UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

PALOMAR MEDICAL TECHNOLOGIES, INC., and THE GENERAL HOSPITAL CORPORATION, Plaintiffs, v. CANDELA CORPORATION, Defendant.	Civil Action No. 06-11400-RWZ

DECLARATION OF GERALD H. BJORGE IN REPLY TO PALOMAR'S OPPOSITION TO CANDELA'S MOTION FOR SUMMARY JUDGMENT

DECLARATION OF GERALD H. BJORGE

1. I have been retained as an expert in this case by defendant Candela Corporation with respect to, among other things, the practices and procedures of the United States Patent and Trademark Office ("PTO"). In this declaration, I briefly respond to certain statements in Palomar's opposition brief to Candela's Motion for Summary Judgment regarding the reexamination by the PTO of U.S. Patent No. 5,735,844. I have personal knowledge of the facts stated in this declaration and if called as a witness I could and would testify competently to them.

Qualifications and Materials Reviewed

2. I received a Bachelor of Science degree in Chemical Engineering from Northwestern University in 1959, a Master of Science degree in Chemical Engineering from Princeton University in 1962 and a Juris Doctor degree from George Washington University Law School in 1964. I am admitted to practice before the U.S. Supreme Court, the U.S. Court of Appeals for the Federal Circuit, and the U.S. Court of Appeals, D.C. Circuit. I have been registered to practice before the PTO since 1986.

3. From 1961 to 1964, I was an Examiner in the United States Patent Office, and from 1964 to 1973, I was technical advisor to Chief Judge Eugene Worley of the U.S. Court of Customs and Patent Appeals (a predecessor to the Federal Circuit). I am the founding editor of the Federal Circuit Bar Journal. I was an Examiner-in-Chief from 1983 to 1986 on the Board of Patent Appeals and Interferences in the PTO, and I was an associate Solicitor from 1973 to 1983 with the Office of the Solicitor in the PTO.

4. Over the past 49 years, I have reviewed thousands of patent applications and their prosecution histories, and have participated as an expert witness in over 100 litigation matters involving patents, trademarks, unfair competition and trade secrets

in the Federal Courts throughout the United States and in the International Trade Commission.

5. In connection with my work on this matter, I have reviewed, among other things, the prosecution history of the original prosecution and the prosecution history of the reexamination proceedings pertaining to the ’844 patent.

The Reexamination Proceedings Regarding the ’844 Patent

6. On July 10, 2008, an anonymous nonparty to this litigation submitted a request for *ex parte* reexamination of Claims 11, 12, 14, 17, 18, 27, and 32 of the ’844 patent based on a 1967 book authored by Leon Goldman, M.D., entitled “Biomedical Aspects of the Laser.” On December 8, 2008, Candela submitted a request for *ex parte* reexamination of the Claims 1-3, 6-8, 11-14, 17-20, 27, 28, 30-32 of the ’844 patent based on U.S. Patent No. 5,059,192 (“Zaias”) in light of either U.S. Patent Nos. 3,538,919 (“Meyer”), 5,344,418 (“Ghaffari”), and/or 4,733,660 (“Itzkan”).

7. On January 16, 2009, Palomar submitted a preliminary statement that included 27 new dependent claims for the ’844 patent, each of which were ultimately dependent on Claim 32.

8. On June 5, 2009, the Examiner issued an Office Action merging the reexamination proceedings arising from the two reexamination requests. At that time, the Examiner rejected Claims 12 and 14 of the ’844 patent as obvious in light of Zaias alone. Claim 13 was rejected as being unpatentable over Zaias in view of Itzkan.

9. On June 12, 2009, Palomar voluntarily cancelled Claims 12-14 of the ’844 patent “in order to expedite further prosecution and confirmation of the patentability of the remaining claims.”

10. On July 20, 2009, the Examiner issued a “Notice of Intent to Issue Ex Parte Reexamination Certificate.” In his “Statement of Reasons for Patentability And/Or Confirmation,” the Examiner confirmed the remaining claims over Zaias, Ghaffari, Meyer, and the 1967 Goldman Book.

