petition under §§ 1.59(b) and 182 filed on 6 June 2008 as to Appendix 3. Owners do not maintain their petition to expunge information either as to the balance of Dr. Walton's report (*i.e.*, the body of the report and Appendices 1 and 2), or as to the other document cited in that submission (*i.e.*, a transcript of the deposition of Dr. Walton taken in connection with the *MedImmune* litigation).

A copy of the expert report, from which only Appendix 3 has been deleted, is provided as an exhibit to this petition. Owners request that this document be entered in the public file in place of the copy of Dr. Walton's expert report filed on 6 June 2008.

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Owners and their licensees would suffer significant harm if the terms of specific licenses were made public. The Office should provide relief that adequately protects the business interests of Owners and their licensees while also ensuring the integrity of the public record. Expungement of only Appendix 3 will not impair the ability of the public to appreciate the basis for the Office's determination of patentability in this proceeding. The extent and economic value of the licenses under the Cabilly patents, as well as Dr. Walton's discussion of why the licenses demonstrate the commercial success of the invention claimed in the '415 patent, are fully discussed in aggregate in the body of Dr. Walton's report.

Service of documents on third-party requesters

In the decision mailed on 5 May 2009, the Office required Owners to serve copies of the information submitted under M.P.E.P. § 724.02 on 6 June 2008 on the third-party requesters in the reexamination proceeding.

Specifically with reference only to Appendix 3 to of Dr. Walton's expert report, Owners renew their petition under § 1.183 that the Office waive the service requirement of § 1.550(f). Owners further request that the Office stay the requirement set forth in the decision mailed on 5 May 2009 to serve the papers filed on 6 May 2009, insofar as that requirement applies to Appendix 3, pending a decision on this renewed petition.

Owners are concurrently serving on the third-party requesters a copy of Dr. Walton's expert report from which Appendix 3 has been removed, inasmuch as that document is provided as an exhibit to this petition. Owners are also concurrently serving on the third parties a copy of Dr. Walton's deposition transcript, which was the only other item of information cited in the submission under M.P.E.P. § 724.02 on 6 June 2008, as indicated on the attached certificate of service.

Alternative basis under § 1.183 for providing the requested relief

Should the Office consider that the result stated in its 5 May 2009 decision is required by the Rules, Owners submit that the Office should grant the requested relief under the authority of § 1.183. The Office's policies concerning petitions to expunge material from the records of public files are not mandated by statute. Moreover, the interest of justice requires that the Office act to protect the business interests of Owners and their licensees, as well as the public interest, in its treatment of the proprietary information at issue. Finally, Owners

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respectfully submit that this is an extraordinary situation within the meaning of § 1.183 that

justifies granting the requested relief.

Owners appreciate the procedural difficulties for the Office in responding to this request at this point in this reexamination proceeding. Key personnel only recently came to

appreciate the nature of the information that is the subject of the Office's denial of the

petitions filed on 6 June 2008, thus necessitating the present petition. Owners regret the

inconvenience to the Office caused by this request.

Conclusion

Owners respectfully request that the Office reconsider its decision mailed on 5 May

2009, and grant the petitions to expunge proprietary information from the record and to waive

the service requirement of § 1.550(f), to the limited extent discussed above. Owners request

that the attached copy of the expert report of Dr. E. Fintan Walton, from which Appendix 3

has been removed, replace the copy filed on 6 June 2008.

Additionally or in the alternative, Owners request that the Office waive or suspend its

rules under the authority of § 1.183 to grant the relief requested above.

Respectfully submitted,

/David L. Fitzgerald/

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