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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HENRIK NILSSON and BERND W. MUELLER

Appeal 2017-003061[1]
Application 14/212,503
Technology Center 1600

Before FRANCISCO C. PRATS, ULRIKE W. JENKS, and JOHN G. NEW, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims to methods of treating multiple sclerosis with dimethylfumarate (DMF). The Examiner provisionally rejected the claims for obviousness-type double patenting.

We have jurisdiction under 35 U.S.C. § 6(b).

We affirm the Examiner's provisional obviousness-type double patenting rejections.

We also enter a new ground of rejection for lack of written description under 35 U.S.C. § 112, first paragraph, pursuant to 37 C.F.R. § 41.50(b).

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[1] Appellants state that the real party in interest in this appeal is Forward Pharma A/S. Appeal Br. 1.

STATEMENT OF THE CASE

The following rejections are before us for review:

(1) Claims 46–50 and 63–66, provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 55–70 of copending Application No. 11/576,871 ("the '871 application") (Ans. 2); and

(2) Claims 51–62 and 67–70, provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 55–70 of the '871 application in view of Joshi '999[2] or Joshi '992[3] (Ans. 3–5).

Claim 46, the only independent claim on appeal, is representative and reads as follows:

> 46. A method of treating a subject in need of treatment for multiple sclerosis comprising orally administering to the subject in need thereof a pharmaceutical composition in unit dosage form consisting essentially of (a) from 120 mg to 240 mg of dimethylfumarate formulated for delayed release, and (b) one or more pharmaceutically acceptable excipients, wherein following the orally administering of the unit dosage form monomethylfumarate appears in the plasma of the subject and the Cmax of the monomethylfumarate in the plasma of the subject is between about 0.4 and about 2 mg/L, and wherein 480 mg of dimethylfumarate per day is orally administered to the subject.

Appeal Br. 5.

DOUBLE PATENTING

The Examiner's Prima Facie Case

The Examiner found that, although rejected claims 46–50 and 63–66, and claims 55–70 of the '871 application, do not recite identical subject

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[2] US 7,320,999 B2 (issued Jan. 22, 2008).
[3] US 6,436,992 B1 (issued Aug. 20, 2002).

matter, the rejected claims are not patentably distinct from the claims of the '871 application "because both instant and the copending application[] claim a method of treating multiple sclerosis by administrating an oral delayed release composition comprising dimethylfumarate in combination with pharmaceutical excipients such that a total daily dose of 480mg dimethylfumarate is administered per day." Ans. 2. The Examiner noted, in particular, that "[b]oth sets of claims recite twice daily administration of administering dimethylfumarate in the form of tablet or capsule." *Id.*

Further, the Examiner reasoned, "[w]hile the copending claims do not recite the claimed plasma levels of monomethylfumarate, the compositions of both sets of claims recite the same amount of the active agent and therefore the claimed plasma levels are inherent to the composition of the claims of 11/576,871." *Id.*

As to claims 51–62 and 67–70, all of which depend directly or ultimately from claim 46, the Examiner cited Joshi '999 and Joshi '992 as evidence that the additional elements recited in those dependent claims would have been obvious variations of the process recited in claim 46. *Id.* at 3–5.

Analysis

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .
>
> After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

In evaluating whether claims under examination should be rejected for obviousness-type double patenting, the Examiner must determine, in an analysis comparable to that under 35 U.S.C. § 103, whether one of ordinary skill would have considered the examined claims obvious in view of the conflicting claims. *See In re Braat*, 937 F.2d 589, 592–93 (Fed. Cir. 1991).

In the present appeal, having carefully considered all of the evidence and arguments presented by Appellants and the Examiner, Appellants do not persuade us that the preponderance of the evidence fails to support the Examiner's conclusion that the invention recited in claims 55–70 of the '871 application would have rendered obvious the invention recited in rejected claims 46–50 and 63–66.