Palomar's Submission of Other References During the Reexamination

11. On December 8, 2008, February 17, 2009, February 20, 2009, April 22, 2009, and June 19, 2009, Palomar's submitted Information Disclosure Statements listing no less than 370 different prior art references. While voluminous, Palomar's submissions did not specifically direct the Examiner's attention to any particular reference or document, and did not provide any summary, analysis or explanation that would direct the Examiner's attention to pertinent information contained in those documents.

12. Because Palomar provided no explanation and no analysis of the content or relevance of documents it submitted, its submission of over 370 prior art references was not helpful to the Examiner. *See* Changes to Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. 131, 38810 (July 10, 2006) ("If an applicant presents unusually long documents, foreign language documents, or a large number of documents, more than a brief review by the Examiner is likely to be needed to reveal the most pertinent portions of the documents. In such situations, the applicant's help is needed so that the Examiner may provide the best and most efficient examination possible."); *Rohm & Haas Co. v Crystal Chemical Co.*, 722 F.2d 1556, 1573 (Fed. Cir. 1983) ("The conclusion that he was 'fully informed' rests solely on the presentation to him of a mountain of largely irrelevant data from which he is presumed to have been able, with his expertise and with adequate time, to have found the critical data. It ignores the real world conditions under which Examiners work.").

Palomar's Assertion that the Examiner "Considered" the Tanino Reference

13. Palomar argues in its Opposition brief that the Tanino reference that is the subject of Candela's Summary Judgment Motion was "considered by the Examiner" during the reexamination. There is no basis for this assertion.

14. According to the Manual of Patent Examining Procedure, during an ex parte reexamination proceeding, references submitted to the Examiner are only considered to the extent explained by the party filing the information:

> Where patents, publications, and other such items of information are submitted by a party (patent owner or requester) in compliance with the requirements of the rules, the requisite degree of consideration to be given to such information will be normally limited by the degree to which the party filing the information citation has explained the content and relevance of the information. The initials of the Examiner placed adjacent to the citations on the form PTO/SB/08A and 08B or its equivalent, without an indication to the contrary in the record, do not signify that the information has been considered by the Examiner any further than to the extent noted above.

MPEP § 2256, a true and correct copy of which is attached to this Declaration as Exhibit 1.

15. Palomar did not explain or discuss the Tanino reference, or any of the other references it submitted, in its submissions during the reexamination. The Examiner's office action communications only include analyses with respect to Zaias, Ghaffari, Meyer, Itzkan, and the 1967 Goldman book. There is no evidence that the Examiner considered or reviewed any of the other documents submitted by Palomar, including the Tanino reference, during the reexamination.[1]

16. Palomar's expert testified that MPEP § 2256 means that, in an *ex parte* reexamination, the Examiner "is going to spend time considering that which has been put forth in argument, discussion of the references." Nixon Deposition Transcript, a true and correct excerpt of which is attached as **Exhibit 2** to this Declaration, at 153:5-8. He stated that while additional references may be submitted during reexamination, the Examiner's initials and signature on PTO disclosure forms "does not mean, necessarily, that the examiner considered the references any further than the degree to which they were discussed in the accompanying argument or disclosure." *Id.* at 9-20. Mr. Nixon testified that "if you take [MPEP § 2256] literally, it means that if you didn't discuss it, the examiner didn't consider it." *Id*. at 155:10-12. He further testified that while it is

[1] The Tanino reference was not disclosed to the PTO during the original prosecution of the '844 patent.

possible that an Examiner might consider something that wasn't discussed by the parties to the reexamination, it is also possible that he didn't consider it. *Id.* at 156:6-15.

17. Accordingly, there is no basis upon which to conclude that the Examiner actually considered or reviewed the Tanino reference during the reexamination. Moreover, because the Tanino reference was one of over three hundred references that Palomar submitted during the reexamination proceedings, it is highly unlikely that the Examiner actually evaluated whether Tanino anticipates, expressly or inherently, claims 27 and 32 of the '844 patent.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed on September 9, 2010, in Washington, D.C.

Gerald H. Bjorge

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