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Paper 20
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS V LLC,
Petitioner,

v.

BIOGEN INTERNATIONAL GmbH,
Patent Owner.

Case IPR2015-01086
Patent 8,759,393 B2

Before LORA M. GREEN, JACQUELINE WRIGHT BONILLA, and TINA E. HULSE, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

DECISION
Denying Petitioner's Request for Rehearing of Institution Decision
37 C.F.R. § 42.71(d)

I. INTRODUCTION

Coalition for Affordable Drugs V LLC ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–13 of U.S. Patent No. 8,759,393 B2 (Ex. 1001, "the '393 patent") based on two asserted grounds. Paper 1 ("Pet."). Biogen International GmbH ("Patent Owner") filed a Preliminary Response to the Petition. Paper 14 ("Prelim. Resp."). Upon considering the arguments and evidence presented, we denied the Petition. Paper 18 ("Dec." or "Decision").

Petitioner filed a Request for Rehearing of the Decision not to institute trial on both grounds: (1) claims 1, 2, and 8 as anticipated by Nieboer;[1] and (2) claims 1–13 as unpatentable as obvious over Nieboer and Kolter.[2] Paper 19 ("Reh'g Req."), 2–11.

For the following reasons, Petitioner's request is *denied*.

II. ANALYSIS

A party requesting rehearing has the burden to show a decision should be modified by specifically identifying all matters the party believes the Board misapprehended or overlooked, and the place where each matter was addressed previously in a motion, opposition, or a reply. 37 C.F.R. § 42.71(d). When rehearing a decision on institution, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion may be indicated if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if the

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[1] Nieboer et al., *Systemic Therapy with Fumaric Acid Derivates: New Possibilities in the Treatment of Psoriasis*, 20 J. AMER. ACAD. DERM. 601–08 (Apr. 1989) (Ex. 1002).

[2] Kolter et al., US 5,681,588, issued Oct. 28, 1997 (Ex. 1003).

decision represents an unreasonable judgment in weighing relevant factors. *Star Fruits S.N.C. v. U.S.*, 393 F.3d 1277, 1281 (Fed. Cir. 2005); *Arnold P'ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004); *In re Gartside*, 203 F.3d 1305, 1315–16 (Fed. Cir. 2000).

A. Anticipation Grounds

In the Decision, we determined that the term "microtablets" does not encompass granulates, which is a determinative issue for the anticipation ground. Dec. 4–6. Petitioner argues that our construction is not supported by substantial evidence for two reasons.

First, Petitioner disagrees with the Board's alleged "conclusion that 'binder granulate' or 'granulate' is a precursor, and implicitly not also a final preparation (encapsulated) form." Reh'g Req. 3. Petitioner continues, stating "[t]he Board misapprehends or overlooks that substantial evidence of record exists that indicates granulates can be used as both a *precursor* to a microtablet (or some other preparation form) as well *as a final preparation (encapsulated) form* in its own right." *Id.*

Whether granulates can be both a precursor and a final preparation, however, is not the determinative issue. The issue we addressed in the Decision is whether the broadest reasonable interpretation of the term "microtablets" encompasses granulates. We determine that it does not, and Petitioner does not persuade us otherwise.

We do not disagree that Nieboer discloses a medication consisting of capsules filled with enteric-coated granulate of DMFAE. *Id.* (citing Ex. 1002, 2:35–38). Nor do we disagree that the '393 patent discloses "granulates" as preferred oral preparations, along with tablets, microtablets, and pellets. *Id.* (citing Ex. 1001, 4:24–26). But neither of these facts supports a finding that the term "microtablets" encompasses granulates.

Rather, as stated in our Decision, the Specification supports our construction by distinguishing between microtablets and granulates: "Preferably, the active ingredients are used for preparing oral preparations in the form of tablets, micro-tablets, pellets or granulates, optionally in capsules or sachets. *Preparations in the form of micro-tablets or pellets, optionally filled in capsules or sachets are preferred* . . . ." Ex. 1001, 4:24–28 (emphasis added). Thus, whether "granulates" can be a precursor or a final preparation, as Petitioner asserts, is irrelevant to our Decision.

Petitioner also argues that if granulates are not microtablets, then tablets are not microtablets, either. *Id.* at 4–6. Again, Petitioner misses the point. The sole issue is whether the term "microtablets" encompasses granulates, not whether "microtablets" encompass "tablets." Even if it were true that the Board misapprehended or overlooked whether "microtablets" and "tablets" are interchangeable, that does not change our opinion that the Specification and extrinsic evidence support our construction that the broadest reasonable interpretation of "microtablets" does not encompass granulates (as a precursor or a final preparation).

Thus, we are not persuaded that Petitioner has shown that we misapprehended or overlooked any evidence or argument in construing the claim term "microtablets," or in determining whether Petitioner had established a reasonable likelihood that the challenged claims are anticipated by Nieboer.

B. Obviousness Grounds

In our Decision, we found that Petitioner's declarant, Dr. Polli, "does not explain adequately why a person of ordinary skill in the art would have expected the addition of wetting agents, and the resulting increase in the rate of dissolution, to control the rate of release of the DMFAE of Nieboer as it

did for the β-phenylpropiophenone derivates of Kolter." Dec. 10. Petitioner argues that we overlooked or misapprehended Dr. Polli's opinion, citing paragraph 23 of Dr. Polli's declaration. Paragraph 23 states:

> 23. A person of ordinary skill in the art would have also known that an additional way of controlling the release of the active ingredient of a powder-based oral pharmaceutical preparation active ingredient is to vary the amount of wetting agents. Wetting agents help improve water penetration thereby allowing for a faster release of an active ingredient. In particular, a smaller amount of the wetting agent will result in a slower release of the active ingredient in the body. Ex. 1003, 4:25-37.