Claims 55–70 of the '871 application, like the claims under rejection herein, recite treating multiple sclerosis by administering 480 mg/day of dimethylfumarate (DMF). *See* '871 application, Response filed January 21, 2014, pp. 3–5.

We acknowledge, as Appellants contend (Appeal Br. 2–3; Reply Br. 2), that representative rejected claim 46 recites a DMF dosage form formulated for delayed release (Appeal Br. 5). Appellants' Specification, however, broadly defines delayed release as simply being release of the active substance at any point in time later than the commercial product Fumaderm®. *See* Spec. 6.

We acknowledge that, in contrast to the rejected claims, claims 55–70 of the '871 application do not expressly recite a delayed release formulation. *See* '871 application, Response filed January 21, 2014, pp. 3–5.

As the Examiner contends, however (*see* Ans. 6–7), a number of the claims of the '871 application recite achieving a daily dosage of 480 mg/day

of DMF in as many as three separately administered dosages. *See id.* at 3–4 (claims 57 and 59), *id.* at 5 (claims 66 and 68 also reciting administration of 480 mg/day DMF spread across three separate doses).

Because the '871 application recites that the daily dosage of 480 mg/day of DMF may be spread across as many as three separately administered dosages, whereas the claims under rejection recite administering the drug in a single daily dosage (*see, e.g.*, Appeal Br. 5 (claim 47)), we discern no error in the Examiner's determination that it would have been obvious in view of the '871 application claims to prepare and administer, a single daily dosage, in a delayed release dosage form as recited in rejected claim 46, in order to achieve the same three-dosage daily profile of the MS treatment regimen as recited in the '871 application claims.

We acknowledge, as Appellants contend (Appeal Br. 3; Reply Br. 2–3), that rejected claim 46 recites that, following oral administration of the unit dosage form, monomethylfumarate appears in the plasma of the patient, and the C_{max} of the monomethylfumarate in the patient's plasma is between about 0.4 and about 2 mg/L (Appeal Br. 5).

Appellants' Specification explains, however, that the claimed C_{max} range is simply the result obtained by oral administration of 120 to 240 mg of DMF, including in a delayed release formulation:

> Apart from the characteristic *in vitro* release patterns described herein, such a prolonged release is reflected in the pharmacokinetic parameters obtained after a clinical study as well. Accordingly, it is contemplated that ***the C_{max} of the monoalkylester of fumaric acid (which appears in the plasma upon hydrolysis or metabolism of the dialkylester administered) is of the same order of magnitude as previously***

> ***described in the literature provided that a similar or equivalent dose is administered (i.e. C_{max} of monomethylfumarate in a range of from about 0.4 to about 2.0 mg/l corresponding to an oral dose of 120 to 240 mg dimethylfumarate).***

Spec. 31 (emphasis added).

Because the broad C_{max} range recited in rejected claim 46 is simply the C_{max} range previously described in the literature as being achieved by oral administration of 120 to 240 mg of DMF, and because a number of claims of the '871 application recite administering 240 mg DMF dosage forms (*see* '871 application, Response filed January 21, 2014, pp. 3–5 (claims 58, 63, 70)), Appellants do not persuade us that the Examiner erred in determining that the C_{max} range recited in rejected claim 46 would have been obvious in view of the claims of the '871 application.

To the contrary, on the current record, the C_{max} limitation in claim 46 is simply a recitation of a result that occurs upon performing the process steps positively recited in the claim. *See Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1172 (Fed. Cir. 1993) ("A 'whereby' clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim."). Moreover, given that the monomethylfumarate C_{max} range recited in claim 46 was the known desirable range previously described in the literature (*see* Spec. 31), Appellants do not persuade us that the Examiner erred in concluding that it would have been obvious to administer DMF in a manner that achieves a plasma concentration of monomethylfumarate encompassed by the range recited in claim 46.

