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Paper 9
Entered: February 24, 2014

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

Case IPR2013-00534
Patent 7,351,410 B2

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

SNEDDEN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

BioMarin Pharmaceutical Inc. ("Petitioner") filed a petition to institute an *inter partes* review of claim 1 (Paper 1; "Pet.") of U.S. Patent No. 7,351,410 B2 (Ex. 1001; "the '410 patent"). Genzyme Therapeutic Products Limited Partnership ("Patent Owner") did not file a preliminary response under 37 C.F.R. § 42.107(b).

The Board has jurisdiction under 35 U.S.C. § 314. The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which states:

> THRESHOLD.—The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

Upon consideration of the above-mentioned petition, the Board concludes that Petitioner has established that there is a reasonable likelihood that it will prevail with respect to the challenged claim. The Board, therefore, grants the petition to institute an *inter partes* review.

A. Related Proceedings

Petitioner indicates that there are no other judicial or administrative matters that would affect, or be affected by, a decision in this proceeding. Pet. 1.

The same day this *inter partes* proceeding was filed, Petitioner filed two other petitions seeking *inter partes* review of U.S. Patent No. 7,056,712 ("the '712 patent") (IPR2013-00535) and U.S. Pat. No. 7,655,226 ("the '226 patent") (IPR2013-00537). The '226 patent is a continuation of the '410 patent. Although the '712 patent is not related to the '410 patent or the '226 patent, all three patents relate to similar subject matter, i.e., methods of treating Pompe's disease.

B. The '410 Patent (Ex. 1001)

The technology of the patent is enzyme-replacement therapy for patients with Pompe's disease, which is caused by deficiency of the lysosomal enzyme acid alpha glucosidase. Ex. 1001, col. 1, ll. 59-61. The deficiency in the lysosomal enzyme results in harmful accumulation of glycogen in muscle. *Id.* at col. 15, ll. 26-29. The patent discloses a method for treating Pompe's disease comprising administering to the patient a therapeutically effective amount of human acid alpha glucosidase. *Id.* at col. 2, ll. 34-36. Doses of human acid alpha glucosidase may be administered two weeks apart. *Id.* at col. 24, ll. 22-23.

C. The Claim

Claim 1 is the only claim of the '410 patent, and is reproduced below:

> 1. A method of treating a human patient with Pompe's disease, comprising intravenously administering biweekly to the patient a therapeutically effective amount of human acid alpha glucosidase, whereby the concentration of accumulated glycogen in the patient is reduced and/or further accumulation of glycogen is arrested.

D. The Prior Art

Petitioner relies on the following prior art:

Duke University, "Duke Obtains FDA Designation for Pompe Disease Therapy," press release dated September 2, 1997, 2 pages (Ex. 1002).

Bembi et al., "Enzyme replacement treatment in type 1 and type 3 Gaucher's disease," 344 THE LANCET 1679-1682 (1994) (Ex. 1003).

Barton et al., "Replacement Therapy for Inherited Enzyme Deficiency – Macrophage-Targeted Glucocerebrosidase for Gaucher's Disease," 324 N. ENG. J. MED. 1464-1470 (1991) (Ex. 1004).

Reuser et al., WO 97/05771, published Feb. 20, 1997 (Ex. 1005).

Kikuchi et al., "Clinical and Metabolic Correction of Pompe Disease by Enzyme Therapy in Acid Maltase-deficient Quail," 101(4) J. CLIN. INVEST., 827-833 (1998) (Ex. 1007).

Van der Ploeg et al., "Receptor-Mediated Uptake of Acid α-Glucosidase Corrects Lysosomal Glycogen Storage in Cultured Skeletal Muscle," 24(1) PEDIATRIC RESEARCH 90-94 (1988) (Ex. 1032).

Pompe's Bulletin, The Newsletter for Families Affected by Glycogen Storage Disease Type II, Issue 4, March 1997 (Ex. 1064).

E. The Asserted Grounds

Petitioner challenges claim 1 of the '410 patent on the following grounds. Pet. 30-53.

Reference[s]	**Basis**	**Claim challenged**
Duke Press Release 1997, Barton or Bembi, and Van der Ploeg	§ 103(a)	1
Reuser, Barton or Bembi, and Van der Ploeg	§ 103(a)	1
Duke Press Release 1997, Reuser, Pompe Bulletin, and Van der Ploeg	§ 103(a)	1
Duke Press Release 1997, Pompe Bulletin and/or Kikuchi, and Van der Ploeg	§ 103(a)	1

II. ANALYSIS

A. Claim Interpretation

Consistent with the statute and legislative history of the America Invents Act (AIA), the Board interprets claims using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R.

