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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CATHERINE ROUGEOT

Appeal 2018-007103
Application 14/730,396
Technology Center 1600

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134(a) involving claims to a method for treating pain. Appellant[1] appeals the Examiner's rejection of claims 17–29 for obviousness-type double patenting is appealed.[2] We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

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[1] "Appellant" herein refers to the "applicant" as defined by 37 C.F.R. § 1.42. Appellant identifies itself, "Institut Pasteur," as the real party-in-interest. Appeal Br. 3.

[2] Oral argument was heard on September 24, 2019; a transcript of the hearing will be made a part of the record in due course.

STATEMENT OF THE CASE

The Specification states that "[t]he present invention relates to peptides derived from human BPLP (Basic Proline-rich Lacrimal Protein) protein coded by the *Prol1* gene, notably opiorphin, for use as psychostimulanting [*sic*] agents. The invention also relates to the use of such peptides for preparing a psychostimulant drug." Spec. 1:3–6. The Specification further explains, "[p]sychostimulant agents are psychotropic substances considered as psychic stimulants, which accelerate the activity of the nervous system and stimulate the motivation and well-being." *Id.* at 1:7–9. The Specification further explains, "[p]sychostimulants act by stimulating neurotransmission. They are used for treat[ing] various symptoms including vigilance drop, narcolepsy, obesity, attention deficit and/or hyperactivity in children, obsessive-compulsive disorders (OCD), depression, mania and bipolar disease." *Id.* at 1:14–17. To summarize the inventor's discovery and the invention's point of novelty, the Specification states:

> The inventors have [*sic* inventor has] found that, surprisingly, opiorphin not only has analgesic properties, but also a psychostimulant effect. Further, this psychostimulant effect is not associated with any adverse effect of the amnesia, sedation, hyperactivity or addiction type. Finally, it was found that the analgesic potency of opiorphin is as powerful as that of morphine and that its psychostimulant potency is as powerful as that of imipramine.
>
> Therefore, opiorphin and derived peptides may advantageously be used as psychostimulants for treating or preventing diseases such as narcolepsy, hypersomnia, vigilance drop, attention deficit in adults and in children, hyperactivity in adults and in children, attention-deficit/hyperactivity disorder (ADHD), obsessive-compulsive disorders (OCD), and mood

> disorders such as depression, bipolar disease, dysthymic disorder and cyclothymic disorder.

Id. at 3:4–15; *see also id.* at 14:1–2 ("the invention relates to peptides according to the invention, described in the above paragraph, for a use as psychostimulants."), *id*. at 15:31–16:3 (defining "psychostimluant agent"), *id.* at 17–18 (describing effective doses for psychostimulation). The Specification also discloses the use of opiorphin as an analgesic and discloses examples relating to testing rats' pain responses after administration of opiorphin. *Id.* at 21–37.

Independent claim 17, which is representative, states:

> 17. A method for treating pain comprising administering a dose of 10-300 mg/day of a peptide consisting of the sequence Gln-Arg-Phe-Ser-Arg (SEQ ID NO:2) or Glp-Arg-Phe-Ser-Arg (SEQ ID NO:55) for 7 days.

Appeal Br. 19 (Claims Appendix).

The following rejection is on appeal:

Claims 17–29 stand rejected on the ground of obviousness-type double patenting over claims 1, 3, 5, 6, 8, 10, 11, and 14 of U.S. Patent 9,403,871 B2 (issued Aug. 2, 2016) ("the '871 patent"). Final Action 3; Answer 4.

DISCUSSION

"[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. [Once] . . . that burden is met, the burden of coming forward with evidence or argument shifts to the applicant." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Arguments made by Appellants in the Appeal Brief and properly presented in the Reply Brief have been considered; arguments not

so-presented are waived. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2017); *see also Ex parte Borden*, 93 USPQ2d 1473, 1474 (BPAI 2010) (informative) ("Any bases for asserting error, whether factual or legal, that are not raised in the principal brief are waived.").