In sum, for the reasons discussed, Appellants do not persuade us that the Examiner erred in determining that the process recited in Appellants'

rejected claim 46 would have been obvious in view of claims 55–70 of the '871 application. We, therefore, affirm the Examiner's provisional rejection of claim 46. Because they were not argued separately, claims 47–50 and 63–66 fall with claim 46. 37 C.F.R. § 41.37(c)(1)(iv).

Other than the arguments discussed above, Appellants do not advance specific argument as to the Examiner's provisional rejection of claims 51–62 and 67–70 over claims 55–70 of the '871 application in view of Joshi '999 or Joshi '992. *See* Appeal Br. 2–4; Reply Br. 2–3. Because Appellants, therefore, do not identify, nor do we discern, error in the Examiner's provisional rejection of claims 51–62 and 67–70, we also affirm the Examiner's provisional rejection of claims 51–62 and 67–70.

NEW GROUND OF REJECTION

Under the provisions of 37 C.F.R. § 41.50(b), we enter the following new ground of rejection:

Claims 46–70 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Claim 46, the sole pending independent claim, recites treating a subject in need of treatment for multiple sclerosis by administering 480 mg of DMF per day. Appeal Br. 5.

Our review of the '871 application, discussed above, to determine the status of the claims forming the basis of the provisional double patenting rejections, uncovered the fact that claims 55–70 of the '871 application had been held by the Board to be unpatentable for failure to meet the written description requirement. *See FWP IP ApS v. Biogen MA, Inc.*, No. 2017-2109, 2018 WL 5292070, at *4 (Fed. Cir. Oct. 24, 2018) ("[T]he

Board concluded that Forward's claims 55–70 failed to meet the written description requirement.").

On appeal, the Federal Circuit agreed with the Board's determination that the specification of the '871 application did not provide adequate descriptive support for treating multiple sclerosis by administering 480 mg/day of DMF. *See id.* at *5 ("For the same reasons set forth by the Board, we agree that the '871 application does not disclose the now-claimed MS treatment as a unified whole."). More specifically, the Federal Circuit stated as follows:

> Given the brief references to MS and the lack of recognition of 480 mg/day as a therapeutically effective daily dosage, we agree with the Board's finding that there is no discussion in the '871 application that would guide one skilled in the art to treat MS with a therapeutically effective dose of 480 mg/day.

Id. at *6 (internal quotations, bracketing, and citation omitted).

The application under consideration herein is a continuation of the '871 application. *See* Application Data Sheet entered March 14, 2014, at p. 4. Therefore, the Specification of application under consideration herein is identical to the specification of the '871 application.

As noted above, claim 46, the sole pending independent claim, recites treating a subject in need of treatment for multiple sclerosis by administering 480 mg of DMF per day. Appeal Br. 5. That is, claim 46 and its dependent claims all recite the same combination of elements held by the Federal Circuit as lacking descriptive support in the specification of the '871 application—treating multiple sclerosis with 480 mg/day of DMF.

Thus, to summarize, the Specification of the application under consideration herein is identical to the specification of the '871 application, and claims 46–70 under consideration herein all require treatment of

multiple sclerosis with 480 mg/day of DMF, the treatment regimen held by the Federal Circuit to be lacking adequate descriptive support under § 112, first paragraph, in the '871 application. Accordingly, for the reasons set forth in the Federal Circuit's decision in *FWP IP ApS v. Biogen MA*, 2018 WL 5292070, claims 46–70 lack adequate descriptive support in the Specification of the application under consideration herein. We, therefore, reject claims 46–70 under 35 U.S.C. § 112, first paragraph, for failure to comply with the written description requirement.

SUMMARY

For the reasons discussed, we affirm both of the Examiner's provisional obviousness-type double patenting rejections and enter a new ground of rejection under 35 U.S.C. § 112, first paragraph, for failure to comply with the written description requirement.

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (2012). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter

> reconsidered by the examiner, in which event the prosecution will be remanded to the examiner. . . .
>
> (2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same record.

AFFIRMED, 37 C.F.R. § 41.50(b)