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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte WILLIAM E. FAHL

Appeal 2020-001355
Application 15/146,020
Technology Center 1600

Before ULRIKE W. JENKS, AMEE A. SHAH, and
RACHEL H. TOWNSEND, *Administrative Patent Judges*.

SHAH, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), the Appellant[1] appeals from the Examiner's decision to reject claims 1, 4–15, 17, 18, and 20–23, which are all of the pending claims. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. The Appellant identifies the real party in interest as the Wisconsin Alumni Research Foundation. Appeal Br. 2.

CLAIMED SUBJECT MATTER

According to the Specification, "[r]adiotherapy-induced dermatitis is a common side effect seen in up to 85% of patients who receive a course of radiotherapy as part of their cancer therapy regimen." Spec. 1. "A topically administered radioprotector that could be applied prior to radiotherapy on each of the 30 irradiation days would reduce pain and long term scarring and would improve patient compliance in receiving all days of treatment." *Id.* "There is also a need for new systemically administered radioprotectors that lack the side effects of nausea/vomiting and hypotension/fainting that have hampered the use of current generation aminothiol radioprotectors, most notably the five carbon aminothiophosphonate, amifostine." *Id.* The Specification

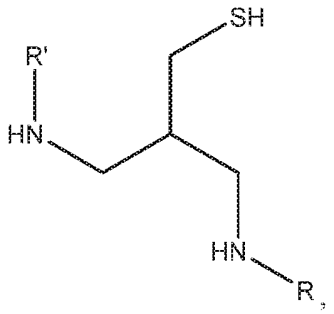
> disclose[s] a process in which: (i) the number of alkylamine segments in the aminothiol backbone is systematically increased to increase drug-DNA affinity and ionic interaction, resulting in increased growth inhibition that is associated with this enhanced drug-DNA interaction, and (ii) the placement or 'display' of a free thiol reactive oxygen species (ROS) scavenger at the end of a short alkyl side chain that displaces or 'displays' the scavenger moiety away from the DNA backbone to theoretically enable ROS scavenging before ROS attack on dG bases within cellular DNA. This work has resulted in a small family of new aminothiol molecules, the prototype of which, PrC-210, . . . described in initial detail here.

Id. at 2.

Claims 1, 15, and 18 are the independent claims. Claim 1 is illustrative of the subject matter on appeal and is reproduced below (with added paragraphing and bracketing for reference):

> 1. A method for protecting a subject from ionizing radiation, the method comprising:

> [a)] administering systemically to the subject a radioprotector compound comprising a free thiol and a positively-charged backbone,
>
> wherein the radioprotector compound comprises a structure according to:



> wherein R and R' are independently selected from H and CH_3,
>
> [b)] wherein systemic administration of the radioprotector compound to the subject protects the subject from ionizing radiation.

REJECTION(S)

Claims 1, 4–15, 17, 18, and 20–23 stand rejected under pre-AIA 35 U.S.C. §§ 102(b)/103(a) as anticipated by, or in the alternate, as obvious over Fahl et al. (US 7,314,959 B2, iss. Jan. 1, 2008) ("Fahl").

OPINION

The Appellant contends that the Examiner's rejection of independent claim 1 is in error because Fahl does not disclose or render obvious "systemically administering certain radioprotector compounds," as recited in limitation a) of claim 1 and similarly recited in limitation a) of independent claim 15 and limitation b) of independent claim 18. Appeal Br. 4.

Conversely, the Examiner finds that Fahl's oral administration meets the claimed systemic administration. *See* Non-Final Act. 6; Ans. 12. After careful review of the record before us, we are not persuaded of Examiner error.

The Appellant contends that the plain and ordinary meaning of "systemic administration" is "a route of administration into the circulatory system so that the entire body is affected. The definition contrasts this with topical administration, in which the effect is generally local." Appeal Br. 15–16. The Examiner does not disagree. *See id.* (quoting Advisory Action 5 (mailed Aug. 15, 2018) ("The Examiner acknowledges that Wikipedia teaches systemic administration is a route of administration into the circulatory system so that the entire body is affected and contrasts this with topical administration, in which the effect is generally local.")). Rather, the issue is whether Fahl's disclosure of oral administration is a systemic administration as claimed. *See* Appeal Br. 7–18; Ans. 15–18, 20–21, 24–25, 29–30, 32, 35–37.

The Examiner finds that Fahl discloses an embodiment whereby "the compositions are formulated for oral administration to reduce or prevent gastrointestinal distress that results from cancer therapy." Non-Final Act. 6 (citing Fahl, col. 10, ll. 25–27); *see also id.* at 11; Ans. 5, 15–16. Specifically, the Examiner finds that Fahl discloses oral administration of the composition and "teaches the patient would be instructed to consume a 'shake' containing the chemoprotective amine in an orally acceptable solution or liposome emulsion before breakfast in the morning, in the 1-5 days preceding chemotherapy." Ans. 11 (citing Fahl, col. 10, ll. 25–31, col. 53, ll. 9–15); Non-Final Act. 11. The Examiner notes that "[i]t [is] well

understood in the art that oral administration is a type of systemic administration" (Non-Final Act. 6), and cites to Verma et al. *(Int. J Pharmaceutical Studies and Research,* 2010; 1(1):54-59) (*id.* at 17) as supporting evidence. The Examiner also notes that the Appellant's Specification includes oral administration such that "it appears clear that what [the Appellant] means by 'systemically' includes oral administration." Non-Final Act. at 6. The Examiner further finds that "Fahl teaches 1%-15% of a drug in most topical formulations is systemically bioavailable." Ans. 12 (citing Spec. "Example 3, page 2"; Fahl, col 45, ll. 37–40); Non-Final Act. 11.