"[T]he law of obviousness-type double patenting looks to the law of obviousness generally. As . . . explained in *Amgen*, '[t]his part of the obviousness-type double patenting analysis is analogous to an obviousness analysis under 35 U.S.C. § 103.'" *AbbVie Inc. v. The Mathilda and Terrence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1378 (Fed. Cir. 2014); *see also In re Braithwaite*, 379 F.2d 594, 600 n.4 (CCPA 1967) (A nonstatutory double patenting rejection is "analogous to the nonobviousness requirement of 35 U.S.C. 103," except that only the claims of, not the disclosure of, the reference patent underlying the double patenting rejection is considered prior art).

Even though the specification of the applied patent or co-pending application is not technically considered to be prior art for obviousness-type double patenting, it may still be used to interpret the applied claims. As held in *Sun Pharmaceutical Industries Ltd. v. Eli Lilly and Co.*, 611 F.3d 1381, 1387 (Fed. Cir. 2010):

> In *Geneva* [*Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003)], we acknowledged the general rule that an earlier patent's specification is not available to show obviousness-type double patenting. 349 F.3d at 1385. We have held, however, that there are "certain instances" where the specification of an earlier patent may be used in the obviousness-type double patenting analysis. *In re Basell* [*Poliolefine Italia S.P.A.*, 547 F.3d 1371, 1378 (Fed. Cir. 2008).] Specifically, the specification's disclosure may be used to determine whether a

> claim "merely define[s] an obvious variation of what is earlier disclosed and claimed," "to learn the meaning of [claim] terms," and to "interpret [ ] the coverage of [a] claim." *Id.* As we recognized in *Geneva*, a court considering a claim to a compound must examine the patent's specification to ascertain the coverage of the claim, because a claim to a compound "[s]tanding alone . . . does not adequately disclose the patentable bounds of the invention." 349 F.3d at 1385. In examining the specification of the earlier patent, the court must consider "the compound's disclosed utility." *Id.*

With these standards in mind, we address the Examiner's rejection and Appellant's arguments there-over.

The Examiner determined claims 17–29, although not identical to, are obvious in view claims 1, 3, 5, 6, 8, 10, 11 and 14 of the '871 patent. Final Action 3; Answer 4. The Examiner determined that the '871 patent's claims are directed to treating pain by administering the same peptides as the appealed claims, at a dosage range overlapping the claimed dosage range. Answer 5. Regarding the '871 claim term "pain," the Examiner determined the scope of this term included acute or chronic pain. *Id.* (citing '871 patent 18:45). Regarding the '871 claim term "administering," the Examiner determined that the scope of this term included, *inter alia*, intravenous administration. *Id.* (citing '871 patent 16:58–60).

The Examiner identified the differences between the appealed claims and those of the '871 patent as follows:

> the difference between the scope of the instant claims and the claims for which patent protection has already been granted is as follows: the patented claims (1) do not recite dose of 10-300 mg/day, (2) do not recite any duration of the treatment, such as specifically 7 days; and (3) do not recite intravenous administration.

Id. Regarding the claimed 7-day treatment duration, the Examiner determined that, because the claimed *treating pain* included within its scope treating chronic pain, it would be obvious, as reasonably expected, to continue to treat chronic pain until the pain is alleviated, making treating for a week obvious. Regarding the claimed daily dose of 10–300 mg/day, the Examiner determined "[i]t is reasonable to interpret that treatment 'administering a dose of 10-100 mg of the peptide' occurs at intervals necessary to alleviate pain, starting with daily administration." *Id.* at 6.

We discern no error in the Examiner's determinations and adopt the Examiner's findings of fact and rationale regarding obviousness-type double patenting. We address Appellant's arguments below.

Appellant argues "[t]he Examiner does not point to any evidence to support her conclusions regarding motivation, and does not address expectation of success at all." Appeal Br. 8. Appellant further argues,

> The Examiner does not point to anything in U.S. Patent No. 9,403,871 that discloses the particular dosing regimen claimed by Appellant. In addition, the Examiner provides no evidence supporting her conclusions and does not identify any reason that would have led the skilled artisan to modify the patented method to make the claimed method with a reasonable expectation of success.