Ex. 1004 ¶ 23. Petitioner argues that both the DMF of Nieboer and the β-phenylpropiophenone derivatives of Kolter are "active ingredient[s] of a powder-based oral pharmaceutical preparation." Reh'g Req. 7. As such, Petitioner contends that Dr. Polli "explained why controlling the rate of release of powder-based oral pharmaceuticals was an obvious thing for a [person of ordinary skill in the art] to do, and *one* obvious way that could be done with powder-based oral preparation, i.e., wetting agents." *Id.*

As an initial matter, we note that Petitioner did not cite paragraph 23 of Dr. Polli's declaration as support for its argument that Kolter would have solved the problem of gastrointestinal complaints by controlling the release rate of DMFAE. *See* Pet. 29 (citing Ex. 1004 ¶ 50.1). Nor did Dr. Polli refer to paragraph 23—or even refer to the fact that Kolter and Nieboer are powder-based pharmaceutical preparations—in his opinion regarding obviousness that was cited by the Petition. *See* Ex. 1004 ¶ 50.1 (failing to cite ¶ 23).

Regardless, even if we did consider paragraph 23 of Dr. Polli's declaration and the fact that Kolter and Nieboer are both powder-based

formulations, we are not persuaded that we have misapprehended or overlooked any arguments or evidence presented by Petitioner. In our Decision, we noted that dimethyl fumarate is highly soluble in water, whereas propafenone HCl is only slightly soluble in water. Dec. 11 (citing Ex. 1008, 8; Ex. 2014, 12). We then found that Dr. Polli failed to address the different properties of the different active ingredients, and instead offered a conclusory opinion that adding the wetting agents of Kolter to Nieboer would have controlled the drug release rate and solved the gastrointestinal problems observed in Nieboer. *Id.*

Petitioner asserts that Dr. Polli's opinion is not conclusory, given his citation to "Ex. 1003 [Kolter], 4:25–37, following his statements in paragraph 23." Reh'g Req. 8. The cited portion of Kolter, however, does not support Dr. Polli's opinion. Kolter states that wetting agents "increase the rate of dissolution" and that "the rate of release increases in parallel with the rise in the wetting agent concentration." Ex. 1003, 4:25–37. Nieboer, however, states that a possible explanation of the gastrointestinal complaints is the granulate's "comparatively rapid release in the stomach." Ex. 1002, 607. Dr. Polli fails to explain how adding wetting agents, which would *increase* the release rate of the drug, would improve Nieboer's gastrointestinal complaints, which are already caused by rapid release of the drug in the stomach. Thus, without further explanation to the contrary, we are not persuaded that we misapprehended or overlooked any arguments or evidence that would alter our Decision.

Finally, in our Decision, we rejected Dr. Polli's opinion that Kolter's microtablets would have solved the gastrointestinal problems of Nieboer's granulates by ensuring that the dosage amount of active ingredient was distributed throughout the digestive tract. Dec. 11. According to Dr. Polli,

Kolter achieves the desired distribution by "making small size microtablets," noting the disadvantages of larger diameter tablets in the prior art. Ex. 1004 ¶ 50.2. We, however, were not persuaded by Dr. Polli's opinion, as Nieboer does not teach the use of larger diameter tablets. Dec. 11. Rather, Nieboer teaches the use of granulates that are small enough to be filled into capsules. *Id.* (citing Ex. 1002, 603). Accordingly, we found that neither Dr. Polli nor Petitioner explained sufficiently why a person of ordinary skill in the art would have modified the small granulates of Nieboer to form Kolter's microtablets with a reasonable expectation that the dosage amount of DMFAE would have been distributed throughout the digestive tract and thereby alleviate gastrointestinal complaints. *Id.*

Petitioner argues that we misapprehended or overlooked that the problem to be solved is that DMF causes gastrointestinal complaints, and not Nieboer's granulate. Reh'g Req. 9. Petitioner points to Dr. Polli's explanation that "[a] person of ordinary skill in the art would have known that in order to control the release in the body of the active ingredient of an oral pharmaceutical preparation, the preparation would be made smaller in size." *Id.* at 10 (citing Ex. 1004 ¶ 22). Petitioner then concludes that Dr. Polli "persuasively explained why a [person of ordinary skill in the art], faced with the gastrointestinal complaints caused by *Nieboer's* DMF formulation would have a reasonable expectation of success in reducing gastrointestinal complain[t]s by modifiying *Nieboer's* granulates to form microtablets, as taught by *Kolter*." *Id.*

We are not persuaded. Even if, as Dr. Polli asserts, a person of ordinary skill in the art would have known to control the drug release rate by making a pharmaceutical preparation "smaller in size," neither Dr. Polli nor Petitioner explains why a skilled artisan would have modified Nieboer's

granulates—which are already small in size—to form microtablets, as disclosed in Kolter. Accordingly, Petitioner has not offered persuasive evidence that suggests that Kolter's small-sized microtablets would solve the gastrointestinal problems of Nieboer's small-sized granulates. Thus, we are not persuaded that we overlooked or misapprehended any matters related to Petitioner's obviousness arguments.

III. CONCLUSION

We conclude that Petitioner has not established that our Decision misapprehended or overlooked any matters that would require modifying our Decision. 37 C.F.R. § 42.71(d).

IV. ORDER

In consideration of the foregoing, it is hereby ordered that Petitioner's request for rehearing is *denied*.

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