

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOMARIN PHARMACEUTICAL INC.,
Petitioner,

v.

GENZYME THERAPEUTIC PRODUCTS LIMITED PARTNERSHIP,
Patent Owner.

Cases IPR2013-00534 (Patent 7,351,410 B2)
IPR2013-00537 (Patent 7,655,226 B2)¹

Before LORA M. GREEN, JACQUELINE WRIGHT BONILLA, and
SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

ORDER
Conduct of Proceedings
37 C.F.R. § 42.5

¹ This order addresses issues that are the same in the identified cases. We exercise our discretion to issue one order to be filed in each case. The parties are authorized to use this style heading when filing a single paper in each proceeding, provided that such heading includes a footnote attesting that “the word-for-word identical paper is filed in each proceeding identified in the heading.”

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I. INTRODUCTION

We address Petitioner’s Motion to Submit Supplemental Information Pursuant to 37 C.F.R. § 42.123 (Paper 68 in IPR2013-00534; Paper 67 in IPR2013-00537) (“Petitioner’s Motion” or “Mot.”)² concerning the submission of Exhibit 1182 as Supplemental Information. Petitioner contends that Exhibit 1182 should be admitted into the record because it is relevant to the issue of public availability of Exhibit 1002 (“Duke Press Release”). Mot. 5. Patent Owner opposes Petitioner’s Motion. Paper 77 in IPR2013-00534; Paper 75 in IPR2013-00537 (“Reply”).³

In both IPR2013-00534 and IPR2013-00537, we instituted *inter partes* review based on obviousness grounds that rely on the Duke Press Release. Paper 9 in IPR2013-00534; Paper 9 in IPR2013-00537. On August 28, 2014, Patent Owner filed a Motion to Exclude Evidence that included, *inter alia*, a request to exclude the Duke Press Release as inadmissible unauthenticated hearsay. Paper 57 in IPR2013-00534; Paper 55 in IPR2013-00537. On September 11, 2014, Petitioner filed its Opposition to Patent Owner’s Motion to Exclude Evidence, wherein Petitioner introduced Exhibit 1182, an affidavit of Ms. Beth Nichol explaining the process in which she obtained from a Duke University library a copy of a Duke Press Release dated September 2, 1997, and entitled “Duke Obtains FDA Designation for Pompe Disease Therapy.” Paper 60 in

² Throughout this Order, any reference to Petitioner’s Motion will be made to Paper 68 in IPR2013-00534.

³ Throughout this Order, any reference to Patent Owner’s Reply will be made to Paper 77 in IPR2013-00534.

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IPR2013-00534; Paper 58 in IPR2013-00537 (A copy of the Duke Press Release obtained by Ms. Nichol is provided as Exhibit C of Exhibit 1182). On September 18, 2014, Patent Owner entered its Reply to Petitioner's Opposition to Patent Owner's Motion to Exclude Evidence arguing, *inter alia*, that Exhibit 1002 is not the press release from Duke University because it lacks indicia that Duke University is the source of the document and contains typographical errors not found in the Duke Press Release provided in Exhibit C of Exhibit 1182. Paper 66 in IPR2013-00534; Paper 65 in IPR2013-00537.

On September 23, 2014, Petitioner filed its Motion to Submit Supplemental Information requesting to file Exhibit 1182. In its Motion, Petitioner summarizes evidence it provided to Patent Owner in order to address Patent Owner's objections based on hearsay and authentication. Such evidence includes a copy of the Duke Press Release from the news service EurekAlert! (Exs. 1140, 1141 & 1154) and an article from the Herald-Sun (Durham, NC) published September 3, 1997, discussing subject matter disclosed in the Duke Press Release (Ex. 1144). Mot. 3–4. According to Petitioner, Patent Owner continues to object to Exhibit 1002, which was filed with the Petition, on grounds of authenticity and public availability. *Id.* Petitioner is requesting to submit Exhibit 1182 as supplemental information, and not just as supplemental evidence with its Opposition to Patent Owner's Motion to Exclude Evidence, which would permit Petitioner to rely on Exhibit 1182 to support its position that the

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Duke Press Release was publicly available.⁴ Paper 60.