§ 42.100(b); *see also Office Patent Trial Practice Guide*, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012).

Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). "Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly disclaim[s] the broader definition." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). "Although an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Claim 1 recites a method of treating a human patient with Pompe's disease having the step of intravenously administering biweekly to the patient a therapeutically effective amount of human acid alpha glucosidase. Petitioner sets forth what it considers to be the ordinary meaning for claim terms: "human acid alpha glucosidase," "therapeutically effective amount," and "biweekly." Pet. 25-30. Petitioner's proposed constructions are reasonable at this stage of the proceeding, and we thus adopt them for the purposes of this decision.

The claim feature of "whereby the concentration of accumulated glycogen in the patient is reduced and/or further accumulation of glycogen is arrested" is not a separate step, but rather a result of administering a therapeutically effective amount of human acid alpha glucosidase according to the claimed method. Such results are not generally considered a patentable feature separate from the expressly recited steps of the claimed method. *See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001) (recognizing that "[n]ewly discovered results of known processes directed to the same purpose are not

patentable."); *see also Abbott Labs. v. Baxter Pharm. Products, Inc*., 471 F.3d 1363, 1369 (Fed. Cir. 2006). Accordingly, for the purposes of this decision, we adopt Petitioner's position that the phrase "the concentration of accumulated glycogen in the patient is reduced and/or further accumulation of glycogen is arrested" does not further limit the phrase "a therapeutically effective amount of human acid alpha glucosidase." Pet. 28.

B. Asserted Grounds of Unpatentability

1. Obviousness of Claim 1 over the Combination of Duke Press Release 1997, Barton, and Van der Ploeg[1]

The Duke Press Release 1997 details an FDA clinical trial study in which infants with Pompe's disease were injected with recombinant acid alpha glucosidase to evaluate the safety and efficacy of the recombinant enzyme treatment. Ex. 1002; Pet. 31-32. The Duke Press Release 1997 does not disclose the dosing regimen or route of administration used for the study, and thus does not expressly disclose the feature of intravenously administering human enzyme biweekly as recited in claim 1. We are persuaded, however, that there is a reasonable likelihood that Petitioner would establish that one of ordinary skill in the art would have found the recited biweekly intravenous administration of a therapeutically effective amount of the enzyme obvious in view of the combination of Duke Press Release 1997, Barton, and Van der Ploeg.

[1] Petitioner's Ground 1 is set forth with reliance on Barton and Bembi in the alternative—that is, "Barton or Bembi." Pet. 30. Petitioner's Ground 1 is therefore a combination of two grounds: one ground that relies on the combination of Duke Press Release 1997, Barton, and van der Ploeg and a second ground that relies on the combination of Duke Press Release 1997, Bembi, and Van der Ploeg. As explained below, the alternative ground that relies on Bembi is denied as redundant.

Barton (Ex. 1004, abstract) discloses a biweekly intravenous administration schedule for enzyme replacement therapy (*i.e.*, biweekly intravenous administration of glucocerebrosidase to patients with Gaucher's Disease). Van der Ploeg discloses a tissue half-life of human acid alpha glucosidase of 6-9 days (Ex. 1032, 91, right col., final ¶). Petitioner relies on the Declaration of Dr. Pastores as evidence that a clinician would have chosen a biweekly dosing schedule based on this half-life (Ex. 1030, ¶¶ [0086]-[0090]). Pet. 36. Such evidence reasonably supports Petitioner's position that it would have been obvious to select a biweekly intravenous administration for the purposes of initially determining the clinical effectiveness of the enzyme replacement therapy disclosed in the Duke Press Release 1997. *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 417 (2007) ("If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.").

Regarding the recited "therapeutically effective amount," the Duke Press Release 1997 describes that the amount of enzyme injected into infants is expected to restore normal glycogen levels. Pet. 37, citing Ex. 1002. We agree with Petitioner's contention that this disclosure amount satisfies the claim element of "therapeutically effective amount" recited in claim 1. Pet. 37-38.

For these reasons, we conclude that there is a reasonable likelihood that Petitioner will prevail in demonstrating that claim 1 is rendered obvious the combination of Duke Press Release 1997, Barton, and Van der Ploeg.