The Examiner's findings are supported. Although Fahl is certainly focused on topical or local administration, Fahl discloses oral administration of a compound "for reducing or preventing toxic side effects of radiotherapy or chemotherapeutic agents" in the gastrointestinal tract. *See* Fahl, col. 1, ll. 20–22, col. 10, ll. 24–28. The pharmaceutical preparation of such a compound is preferably "formulated as a liquid for coating the surface of the gastrointestinal tract." *Id.* at col. 7, ll. 18–23. Delivery vehicles suitable for this compound include, for example, oils encapsulated into standard gel tablets and emulsions (*id.* at col. 49, ll. 34–42) that are delivered by mouth such as by instructing the patient "to consume a 'shake' containing the chemo-protective amine in an orally acceptable solution or liposome emulsion before breakfast in the morning, in the 1–5 days preceding chemotherapy" (*id.* at col. 53, ll. 6–16). Although Fahl states that "[t]he goal of such delivery systems is to contact these internal surfaces topically with the chemoprotective amine" and "[t]opical delivery is not an efficient means for systemic drug delivery," Fahl acknowledges that "between

1%-15% of a drug in most topical formulations is systemically bioavailable." *Id.* at col. 45, ll. 29–40. And although Fahl intends to minimize such biovailability by aiming for "less than 10%, preferably less than 5% and most preferably less than 1% of the chemoprotective amine, provided topically e.g., dermal, intradermal, mucosal or GI epithelial delivery, move to reach the dermis and/or other underlying tissues," it is not altogether avoided. *Id.* at col. 45, ll. 40–45.

We are not persuaded of error by the Appellant's arguments that Fahl "teaches against administering the aminothiols systematically [sic]." Appeal Br. 4; *see also id.* at 5–7. We do not disagree that Fahl discusses the serious side effects as a reason to avoid systemic administration of polyamine analogs (*see* Fahl, col. 1, ll. 51–53, col. 45, ll. 4–9), and teaches that topical administration is the focus of Fahl.

However, Fahl acknowledges that the serious side effects would not occur with low enough systemic delivery (*see id.* at col. 1, ll. 53–60), and Fahl also specifically teaches oral administration (Fahl, col. 53, ll. 5–18). Fahl recognizes that with the oral administration, there is some systemic bioavailability of its formulations (*see id.* at col. 45, ll. 29–45). *See also* Ans. 11. The Appellant does not direct attention to, and we do not see, where Fahl discusses how systemic administration is altogether avoided with the oral intake of a shake or tablet, despite the fact that "[t]he goal of such delivery systems is to contact these internal surfaces[, such as mucosal cells of the gastrointestinal tract], topically with the chemoprotective amine" (Fahl, col. 45, ll. 29–31).

We note that the claims do not require a specific therapeutic amount or a minimum threshold amount that must be systemically administered, just

that radioprotection is provided. The Appellant's Specification discusses topical administration, states a need for systemic administration, and discusses a study regarding topical administration of PrC-210 aminothiol on rats. *See* Spec. 1, ll. 17–27; 4, ll. 17–29. There are no further details on what amount of compound must be systemically bioavailable to be considered systemic administration and provide radioprotection.

Fahl teaches that the oral administration, such as by drinking a shake 1–5 days prior to chemotherapy, which administration would provide for systemic absorption of the drug through the gastrointestinal tract, "would allow the chemoprotective amine to be present when the chemotherapy drugs or radiotherapy act on the GI mucosal epithelium." Fahl, col. 53, ll. 12–18. Thus, we conclude that Fahl teaches the required radioprotection by systemic administration.

We are also not persuaded of error by the Appellant's arguments that Fahl's oral administration is not a form of systemic administration. *See* Appeal Br. 8–17. The Examiner provides evidence that "it is well understood in the art that oral administration wherein a drug is placed in the mouth and swallowed is a known systemic route of administration." Ans., *e.g.*, 16. And, as discussed above, Fahl specifically acknowledges there would be some systemic administration as some of the compound would be absorbed systemically. The Appellant does not provide adequate support or reasoning to explain how Fahl's ingested shake would be processed in the gastrointestinal system in an unconventional manner so as not to be absorbed through the gastrointestinal tract into the circulatory system to some

extent."[2] As also discussed above, the claims do not require a certain amount of "systemic efficacy" (Appeal Br. 16), nor is any such amount discussed in the Specification.

Thus, we are not persuaded of error in the Examiner's rejection under 35 U.S.C. § 102(b) of independents claims 1, 15, and 18. Therefore, we sustain the Examiner's rejection of independent claims 1, 15, and 18 and dependent claims 4–14, 17, and 20–23 under 35 U.S.C. § 102(b) as anticipated by Fahl. Because we sustain this rejection, we do not reach the alternate rejection of the claims under 35 U.S.C. § 103(a).

CONCLUSION

The Examiner's decision to reject claims 1, 4–15, 17, 18, and 20–23 under 35 U.S.C. §§ 102(b)/103(a) is sustained.

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/ Basis	Affirmed	Reversed
1, 4–15, 17, 18, 20–23	102(b)/103(a)	Fahl	1, 4–15, 17, 18, 20–23	

[2] Although the Declarations referred to by the Appellant "confirm that the oral administration in Fahl et al is taught as a form of local or topical administration rather than a form of systemic administration" (Appeal Br. 9), none explains how the drug would be completely prevented from being absorbed through the gastrointestinal tract into the circulatory system.

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

AFFIRMED