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Paper 17
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

COSMO TECHNOLOGIES LIMITED,
Patent Owner.

Case IPR2017-01035
Patent 9,320,716 B2

Before SUSAN L. C. MITCHELL, ZHENYU YANG, and KRISTI L. R. SAWERT, *Administrative Patent Judges*.

MITCHELL, *Administrative Patent Judge*.

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

I. INTRODUCTION

Mylan Pharmaceuticals, Inc. ("Petitioner") filed a Petition (Paper 1, "Pet.") on March 9, 2017, requesting an *inter partes* review of claims 1–29 of U.S. Patent No. 9,320,716 B2 (Ex. 1001, "the '716 patent"). Cosmo Technologies Limited ("Patent Owner") filed a Preliminary Response (Paper 8, "Prelim. Resp.") on June 22, 2017. Institution of an *inter partes* review is authorized by statute when "the information presented in the petition . . . and any response . . . 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." 35 U.S.C. § 314(a); *see also* 37 C.F.R. §§ 42.4, 42.108.

Upon consideration of the information presented in the Petition and the Preliminary Response, we conclude that Petitioner has established a reasonable likelihood that it would prevail in its challenge to at least one of claims 1–29 of the '716 patent. Accordingly, we institute an *inter partes* review of those claims.

A. Related Proceedings

The parties list the following cases in which the '716 has been asserted by Patent Owner: *Cosmo Technologies Limited v. Mylan Pharmaceuticals Inc.*, 16-cv-00152 (D. Del.); *Cosmo Technologies Ltd v. Lupin Ltd.*, 15-cv-00669 (D. Del.); *Cosmo Technologies Limited v. Alvogen Pine Brook, Inc.*, 15-cv-00193 (D. Del.); *Cosmo Technologies Ltd. v. Actavis Laboratories FL, Inc.*, 15-cv-00164 (D. Del.); and *Cosmo Technologies Limited v. Par Pharmaceutical, Inc.* 15-cv-00116 (D. Del.). Pet. 2; Paper 6, 2. In addition, concurrently with the Petition under consideration here, Petitioner has filed a petition challenging the claims of related U.S. Patent

No. 8,784,888 B2, Case No. IPR2017-01034. *See* Pet. 3; Paper 6, 3. The parties also identify several related patents. Pet. 2, Paper 6, 2.

B. The Asserted Grounds of Unpatentability

Petitioner asserts the challenged claims are unpatentable on the following grounds. Pet. 8. Petitioner supports its challenge with the Declaration of Anthony Palmieri III, Ph.D., R.Ph. ("Palmieri Declaration") (Ex. 1006).

Reference(s)	**Basis**	**Claims Challenged**
U.S. Patent No. 5,681,584[1]	§ 102	1–29
'584 Patent	§ 103	1–29
U.S. Patent No. 5,811,388[2]	§ 102	1–7, 9, 11–17, 19, 21–29
'388 Patent	§ 103	1–29
'388 and '584 Patents	§ 103	8, 10, 18, and 20

C. The '716 Patent (Ex. 1001)

The '716 patent, titled "Controlled Release and Taste Masking Oral Pharmaceutical Compositions," describes an oral pharmaceutical composition with an active agent, a macroscopically homogeneous structure, and a gastro-resistant coating. Ex. 1001, Abst. Specifically, the "macroscopically homogenous structure comprises at least one hydrophilic compound and at least one lipophilic compound and/or at least one

[1] U.S. Patent No. 5,681,584, issued October 28, 1997, to Louis Savastano *et al.* ("'584 Patent") (Ex. 1008).
[2] U.S. Patent No. 5,811,388, issued September 22, 1998 to David R. Friend and David Wong ("'388 Patent") (Ex. 1009).

amphiphilic compound. The macroscopically homogeneous structure controls the release of the active ingredient, and the gastro-resistant film prevents release of the active agent in the stomach." *Id*.

The macroscopically homogeneous structure is further described as "a three-component matrix structure, i.e. a structure formed by successive amphiphilic, lipophilic or inert matrices and finally incorporated or dispersed in hydrophilic matrices." *Id*. at 1:25–28. This structure serves the dual purposes of modulating the dissolution rate of the active ingredient in aqueous or biological fluids to control the release kinetics in the gastrointestinal tract, and allows for oral administration of an active agent that has an unpleasant taste or irritates the mucosae of the administration site. *Id*. at 29–36. Therefore, "[t]he compositions of the invention are characterized by the absence of a first phase in which the medicament superficially present on the matrix is quickly solubilized, and by the fact the amphiphilic layer compensate the lack of affinity of the aqueous solvent with the lipophilic compounds forming the inner matrix." *Id*. 2:65–3:4.

The composition having the three-component matrix structure as described in the '716 Patent can be prepared using the following three steps.

> a) the active ingredient is first inglobated by simple kneading or mixing in a matrix or coating consisting of compounds having amphiphilic properties, which will be further specified below. The active principle(s) can be mixed with the amphiphilic compounds without the aid of solvents or with small amounts of water-alcoholic solvents.
>
> b) The matrix obtained in a) is incorporated in a low melting lipophilic excipient or mixture of excipients, while heating to soften and/or melt the excipient itself, which thereby incorporates the active ingredient by simple dispersion. After cooling at room temperature an inert matrix forms, which can be

> reduced in size to obtain inert matrix granules containing the active ingredient particles.
>
> c) The inert matrix granules are subsequently mixed together with one or more hydrophilic water-swellable excipients. The mixture is then subjected to compression or tableting. This way, when the tablet is contacted with biological fluids, a high viscosity swollen layer is formed, which coordinates the solvent molecules and acts as a barrier to penetration of the aqueous fluid itself inside the new structure. Said barrier antagonizes the starting "burst effect" caused by the dissolution of the medicament inglobated inside the inert matrix, which is in its turn inside the hydrophilic matrix.

Id. at 3:47–4:3.

D. Illustrative Claim

Petitioner challenges claims 1–29 of the '716 patent. Claims 1, 12, and 22 are independent claims. Claim 1, reproduced below, is illustrative.

> 1. A controlled release oral pharmaceutical composition comprising:
>
> (i) budesonide in an amount effective to treat intestinal inflammatory disease;
>
> (ii) a macroscopically homogenous structure comprising:
>
> (a) at least one lipophilic compound and
>
> (b) at least one hydrophilic compound,
>
> wherein the macroscopically homogenous structure controls the release of the budesonide; and
>
> (iii) a gastro-resistant coating on the macroscopically homogenous structure that prevents release of budesonide in the stomach,
>
> wherein the macroscopically homogenous structure is a tablet.

Ex. 1001, 10:13–26. Claim 12 differs from claim 1 in that "at least one amphiphilic compound" is substituted for "at least one lipophilic

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