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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner,

v.

MERCK SHARP & DOHME CORP.,
Patent Owner.

Case IPR2015-00419
Patent 5,691,336

Before LORA M. GREEN, ZHENYU YANG, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

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

INTRODUCTION

Apotex Inc. ("Petitioner") filed a Petition for an *inter partes* review of claims 1, 3–8, and 10–25 of U.S. Patent No. 5,691,336 ("the '336 patent," Ex. 1001). Paper 1 ("Pet."). Merck Sharp & Dohme Corp. ("Patent Owner") timely filed a Preliminary Response. Paper 13 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314.

For the reasons provided below, we determine Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim. *See* 35 U.S.C. § 314(a). Therefore, we deny the Petition for an *inter partes* review.

Related Proceedings

According to the parties, Patent Owner previously asserted the '336 patent against several entities, but not Petitioner, in district court proceedings. Pet. 1, 2; Paper 9, 1–2.

The '336 Patent

The '336 patent is directed to a genus of tachykinin receptor antagonists useful in treating inflammatory diseases, pain or migraine, asthma, and emesis. Ex. 1001, 5:15–39. The compounds are prodrugs of their parent compounds. *Id.* at 12:26–27.

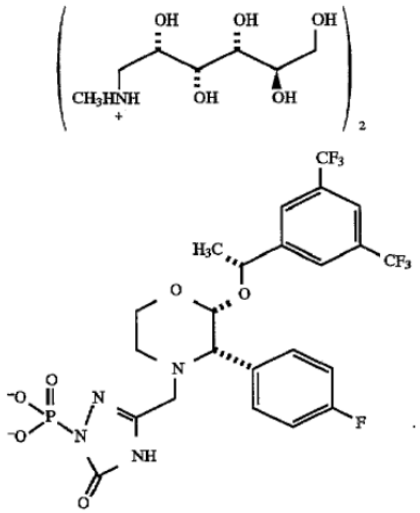
According to the '336 patent,

> Prodrugs are entities structurally related to a[] biologically active substance (the "parent drug")[,] which, after administration, release the parent drug in vivo as the result of some metabolic process, such as enzymatic or chemical

> hydrolysis of a carboxylic, phosphoric or sulfate ester or reduction or oxidation of a susceptible functionality.

Id. at 12:38–43. "[T]he activity exhibited upon administration of the prodrug is principally due to the presence of the parent compound that results from cleavage of the prodrug." *Id.* at 12:31–34. Compared with their parent compounds, the prodrugs of the '336 patent have enhanced solubility. *Id.* at 12:27–29, 13:9–12.

The '336 patent discloses 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(1-phosphoryl-5-oxo-4H-1,2,4-triazolo)methylmorpholine as "a particularly preferred compound" within the scope of its invention. *Id.* at 43:19–23. Today this compound is referred to as fosaprepitant. Pet. 5. The '336 patent also discloses 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)pheny l-4-(3-(1-phosphoryl-5-oxo-4H-1,2,4-triazolo)methylmorpholine, bis(N-methyl-D-glucamine) as "a specific particularly preferred compound" within the scope of its invention. *Id.* at 43:23–27. It has the structure:



Id. at 159:23–45. Today this compound is referred to as fosaprepitant dimeglumine, which is the active ingredient in Patent Owner's FDA-approved product, Emend® for Injection. Prelim. Resp. 1.

Among the challenged claims, claims 15, 16, 18, and 19 are directed to the compound fosaprepitant dimeglumine; and claim 23 is directed to a pharmaceutical composition comprising fosaprepitant dimeglumine. The other claims are broader in scope, but each encompasses fosaprepitant dimeglumine, the composition thereof, or the use thereof.

Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claims	Basis	References
1, 3–8, and 10–25	§ 103	Dorn '699[1] and Murdock '082[2]
1, 3–8, and 10–25	§ 103	Dorn '699, Murdock '082, Atanassova,[3] and Van Den Bos[4]
12, 15, 16, 18, 19, and 23	§ 103	Dorn '699, Murdock '082, Atanassova, Van Den Bos, Sommer,[5] Veronesi,[6] and Chromy[7]

[1] Dorn et al., U.S. Patent No. 5,637,699, issued June 10, 1997 (Ex. 1003, "Dorn '699").
[2] Murdock et al., U.S. Patent No. 5,070,082, issued December 3, 1991 (Ex. 1004, "Murdock '082").
[3] Atanassova, T. et al., *Synthesis of N-substituted derivatives of 2-imidazolidinone*, 46 PHARMAZIE 670–71 (1991) (Ex. 1007, "Atanassova").
[4] Van Den Bos et al., U.S. Patent No. 3,661,926, issued May 9, 1972 (Ex. 1006, "Van Den Bos").
[5] Sommer, F.G., et al., *Pain Accompanying Leg Venography: A Comparison of Sodium and Methylglucamine Diatrizoates*, 133 RADIOLOGY 790–91 (1979) (Ex. 1017, "Sommer").

According to Petitioner, Dorn '699 is prior art under 35 U.S.C. § 102(e) because it has an effective filing date of at least December 17, 1993, before the priority date of the challenged claims.[8] Pet. 32. Petitioner asserts that the other references are prior art under 35 U.S.C. § 102(b). *Id.* at 33, 48, 53.

In support of its patentability challenge, Petitioner relies on the Declaration of Dr. Longqin Hu. Ex. 1002.

ANALYSIS

Claim Construction

In an *inter partes* review, the Board interprets a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1278–81 (Fed. Cir. 2015). Under that standard, and absent any special definitions, we assign claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention, in the context of the

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[6] Veronesi, U.S. Patent No. 4,748,174, issued May 31, 1988 (Ex. 1022, "Veronesi").
[7] Chromy, V., et al., *D(–)-N-Methylglucamine Buffer for pH 8.5 to 10.5*, 24 CLIN. CHEM. 379–81 (1978) (Ex. 1018, "Chromy").
[8] The earliest possible priority date of the '336 patent is March 4, 1994. Ex. 1001, 1:9–10. For purposes of its Preliminary Response, Patent Owner asserts February 28, 1995 as the priority date. Prelim. Resp. 9–10 & n.2.

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