Id. at 11. Appellant makes several other points along this same line of reasoning.[3] We do not find Appellant's arguments persuasive.

As a starting point, the claims of the '871 patent are directed to "[a] method for treating pain," which comprises "administering an effective

[3] Appellant does not brief any arguments concerning secondary indicia of non-obviousness, e.g., unexpected results, in the Appeal Brief. *See generally* Appeal Br. and Reply Br.

amount of" the peptide "Glu-Arg-Phe-Ser-Arg," which is the same peptide sequence expressly recited in the appealed claims and corresponding to SEQ ID NO:2. '871 patent 41:26–40. The '871 patent also claims (*see*, *e.g.*, claim 8) that this peptide is administered at a dose of 10–100 mg, again, for the purpose of *treating pain*, also as recited by appealed claim 1. *Id.* at 42:30–31.

As noted above, when analyzing the patentability of claims under the doctrine of obviousness-type double patenting, the reference patent's specification may be examined and considered to ascertain the meaning and scope of claim language and when analyzing whether a claim in the application defines an obvious variation of an invention claimed in the reference patent. *Sun Pharmaceutical*, 611 F.3d at 1387. As did the Examiner, we consult the '871 patent's disclosure, not as prior art, but for these purposes.

In determining what the '871 patent's claim term "pain" includes within its scope, we find, as did the Examiner, that it includes at least "acute pain" and "chronic inflammatory pain such as arthritis or inflammatory bowel disease." '871 patent 18:15–17; *see also* Answer 5. In determining what the '871 patent's claim term "effective amount of an isolated peptide" includes within its scope, we find, as did the Examiner, that it includes a therapeutic mixture including about 0.0001 to 100 milligrams of the peptide, or, most preferably, 10–100 milligrams per dose, and that "[m]ultiple doses can also be administered." '871 patent 16:49–57; *see also* Answer 5. For example, claim 8 of the patent, as pointed out above, expressly claims "a dose of 10-100 mg of the peptide." In determining what the '871 patent's

claim term "administering" includes within its scope, we find, as did the Examiner, that it includes "topical, oral, sublingual, parenteral, intranasal, intravenous, intramuscular, subcutaneous, transcutaneous or intraocular administration and the like." '871 patent 14:67–15:2; *see also* Answer 5.

In determining whether a treatment period of 7 days, as claimed, would be an obvious variant of the method claimed in the '871 patent, we consider, as did the Examiner, that the type of pain disclosed and claimed as being treated in the '871 patent includes chronic pain, which by its very persisting or reoccurring nature may last several days. Thus, based on the claims of the '871 patent, which encompass treating chronic pain, one of ordinary skill in the art would have found it obvious to treat such pain for 7 days (and more) because of its persistent nature. *See* Answer 5 ("It would have been further obvious for one of ordinary skill in the art to treat chronic pain by the methods of claims 1, 3, 5, 6, 8, 10, 11 and 14 of the ['']871 patent, which would require treatment for several days, as needed, including 7 days where appropriate."). Such a conclusion is reasonable because, as determined by the Examiner, "[i]t is reasonable to interpret that treatment 'administering a dose of 10-l00 mg of the peptide' occurs at intervals necessary to alleviate pain, starting with daily administration" and if pain persists, chronically, to a second day, treatment should likewise extend to the second day, and so on to the claimed 7 days (or beyond). *See* Answer 6.

As noted above, we agree with and adopt the Examiner's findings of fact and rationale regarding the obviousness of the claims. We discern no error in the Examiner's determinations, which we conclude, after

considering Appellant's arguments in their entirety, establish that the rejected claims are obvious over those of the '871 patent.

CONCLUSION

In summary, the obviousness-type double patenting rejection of claims 17–29 is affirmed.

Claims Rejected	Basis	Affirmed	Reversed
17–29	obviousness-type double patenting US 9,403,871 B2	17–29	

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED