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Paper No. 78
Date: September 8, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC., MSN LABORATORIES PRIVATE LTD. and MSN PHARMACEUTICALS INC.,
Petitioners,

v.

BAUSCH HEALTH IRELAND LIMITED,
Patent Owner.

IPR2022-00722[1]
Patent 7,041,786 B2

Before TINA E. HULSE, CYNTHIA M. HARDMAN, and MICHAEL A. VALEK, *Administrative Patent Judges*.

VALEK, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)
Granting-in-Part Patent Owner's Motion to Exclude
Denying Petitioner's Motion to Exclude
37 C.F.R. § 42.64(c)

[1] IPR2023-00016 has been joined with this proceeding.

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Mylan") filed a Petition (Paper 1, "Pet."), seeking *inter partes* review of claims 1–6 of U.S. Patent No. 7,041,786 B2 (Ex. 1001, "the '786 patent"). We instituted trial on all of the grounds in the Petition. Paper 16, 32.

Following institution, MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. (collectively "MSN") filed a substantially identical petition in IPR2023-00016. That proceeding was instituted and joined with this one. *See* Paper 25 (granting joinder). Herein, we refer to Mylan and MSN collectively as "Petitioner."[2]

Bausch Health Ireland Limited ("Patent Owner") then filed a Response (Paper 70,[3] "Resp."), Petitioner filed a Reply (Paper 38, "Reply"), and Patent Owner filed a Sur-reply (Paper 71, "Sur-reply"). We held a hearing on June 14, 2023, and a transcript is of record. Paper 75 ("Tr."). In addition, both Parties have filed motions to exclude certain exhibits. Paper 53 ("PO MTE"); Paper 67 ("Pet. MTE").

After considering the parties' arguments and evidence, we find that Petitioner has not shown by a preponderance of the evidence that the challenged claims of the '786 patent are unpatentable. *See* 35 U.S.C. § 316(e). Moreover, as explained below, we grant Patent Owner's motion to exclude in part and deny Petitioner's motion to exclude.

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[2] MSN has agreed to an "understudy role" in this proceeding. *See* IPR2023-00016, Paper 14.

[3] Portions of Patent Owner's Response and Sur-reply were initially filed under seal. *See* Papers 28 and 51. Patent Owner has since filed unredacted versions that we refer to herein. *See* Paper 73 (Patent Owner agreeing to make these papers public).

II. BACKGROUND

A. Real Parties in Interest

In addition to itself, Mylan identifies the following real parties in interest ("RPI"): Mylan Inc. and Viatris Inc. *See* Paper 9, 2 (identifying these entities as parent companies); Paper 16, 31 (accepting Petitioner's representation that these entities are RPI). MSN identifies MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. as RPI. IPR2023-00016, Paper 16, 2. Patent Owner identifies itself and Salix Pharmaceuticals, Inc. as RPI. Paper 4, 2.

B. The '786 Patent

The '786 patent issued on May 9, 2006, from a utility application filed on March 28, 2002, and claims priority to a provisional application filed on January 17, 2002. Ex. 1001, codes (22), (45), (60).

The '786 patent is titled "Guanylate Cyclase Receptor Agonists for the Treatment of Tissue Inflammation and Carcinogenesis." Ex. 1001, code (54). According to the Specification,

> [t]he present invention relates to the therapeutic use of guanylate cyclase receptor agonists as a means for enhancing the intracellular production of cGMP. The agonists may be used either alone or in combination with inhibitors of cGMP-specific phosphodiesterase to prevent or treat cancerous, pre-cancerous and metastatic growths, particularly in the gastrointestinal tract and lungs. In addition, the agonists may be used in the treatment of inflammatory disorders such as ulcerative colitis and asthma.

Id. at 1:14–23.

