Trials@uspto.gov
Tel.: 571-272-7822

Paper No. 10
Entered: February 22, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS IX LLC,
Petitioner,

v.

BRISTOL-MYERS SQUIBB COMPANY,
Patent Owner.

Case IPR2015-01723
Patent 6,967,208 B2

Before GRACE KARAFFA OBERMANN, BRIAN P. MURPHY, and TINA E. HULSE, *Administrative Patent Judges.*

MURPHY, *Administrative Patent Judge*.

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

I. INTRODUCTION

Coalition For Affordable Drugs IX LLC ("Petitioner") filed a Petition requesting *inter partes* review of claims 1–13, 20–27, and 34–61 of U.S. Patent No. 6,967,208 B2 ("the '208 patent"). Paper 1 ("Pet."). Bristol-Myers Squibb Company ("Patent Owner") filed a Preliminary Response to the Petition. Paper 8 ("Prelim. Resp."). We have statutory authority under 35 U.S.C. § 314(a), 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."

Petitioner challenges claims 1–13, 20–27, and 34–61 of the '208 patent as unpatentable for alleged anticipation under 35 U.S.C. § 102 and obviousness under 35 U.S.C. § 103. Pet. 15. Based on the information presented in the Petition and Preliminary Response, we are not persuaded there is a reasonable likelihood Petitioner would prevail with respect to at least one of the claims challenged in the Petition. Therefore, we decline to institute *inter partes* review.

A. Related Proceedings

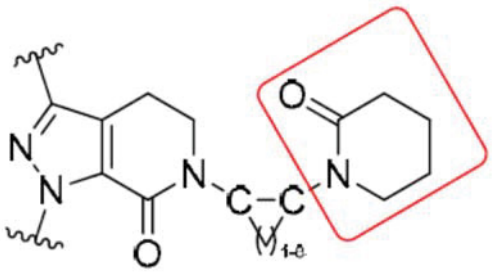
The parties do not identify any related matters. Pet. 2–3; Paper 6, 1.

B. The '208 Patent

The '208 patent, titled "Lactam-Containing Compounds and Derivatives Thereof as Factor Xa Inhibitors," issued November 22, 2005 from an application filed September 17, 2002, which claims priority to provisional applications filed September 21, 2001 and August 9, 2002. Ex. 1001, (22), (45), (60). The '208 patent is directed to genus, sub-genus, and species claims for lactam-containing compounds, pharmaceutical compositions, and methods of treatment, particularly

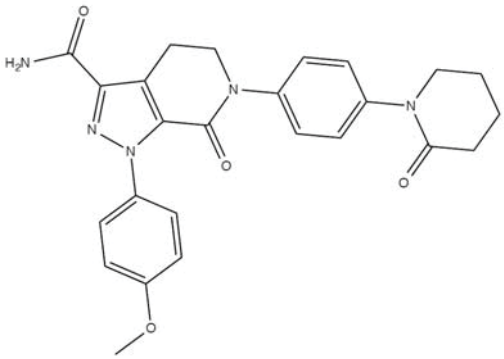
including a compound called "apixaban." *Id.* at 5:53–67. Apixaban is the active ingredient in ELIQUIS®, a lactam-containing compound used as an anticoagulant (blood factor Xa inhibitor) to reduce the risk of blood clots that can cause strokes and heart attacks. Ex. 1001, 1:20–25, 174:21–25; Ex. 1009. A lactam is a cyclic amide (O=C–N–) that includes a nitrogen in the ring structure. Prelim. Resp. 10 n.3; Ex. 1003, 79, 83–84.

Claim 1 of the '208 patent is directed to lactam genera—that is, compounds (or pharmaceutically acceptable salts thereof) having the lactam-containing core structure below:



Prelim. Resp. 12. The portion of the structure identified within the box, above, is a lactam ring. *Id.* In claim 1 of the '208 patent (reproduced below), the lactam ring at issue is defined as "M_4" substituent "B."

Claims 2 through 8 are claims to progressively smaller subgenera of claim 1. Claim 8 depends from claim 1 and is limited to 65 enumerated compounds (and their pharmaceutically acceptable salts). The ninth compound listed in claim 8 is apixaban. Claim 13 claims apixaban as a single species, dependent from claim 8. The chemical structure of apixaban is reproduced below.

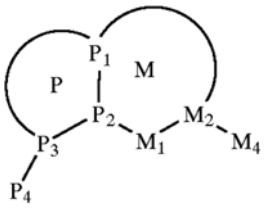


Pet. 14 (citing Ex. 1008 ¶¶ 51, 52); Prelim. Resp. 16 (noting the synthesis of apixaban is described in Example 18 of the '208 patent (Ex. 1001, 174:21–175:51)).

C. The '208 Patent Claims

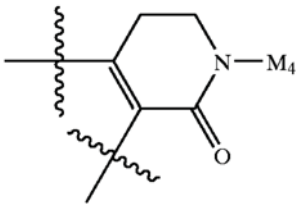
Abbreviated forms of claims 1 and 8, and claim 13 of the '208 patent are illustrative and reproduced below (emphasis added):[1]

1. A compound of Formula I:

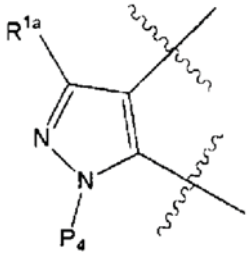


or a stereoisomer or pharmaceutically acceptable salt thereof, wherein;
ring M, including P_1, P_2, M_1, and M_2 is substituted with 0–2 R^{1a} and is[2]

[1] Claim 1 comprises over five columns of text in the '208 patent and includes numerous Markush group substitutions. The claims of the patent were corrected by a thirteen-page Certificate of Correction issued December 2, 2008, which can be located in Exhibit 1001 following column 276. The claims reproduced here incorporate the changes identified in the Certificate of Correction. *See* Ex. 1001, Certificate of Correction, 1–2 (claim 1), 7 (claim 8), 10 (claim 13).
[2] We note ring M does not contain an R^{1a} substitution group. *See* Ex. 1001, Certificate of Correction, 1–2.



ring P, including P_1, P_2, and P_3, is



M_4 is –A–B;

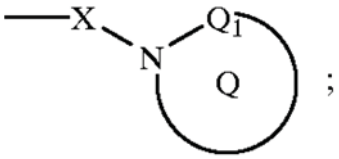
P_4 is $–G_1–G$;

. . .

A is selected from:

$C_{3\text{-}10}$ carbocycle substituted with 0–2 R^4,

B is



;

. . .

Q_1 is C=O;

ring Q is a 6 membered monocyclic ring, wherein: 0 double bond is present within the ring and the ring is substituted with 0–2 R^{4a} ;

X is absent; . . . .

8. A compound according to claim 1, wherein the compound is selected from the group:

[first 8 compounds] . . .

1-(4-methoxypheny1)-7-oxo-6-[4-(2-oxo-l-piperidinyl)

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