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Paper 8
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

3M COMPANY,
Patent Owner.

Case IPR2015-02002
Patent 6,743,413 B1

Before LORA M. GREEN, RAMA G. ELLURU, and
ELIZABETH A. LAVIER, *Administrative Patent Judges.*

LAVIER, *Administrative Patent Judge.*

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

I. INTRODUCTION

Petitioner, Mylan Pharmaceuticals Inc. ("Mylan"), filed a Petition requesting an *inter partes* review of claims 1–24 of U.S. Patent No. 6,743,413 B1 ("the '413 patent"; Ex. 1001). Paper 2 ("Pet."). Patent Owner, 3M Company ("3M"), filed a Preliminary Response (Paper 7 ("Prelim. Resp.")), indicating 3M filed a statutory disclaimer of claims 1–13, 20, and 21. Prelim. Resp. 1 (citing Ex. 2007). We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the petition "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."

For the reasons set forth below, on this record we find that Mylan has established a reasonable likelihood of prevailing with respect to at least one of the remaining challenged claims of the '413 patent. Accordingly, we institute an *inter partes* review of claims 14–19 and 22–24 of the '413 patent.[1]

A. The '413 Patent

The '413 patent is titled "Suspension Aerosol Formulations." Ex. 1001, at [54]. The Specification states: "[t]he term 'suspension aerosol formulation' as used herein refers to a formulation in which the drug is in particulate form and is substantially insoluble in the propellant." *Id.* at 3:26–

[1] We do not institute review of the disclaimed claims. *See* 37 C.F.R. § 42.107(e).

28. One of the disclosed propellants is 1,1,1,2-tetrafluoroethane, also known as "hydrofluorocarbon 134a" or "HFC 134a." *Id.* at 1:29–30. The '413 patent explains that HFC 134a is an ozone-friendlier alternative to chlorofluorocarbon (CFC) propellants. *Id.* at 1:29–34.

B. Illustrative Claim

The non-disclaimed claims are all method of treatment claims. Claims 14, 17, and 22 are independent. Claim 14 is illustrative of the challenged claims and is reproduced below:

> 14. A method of treating a mammal having a condition capable of treatment by inhalation, comprising the step of:
>
> administering by inhalation a formulation suitable for aerosol administration, wherein the formulation consists essentially of:
>
> (i) particulate drug; and
>
> (ii) 1,1,1,2-tetrafluoroethane as propellant,
>
> wherein the formulation is substantially free of surfactant.

Ex. 1001, 16:66–17:7.

C. Asserted Grounds of Unpatentability

Mylan asserts the following grounds of unpatentability as to the non-disclaimed claims:

Challenged Claims	Basis[2]	Reference(s)
14–19, 22–24[3]	§ 102(a) or (b)[4]	'011 publication[5]
14–19, 22–24[6]	§ 103(a)	'011 publication
15, 18, 23[7]	§ 103(a)	'011 publication and '051 patent[8]
16, 19, 24[9]	§ 103(a)	'011 publication and Weir[10]

[2] The relevant sections of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, took effect on March 16, 2013. Because the application from which the '413 patent issued was filed before that date, our citations to Title 35 are to its pre-AIA version.

[3] *See* Pet. 10–27.

[4] Mylan asserts that the '011 publication qualifies as prior art under 35 U.S.C. § 102(b) because the earliest priority date to which the '413 patent is entitled is May 4, 1992. *See* Pet. 10; *see also id.* at 2–5. In the alternative, if the '413 patent is entitled to an earlier filing date (of December 18, 1991), Mylan asserts the '011 publication nonetheless qualifies as prior art under § 102(a). *See id.* at 2, 10. 3M does not contest the priority date issue at this stage of the proceeding. As the '011 publication is available as prior art in either case, we need not reach this issue at this time.

[5] PCT International Publication WO 91/04011, published Apr. 4, 1991 (Ex. 1007).

[6] *See* Pet. 28–41.

[7] *See id.* at 39–41.

[8] Hunt et al., U.S. Patent No. 4,866,051, issued Sept. 12, 1989 (Ex. 1009).

[9] *See* Pet. 39–41.

[10] Weir et al., *Corticosteroid Trials in Non-Asthmatic Chronic Airflow Obstruction: A Comparison of Oral Prednisolone and Inhaled Beclomethasone Dipropionate*, 45 THORAX 112–17 (1990) (Ex. 1010).

Challenged Claims	Basis[2]	Reference(s)
14, 20–22[11]	§ 102(b)[12]	'333 publication[13]
14–19, 22–24[14]	§ 103(a)	'333 publication
15, 18, 23[15]	§ 103(a)	'333 publication and '051 patent
16, 19, 24[16]	§ 103(a)	'333 publication and Weir

In support of its contentions, Mylan relies on the Declaration of Dr. Hugh Smyth (Smyth Declaration) (Ex. 1006).[17]

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[11] *See* Pet. 41–50.

[12] Mylan asserts that the '333 publication qualifies as prior art under § 102(b) regardless of the priority date issue noted above. Pet. 41–42.

[13] PCT International Publication WO 90/07333, published July 12, 1990 (Ex. 1011).

[14] *See* Pet. 50–58.

[15] *See id.* at 57–58.

[16] *See id.*

[17] 3M asserts that Dr. Smyth's testimony should be given little or no weight because Dr. Smyth "had not even finished college" at the time of the invention and thus was not a person of ordinary skill in the art at the relevant time. Prelim. Resp. 31. 3M cites no authority for the proposition that an expert must have been a person of ordinary skill in the art at the time of the invention, and we are not persuaded that Dr. Smyth's age relative to the '413 patent is dispositive of his qualifications. *See* Fed. R. Evidence 702 (stating that an expert witness may be qualified by "knowledge, skill, experience, training, or education").

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