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Paper No. 14
Entered: July 1, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LOWER DRUG PRICES FOR CONSUMERS, LLC,
Petitioner,

v.

FOREST LABORATORIES HOLDINGS LIMITED,
Patent Owner.

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Case IPR2016-00379
Patent 6,545,040 B1

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Before MICHAEL P. TIERNEY, LORA M. GREEN, and TINA E. HULSE, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

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

# I. INTRODUCTION

Lower Drug Prices for Consumers, LLC ("Petitioner") filed a Corrected Petition requesting an *inter partes* review of claims 1–6 of U.S. Patent No. 6,545,040 B1 (Ex. 1001, "the '040 patent"). Paper 6 ("Pet."). Forest Laboratories Holdings Limited ("Patent Owner") filed a Preliminary Response to the Petition. Paper 12 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the Petition and Preliminary Response, we conclude that the Petition presents substantially the same art and arguments as those previously presented to the Office, and, therefore, exercise our discretion under 35 U.S.C. § 325(d) to deny the Petition.

## *A. Related Proceedings*

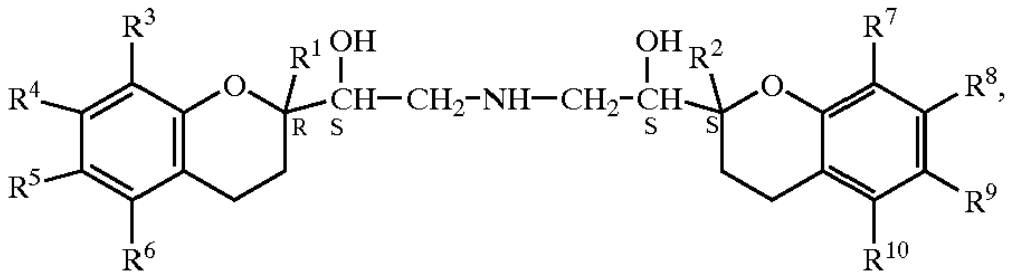
The parties identify several district court proceedings as relating to the '040 patent, all of which are now closed. Pet. 59; Paper 5, 1.

Patent Owner also states the '040 patent was the subject of *ex parte* reexamination proceeding 90/008,356, which is concluded. Paper 5, 2.

## *B. The '040 Patent*

The '040 patent relates to a certain class of isomers of 2,2'-iminobisethanol derivatives having β-adrenergic blocking properties that potentiate the activity of blood pressure reducing agents. Ex. 1001, 1:13–17. The class of compounds is represented by formula (I):

(I)



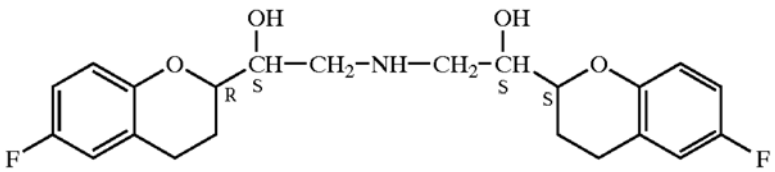
or the pharmaceutically acceptable acid addition salts thereof. *Id.* at 1:21–37.

According to the '040 patent, the most preferred compound is [2R,αS,2'S, α'S]-α, α'-[iminobismethylene]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] or a pharmaceutically acceptable acid addition salt thereof. *Id.* at 1:60–63. The Specification states that the compounds of formula (I) potentiate the activity of blood pressure reducing agents and, in particular, potentiate the reduction of blood pressure and heart rate. *Id.* at 4:6–9. The Specification also provides examples of such blood pressure reducing agents, including the SRRR-isomers of the compounds of formula (I). *Id.* at 4:51–55.

### *C. Illustrative Claim*

Petitioner challenges claims 1–6 of the '040 patent. Claims 1 and 2 are the only independent claims and are reproduced below:

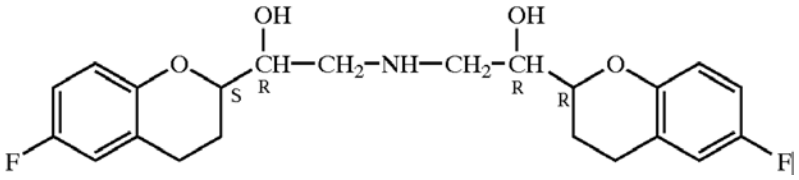
> 1. A composition consisting of the compound [2R,αS,2'S, α'S]-α, α'-[iminobismethylene]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] having the formula:



> or a pharmaceutically acceptable acid addition salt thereof.

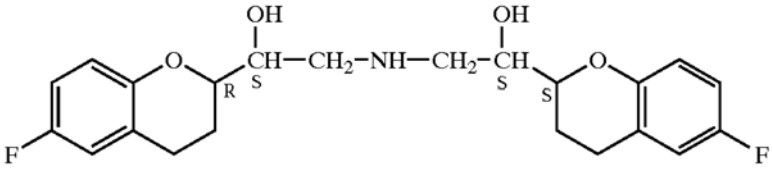
2. A pharmaceutical composition consisting of a pharmaceutically acceptable carrier and, as active ingredients:

(a) the blood pressure reducing compound [2S,αR,2'R, α'R]-α, α'-[iminobismethylene]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] having the formula:



or a pharmaceutically acceptable acid addition salt thereof; and

(b) the compound [2R,αS,2'S, α'S]-α, α'-[iminobismethylene]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] having the formula:



*D. The Asserted Grounds of Unpatentability*

Petitioner challenges the patentability of claims 1–6 of the '040 patent on the following grounds:

| References | Basis | Claim(s) challenged |
|---|---|---|
| Van Lommen[1] in view of Handbook of Chromatography[2] | § 103 | 2–6 |
| Van Lommen and Handbook of Chromatography in view of Okamoto[3] | § 103 | 1 |

[1] Van Lommen et al., US 4,654,362, issued Mar. 31, 1987 (Ex. 1004).
[2] HANDBOOK OF CHROMATOGRAPHY, Vol. II (Gunter Zweig, Ph.D. & Joseph Sherma, Ph.D. eds. 1972) (Ex. 1005).
[3] Okamoto et al., *Optical Resolution of β-Blockers by HPLC on Cellulose Triphenylcarbamate Derivatives*, CHEMISTRY LETTERS 1237–40 (1986) (Ex. 1006).

| References | Basis | Claim(s) challenged |
|---|---|---|
| Van Lommen and Handbook of Chromatography in view of Armstrong[4] | § 103 | 1 |

Petitioner also relies on the testimony of Ronald W. Millard, Ph.D. (Ex. 1052) and Daniel W. Armstrong, Ph.D. (Ex. 1050).

## II. ANALYSIS

### *A. Claim Construction*

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 100(b); *Cuozzo Speed Techs., LLC v. Lee*, No. 15–446, 2016 WL 3369425, at *12 (U.S. June 20, 2016) (upholding the use of the broadest reasonable interpretation standard). Under that standard, and absent any special definitions, we give 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. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

The claims recite a composition "consisting of" the claimed compound. The parties agree that the transitional phrase "consisting of" is a term of art in patent law that "closes" the claim and excludes other elements, steps, or ingredients not specified in the claim. Pet. 29–30; Prelim. Resp. 23.

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[4] Armstrong et al., *Separation of Drug Stereoisomers by the Formation of β-Cyclodextrin Inclusion Complexes*, 232 SCIENCE 1132–35 (1986) (Ex. 1007).

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