The Specification explains that "[u]roguanylin, guanylin and bacterial ST [i.e., heat-stable enterotoxin] peptides are structurally related peptides

that bind to a guanylate cyclase receptor and stimulate intracellular production of cyclic guanosine monophosphate (cGMP)." Ex. 1001, 1:26–30. "This results in the activation of the cystic fibrosis transmembrane conductance regulator (CFTR)," which in turn "leads to stimulation of sodium and water secretion into the intestinal lumen." *Id.* at 1:30–36. "Therefore, by serving as paracrine regulators of CFTR activity, cGMP receptor agonists," such as uroguanylin, guanylin, and bacterial ST peptides, "regulate fluid and electrolyte transport in the GI tract." *Id.* at 1:36–39.

"The present invention is based upon the development of new agonists of guanylate cyclase receptor" that "are analogs of uroguanylin." Ex. 1001, 3:3–6. The Specification describes the sequence for its "most preferred" uroguanylin analog in SEQ ID NO:20, which is reproduced below.

$$\underset{}{\text{Asn}^{1}}\ \underset{}{\text{Asp}^{2}}\ \underset{}{\text{Glu}^{3}}\ \underset{*}{\text{Cys}^{4}}\ \underset{}{\text{Glu}^{5}}\ \underset{}{\text{Leu}^{6}}\ \underset{**}{\text{Cys}^{7}}\ \underset{}{\text{Val}^{8}}\ \underset{}{\text{Asn}^{9}}\ \underset{}{\text{Val}^{10}}\ \underset{}{\text{Ala}^{11}}\ \underset{*}{\text{Cys}^{12}}\ \underset{}{\text{Thr}^{13}}\ \underset{}{\text{Gly}^{14}}\ \underset{**}{\text{Cys}^{15}}\ \underset{}{\text{Leu}^{16}}$$

Id. at 5:7–12. SEQ ID NO:20 provides the primary structure of a 16-amino acid long peptide. The sequence in SEQ ID NO:20 differs from that of the "Parent compound: uroguanylin" (shown in SEQ ID NO: 1) in that it has a "Glu^{3}," i.e., a glutamic acid (Glu) at position 3 in the peptide sequence, whereas human uroguanylin has an "Asp^{3}," i.e., an aspartic acid (Asp) at that position.[4] *See id.* at 11 (Table 2). This is the only difference between the

[4] Both parties use a superscript to denote the position of the residue in an amino acid sequence. *See, e.g.*, Pet. 1, 38; Resp. 2 (referring to "Glu^{3}" and "Asp^{3}"). In addition to Glu, other synonyms for glutamic acid appearing in the record include "glutamate" and the letter "E" from the single-letter code for amino acids. In addition to Asp, other synonyms for aspartic acid include "aspartate" and the letter "D."

sequence in SEQ ID NO:20 and the naturally–occurring human uroguanylin sequence in SEQ ID NO:1. *Id.*; *see also* Ex. 1002 ¶¶ 24–25.

> According to the Specification, the peptide of SEQ ID NO:20 has been found to have enhanced biological activity as an agonist of cGMP production due to its enhanced binding constant for the guanylate cyclase receptor, and is superior to uroguanylin with regard to temperature and protease stability and with regard to its biological activity at the physiologically favorable pH range (pH 6 to 7) in the large intestine.

Ex. 1001, 5:16–23. Table 4, reproduced below, shows data from a "T84 cell-based assay for determining the intracellular levels of cGMP." *Id.* at 15:35–36.

TABLE 4

Peptide agonists evaluated for biological activity in the T84 cell bioassay.

SEQ ID NO.*	Compound Code	cGMP Level** (pmol/well)
1	SP301	205
6	SP302	225
7	SP303	195
20	SP304	315
14	SP306	0
4	SP310	0
21	SP316	275

*SEQ ID's for SP301, SP304 and SP316 are the precise amino acid sequences for these analogs as given in the text.
**Intracellular cGMP level observed in T84 cells following treatment with 1 micromolar solution of the respective peptide agonist for 30 minutes. The value observed for SP304 was statistically significant with a $p > 0.5$.

"As shown in Table 4, SP304 (SEQ ID NO:20) gave the greatest enhancement of intracellular cGMP of all the" peptides tested. *Id.* at 15:53–58.

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