Upon consideration of the documents and the parties' arguments, and for the reasons stated below, Petitioner's Motion is granted.

II. ANALYSIS

As the moving party, Petitioner bears the burden of proving that it is entitled to the requested relief. 37 C.F.R. § 42.20(c). Under 37 C.F.R. § 42.123(b), a party may file a motion to submit supplemental information more than one month after the date the trial is instituted if the party demonstrates why the supplemental information could not have been obtained earlier, and why its consideration would be in the interest of justice.

Petitioner contends that it has made several attempts to obtain a copy of the original Duke Press Release. Mot. 2–5. To start, Petitioner requested permission to file a Motion to Compel Additional Discovery, which we denied on June 10, 2014. Paper 42 in IPR2013-00534; Paper 41 in

⁴ The difference between supplemental information and supplemental evidence is that:

supplemental *evidence*—served in response to an evidentiary objection and filed in response to a motion to exclude—is offered solely to support admissibility of the originally filed evidence and to defeat a motion to exclude that evidence, and not to support any argument on the merits (i.e., regarding the patentability or unpatentability of a claim). Supplemental *information*, on the other hand, is evidence a party intends to support an argument on the merits.

Handi Quilter, Inc. and Tacony Corporation v. Bernina International Ag, IPR2013-00364, Paper 30 at 2-3.

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IPR2013-00537. Petitioner noted that in our denial of that request, we reminded the Patent Owner that, “to the extent Patent Owner has knowledge of non-privileged information that is inconsistent with its position regarding the authenticity of [the Duke Press Release], it is obligated to produce such information.” Mot. 4 (quoting Paper 41, 6 in IPR2013-00534). On June 18, 2014, Petitioner sent a letter to counsel for Duke University requesting information regarding the press release (Ex 1188). *Id.* Finally, on August 1, 2014, Petitioner contacted Ms. Beth Nichol, an Investigative Associate at Nichol Investigative Services, LLC, who obtained a copy of the original Duke Press Release from a Duke University library (Ex 1182, Ex C). *Id.* at 5.

Patent Owner contends there is no reason that Petitioner could not have obtained Exhibit C of Exhibit 1182 before filing its original Petition in this case, and points us to the ease with which Ms. Nichol obtained a copy of the original Duke Press Release. Reply 7–8. While we do not disagree, we determine the submission of Exhibit 1182 is in the interests of justice, and we waive the requirement of 37 C.F.R. § 42.123(b) that a party show that the supplemental information reasonably could not have been obtained earlier. 37 C.F.R. § 42.5(b) (permitting the Board to waive or suspend a requirement of parts 1, 41, and 42). In doing so, we note that the supplemental information Petitioner seeks to submit does not change the grounds of unpatentability authorized in this proceeding, nor does it change the evidence initially presented in the Petition to support those grounds of unpatentability. Instead, such information merely constitutes additional evidence that allegedly confirms that the public accessibility of the information contained in the Duke Press Release. In addition, there is no

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indication in the record that the supplemental information Petitioner now seeks to submit was withheld intentionally. Rather, the record indicates that Petitioner made continuous attempts to obtain the information. Finally, the record does not suggest that submission of such information at this juncture would limit our ability to complete this proceeding in a timely manner. *Cf. Illumina, Inc. v. The Trustees of Columbia Univ. in the City of New York*, IPR2012-00006, Paper 125, at 3 (denying motion to submit supplemental information based on nineteen day delay in seeking relief and proximity to end of proceedings) (Ex 2136).

We emphasize that our decision to grant Petitioner's Motion should not be read as an advisory decision on whether any document or evidence is admissible.

Accordingly, it is:

ORDERED that Petitioner's Motion to Submit Supplemental Information is granted.

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