2. Obviousness of Claim 1 over the Combination of Reuser, Barton, and Van der Ploeg

Upon review of Petitioner's analysis and supporting evidence, we determine that Petitioner has demonstrated that there is a reasonable likelihood that it would prevail on the ground that claim 1 would have been obvious over Reuser, Barton,

and Van der Ploeg.

Reuser discloses the production of human acid alpha glucosidase for use in enzyme replacement therapy to treat Pompe's disease. Ex. 1005, 2-3 and 21-23 (Example 1); Pet. 41-42. Reuser discloses intravenous administration "in an amount sufficient to reduce the concentration of accumulated metabolite and/or prevent or arrest further accumulation of metabolite." *Id.* at 20, ll. 9-28. In the case of Pompe's disease, glycogen is the metabolite. *Id.* at 2. Reuser further describes a "therapeutically effective dose" as being dependent on the condition and general state of the patient's health. *Id.* at 20, ll. 25-28.

Reuser does not disclose biweekly administration as recited in claim 1. Nevertheless, there is a reasonable likelihood that Petitioner would demonstrate that one of ordinary skill in the art would have found the recited biweekly intravenous administration of a therapeutically effective amount of the enzyme obvious in view of the combination of Reuser, Barton, and Van der Ploeg. As discussed above, Barton and Van der Ploeg reasonably support the Petitioner's position that it would have been obvious to select a biweekly intravenous administration for the purposes of initially determining the clinical effectiveness of the enzyme replacement therapy disclosed in Reuser. *KSR*, 550 U.S. at 417.

For those reasons, we conclude that there is a reasonable likelihood that Petitioner will prevail in demonstrating that claim 1 is rendered obvious by the combination of Reuser, Barton, and Van der Ploeg.

3. Redundant Grounds

Petitioner also asserts that claim 1 is obvious over the combination of: (i) Duke Press Release 1997, Bembi, and Van der Ploeg; (ii) Duke Press Release 1997, Reuser, Pompe Bulletin, and Van der Ploeg; and (iii) Duke Press Release 1997, Pompe Bulletin, Kikuchi and Van der Ploeg. Petitioner makes no

meaningful distinction between these grounds and the grounds on which the Board has already granted the Petition to institute *inter partes* review. Petitioner's remaining grounds, therefore, are denied as redundant. 37 C.F.R. § 42.108(a). *See also Liberty Mutual Ins. Co. v. Progressive Casualty Ins. Co*., CBM-2012-00003 (Paper No. 7), at *2 (PTAB Oct. 25, 2012) (not proceeding on redundant grounds in absence of meaningful distinction); *see also* 37 C.F.R. § 42.1(b) ("This part [i.e., Part 42 of Title 37, Code of Federal Regulations] shall be construed to secure the just, speedy, and inexpensive resolution of every proceeding.")

III. CONCLUSION

Petitioner has demonstrated a reasonable likelihood of prevailing on its challenge of claim 1 of the '410 patent under 35 U.S.C. § 103 as obvious over the combination of Duke Press Release 1997, Barton, and Van der Ploeg.

Petitioner has demonstrated a reasonable likelihood of prevailing on its challenge of claim 1 of the '410 patent under 35 U.S.C. § 103 as obvious over the combination of Reuser, Barton, and Van der Ploeg.

Petitioner's other challenges are denied as redundant to the above challenges.

IV. ORDER

For the reasons given, it is

ORDERED that the Petition is *granted* as to claim 1 of the '410 patent with respect to the following alleged grounds:

1. Claim 1 under 35 U.S.C. § 103 as obvious over the combination of Duke Press Release 1997, Barton, and Van der Ploeg;
2. Claim 1 under 35 U.S.C. § 103 as obvious over the combination of Reuser, Barton, and Van der Ploeg;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the ’410 patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial;

FURTHER ORDERED that all other grounds presented in the Petition are *denied*, and no ground other than those specifically granted above is authorized for the *inter partes* review as to claim 1; and

FURTHER ORDERED that an initial conference call with the Board is scheduled for 2 PM Eastern Time on March 17, 2014. The parties are directed to the Office Trial Practice Guide, 77 Fed. Reg. 48756, 48765-66 (Aug. 14, 2012) for guidance in preparing for the initial conference call, and should come prepared to discuss any proposed changes to the Scheduling Order entered herewith and any motions the parties anticipate filing during the trial.

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