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JOSEPH F. SHIRTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
CHONG, YONG SOO	

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte LIEVEN ELVIRE COLETTE BAERT, GUENTER KRAUS, and GERBEN ALBERT ELEUTHERIUS VAN 'T KLOOSTER

Appeal 2019-006010
Application 12/161,445
Technology Center 1600

Before DONALD E. ADAMS, ERIC B. GRIMES, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from Examiner's decision to reject claims 10, 17–25, and 28–30 (*see* Appeal Br. 2; *see also* Final Act. 2). We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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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 the real party in interest as "Janssen Sciences Ireland UC, an affiliate of Johnson & Johnson." (Appellant's April 3, 2019 Appeal Brief (Appeal Br.) 1).

STATEMENT OF THE CASE

Appellant's disclosure "relates to the long term treatment of HIV infection by intermittently administering a parenteral formulation comprising the . . . [non-nucleoside reverse transcriptase inhibitor (NNRTI) 4-[[4-[[4-(2-cyanoethenyl)-2,6-dimethylphenyl]-amino]-2-pyrimidinyl]-amino]-benzonitrile, also referred to as] TMC278 at relatively long time intervals" (Spec. 1: 5–7, 35–37). Appellant's claim 10 is reproduced below:

> 10. A method of treating HIV in a subject comprising administering to the subject a solution comprising
>
> an amount of 4-[[4-[[4-(2-cyanoethenyl)-2,6-dimethylphenyl]amino]-2-pyrimidinyl]amino]benzonitrile (TMC278) or a pharmaceutically acceptable acid addition salt thereof, and a carrier,
>
> wherein the solution is administered intermittently by subcutaneous or intramuscular administration at a time interval that is once every one month or once every four weeks,
>
> and
>
> wherein the amount of TMC278, or the pharmaceutically acceptable acid-addition salt thereof, is effective in keeping a minimum blood plasma level of TMC278 in the subject during the time interval.

(Appeal Br. 12.)

Claims 10, 17–25, and 28–30 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Buelow[2] and Susman.[3]

[2] Buelow et al., US 2004/0127422 A1, published July 1, 2004.
[3] Edward Susman, *Retroviruses and Opportunistic Infections – 12th Conference*, 8 IDrugs 299–302 (2005).

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

FACTUAL FINDINGS (FF)

FF 1. Buelow "relates to pharmaceutical preparations and methods for treating HIV and AIDS, and in particular, to novel combinations of immunomodulatory peptides and anti-retroviral agents" (Buelow ¶ 2; *see* Ans. 4).

FF 2. Buelow discloses that its anti-retroviral agent may be a "non-nucleoside reverse transcriptase inhibitor [(NNRTI)] selected from the group consisting of Nevirapine, Dlavirdine, and Efavirenz" (Buelow ¶ 16; *see* Ans. 4).

FF 3. Buelow discloses that its pharmaceutical preparations, i.e., compositions, comprise a pharmaceutically acceptable carrier and "may be formulated as[, *inter alia*,] solutions" (Buelow ¶ 108; *see* Ans. 4 (citing Buelow ¶¶ 64, 100, 108, 110)).

FF 4. Buelow discloses that its pharmaceutical preparation may be administered "in a variety of ways, including," subcutaneously and intramuscularly (Buelow ¶ 130; *see* Ans. 4–5).

FF 5. Buelow discloses subcutaneous and intramuscular administration is preferably carried out with peptides and anti-retroviral agents dissolved or suspended in suitable aqueous medium" (Buelow ¶ 133; *see also id.* ¶ 130 (Buelow exemplifies the use of "microparticle, microsphere, and microencapsulate formulations . . . for oral, intramuscular, or subcutaneous administrations"); *see* Ans. 4–5, 7).

FF 6. Buelow discloses the use of delivery systems to administer

> a pharmaceutically therapeutic amount of subject compounds for more than a day, preferably more than a week, and most preferabl[y] at least about 30 days to 60 days, or longer[, wherein,] [l]ong term release systems may comprise implantable solids or gels containing the subject peptide, such as biodegradable polymers . . .; pumps, including peristaltic pumps and fluorocarbon propellant pumps; osmotic and mini-osmotic pumps; and the like.

(Buelow ¶ 134; *see* Ans. 5.)

FF 7. Examiner finds that Buelow "fails to disclose the specific NNRTI, TMC278 (also known as rilpivirine)" (Ans. 5).

FF 8. Susman discloses that rilpivirine has "a half-life of 38 [hours]" (Susman 300; *see* Ans. 5).

FF 9. Susman observed a "decline in viral load with rilpivirine [that] was statistically significant at all doses (25, 50, 100 and 150 mg/day; $p < 0.001$)" during "a proof-of-principle 7-day clinical trial" (Susman 300; *see* Ans. 5).

ANALYSIS

Based on the combination of Buelow and Susman, Examiner concludes that, at the time Appellant's invention was made, it would have been prima facie obvious to use Susman's NNRTI, TMC278, as the NNRTI in Buelow's pharmaceutical preparations for the treatment of a patient with HIV (Ans. 5). According to Examiner, a

> person of ordinary skill in the art would have been motivated to substitute TMC278 for [Buelow's NNRTI] because of the functional equivalency of . . . NNRTIs . . . . Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating a subject with HIV by administering a composition comprising the NNRTI, TMC278.

(*Id.* at 5–6.) We are not persuaded that Examiner has established prima facie obviousness for the claimed invention.

As Appellant explains, Susman discloses "that the half-life of TMC278 is only about 38 hours (about 1.5 days)" and Buelow "discloses that pumps or biodegradable solids or gels are needed to achieve extended periods of sustained therapeutic blood plasma levels of anti-HIV agents" (Appeal Br. 10; *see* FF 6 and 8). Thus, Appellant contends that "[e]ven if those of ordinary skill in the art would have prepared a TMC278-containing solution for subcutaneous or intramuscular injection, they would not have predicted that a single injection would provide for therapeutically effective plasma levels of TMC278 for at least 4 weeks" (Appeal Br. 9; *see also* Reply Br. 3 (Appellant contends that "the record indicates that those of ordinary skill in the art would not have been able to predict whether or not an injected TMC278 solution would have exhibited the requisite[, i.e. Appellant's claimed pharmacokinetic,] profile")). We agree.

As Appellant further explains, "there is no art of record that would even have been relevant to a person seeking to convert a once-daily, oral treatment regimen to a once-monthly protocol" (Reply Br. 3). To the extent that Examiner would contend that those of ordinary skill in this art would administer the composition suggested by the combination of Buelow and Susman with the aid of a pump, Examiner failed to identify a reasonable expectation of success that TMC278, with its known short half-life, could be formulated for administration once every one month or once every four weeks as required by Appellant's claimed invention.

CONCLUSION

The preponderance of evidence relied upon by Examiner fails to support a conclusion of obviousness. The rejection of claims 10, 17–25, and 28–30 under 35 U.S.C. § 103(a) as unpatentable over the combination of Buelow and Susman is reversed.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
10, 17–25, 28–30	103	Buelow, Susman		10, 17–25, 28–30

REVERSED