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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte URBAIN ALFONS C. DELAET,
PHILIP ERNA H. HEYNS, EUGEEN MARIA JOZEF JANS,
ROEL JOS M. MERTENS,
and GEERT VAN DER AVOORT[1]

Appeal 2017-008306
Application 14/131,282
Technology Center 1600

Before JOHN G. NEW, TAWEN CHANG, and JOHN E. SCHNEIDER, *Administrative Patent Judges.*

NEW, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies Janssen Sciences Ireland UC, an affiliate of Johnson & Johnson, and Gilead Sciences, Inc., as the real parties-in-interest. App. Br. 1.

SUMMARY

Appellant has filed a Request for Rehearing (hereinafter the "Request") under 37 C.F.R. § 41.52(a)(1) for reconsideration of our Decision of June 20, 2019 (the "Decision"). The Decision affirmed the Examiner's rejection of claims 1–6, 9, and 10.

In the Request, Appellant seeks reconsideration of our Decision affirming the Examiner's rejection of (1) claims 1, 2, 4, 9, and 10 as unpatentable under 35 U.S.C. § 103(a) as being obvious over Koziara et al. (WO 2009/135179 A2, November 5, 2009) ("Koziara"); (2) claims 3 and 5 as unpatentable under 35 U.S.C. § 103(a) as being obvious over the combination of Koziara and Shen (US 2008/0113021 Al, May 15, 2008) ("Shen"); and (3) claim 6 as unpatentable under 35 U.S.C. § 103(a) as being obvious over the combination of Koziara and Allaway et al. (US 2008/0039428 Al, February 14, 2008) ("Allaway").

Specifically, Appellant contends that the Board misapprehended the teaching of Koziara as it relates to the claimed subject matter, arguing that the Board made no findings that any combination of the cited prior art would provide an oral dosage form that includes granulates consisting of darunavir, Hypromellose, and residual water. Request 1–2.

Analysis

Appellant points to the language of claim 1 reciting: "said darunavir granulate consisting of darunavir and/or a pharmaceutically acceptable salt or solvate thereof, Hypromellose and any residual water from the granulation." Request 2. Appellant contends that, although the dosage form recited in the claims may contain ingredients additional to those that the

claims mention, the recited darunavir granulate may not. *Id.* (citing *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1359 (Fed. Cir. 2016) (holding that a claim term set off with "consists of" is closed to unrecited elements)).

Appellant argues, however, that, to the contrary, the Board agreed with the Examiner that Koziara (upon which the Examiner relies) teaches a process for producing a granulate that includes both darunavir and another therapeutic agent, i.e., GS-9350. *Id.* (citing Decision 6–7). Appellant asserts that, because a granulate that includes two active agents cannot reasonably be said to consist of only one of them, the Examiner's proposed combination of the cited publications would not have produced any claimed invention and that the Board consequently misapprehended the teachings of Koziara in this respect. *Id.*

We agree with Appellant that the claim term "consisting" as recited in claim 1 limits the "darunavir granulate" to its recited constituents, i.e., "darunavir and/or a pharmaceutically acceptable salt or solvate thereof, Hypromellose and any residual water from the granulation" and precludes any additional constitutive elements in the darunavir granulate. However, we are nevertheless not persuaded that this limitation is not obvious over Koziara.

As we found in the Decision, Koziara teaches, in one exemplary embodiment, a method of synthesizing a composition containing GS-9350 and a second therapeutic agent (i.e., darunavir) comprising:

> (1) mixing GS-9350 with: "a suitable solvent, and a plurality of solid carrier particles to provide a first mixture;" (2) optionally mixing the first mixture; (3) optionally adding one or more pharmaceutically acceptable excipients (e.g., a filler, a binder

> and a disintegrant) to the mixture to provide a second mixture; (4) optionally adding another therapeutic agent (i.e., darunavir) to the mixture; (5) optionally mixing the second mixture; optionally adding water to the second mixture to provide a wet granulate; (6) optionally de-agglomerating the wet granulate; optionally drying to provide a dried material that comprises solid particles.

Decision 7 (citing Koziara 29–30). Koziara also teaches that it was well known in the art that: "For example microcrystalline cellulose (filler) and croscarmellose sodium (disintegrant) were found to be particularly compatible with the subsequent aqueous granulation process. Hydroxypropyl cellulose [i.e., Hypromellose] (binder) was also found to be particularly compatible with the subsequent granulation process." Koziara 7.

As an initial matter, we observe that the claims are rejected under 35 U.S.C. §103, and not under § 102 as being anticipated by Koziara. The test for obviousness is not whether … the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (C.C.P.A. 1981).

We do not dispute Appellant's contention that the particular exemplary embodiment taught by Koziara teaches mixing the GS-9350 with carrier, excipients, and darunavir prior to adding water to provide a wet granulate which can be optionally dried to solid particles. However, as we pointed out in our Decision, Appellant's claim is to a composition, and not a method of making that composition. *See* Decision 8. Furthermore, as the Examiner noted, Koziara is not limited to its preferred embodiments. *See*

Ans. 5. Finally, we note that Appellant has not argued, either in the Appeal Brief[2] or in the Request, that composing the claimed composition so that the darunavir granulate consists only of the recited constituents imparts any unique or especially advantageous qualities to the oral dosage form.

As we explained in our Decision, Koziara teaches or suggests all of the constituents recited in the claims, and teaches methods that are consistent with making the claimed oral dosage form. We conclude that any method of synthesizing the claimed dosage, based upon the teachings and suggestions of the cited prior art, together with the knowledge of a person of ordinary skill in the art, to rearrange the elements in a predictable fashion and which could reasonably be used to arrive at the claimed composition, would be obvious to a person of ordinary skill in the art. One such method would be to separately granulate the GS-9350 and the darunavir (together with Hypromellose) prior to mixing the constituents. "[W]hen a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)). Or, as our reviewing court has held: "*KSR* affirmed … that § 103 bars patentability unless 'the improvement is more than the predictable use of prior art elements according to their established functions.'" *In re Kubin*, 561 F.3d 1351, 1359–60 (Fed. Cir. 2009) (quoting *KSR*, 550 U.S. at 417).

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[2] Appellant did not file a Reply Brief in this appeal.

Furthermore, "[g]ranting patent protection to advances that would occur in the ordinary course *without real innovation* retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility." *KSR*, 550 U.S. at 419 (emphasis added). As we have stated, Appellant makes no argument, nor adduces any evidence, to suggest that including darunavir granulate, consisting only of the claimed constituents, confers any advantageous or unusual properties upon the claimed oral dosage form. We are consequently not persuaded by Appellant that the Board misapprehended the teachings of the prior art in in concluding that the claimed composition would have been obvious to a skilled artisan.

DECISION

We deny the requested relief with respect to making any changes to the Decision.

DENIED

Claims Rejected	**Basis**	**Granted**	**Denied**
1–6, 9, and 10	Request for Rehearing		1–6, 9, and 10
Overall Outcome			1–6, 9, and 10