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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SIVA RAMA KRISHNA NUTALAPATI[1]

Appeal 2018-004192
Application 13/518,038
Technology Center 1600

Before RYAN H. FLAX, RACHEL H. TOWNSEND,
and CYNTHIA M. HARDMAN, *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 functionally coated multilayer tablet for oral administration and a method of formulating the same. The Examiner's rejection of claims 1, 3–5, 7, 8, and 10 under 35 U.S.C. § 103(a) is appealed. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

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[1] The Real Party in Interest is identified as "AptaPharma, Inc." Appeal Br. 1.

STATEMENT OF THE CASE

The Specification states:

> The present invention relates to multilayer functionally coated tablets for oral administration of one or more active pharmaceutical ingredients (API). The multilayer functionally coated tablets contain one or more quick release API containing layers and one or more modified release API containing layers separated by an inert layer. Methods for formulation and use of these tablets are also provided.

Spec. 1:8–15. The Specification describes the quick release API-containing layer or layers as providing "a dissolution profile relatively faster than the modified release layer. In one embodiment, the dissolution profile of the quick release layer ranges from 0 to 120 minutes." *Id.* at 6:29–32. The Specification further describes the modified release API-containing layer or layers as providing "a dissolution profile which is extended, delayed or controlled as compared to the *in vitro* dissolution of the quick release layer. In one embodiment, the modified release layer has a release profile of 4 hours or greater," although it could be shorter than 4 hours. *Id.* at 7:13–24.

Independent claim 1, reproduced below, is representative:

> 1. A functionally coated multilayer tablet for oral administration comprising:
>
> (a) a core tablet comprising
>
> (i) a quick release layer or layers comprising one or more active pharmaceutical ingredients (APIs);
>
> (ii) a modified release layer or layers comprising one or more APIs and a release retarding excipient; and
>
> (iii) an inert layer separating said quick release layer or layers and said modified release layer or layers, wherein said inert layer is insoluble and impermeable;

> (b) a functional coating or film surrounding the core tablet, wherein said coating or film comprises a pore-forming agent which permits quick release of the API from the quick release layer regardless of the functional coating or film being present while providing release of the API from the modified release layer controlled by [ ] the release retarding excipient, inert layer and functional coating or film.

Appeal Br. 14 (Claims Appendix). Independent claim 8 is directed to a method of producing a tablet as defined by claim 1. *Id.* at 15.

The following rejection is on appeal:

Claims 1, 3–5, 7, 8, and 10 stand rejected under 35 U.S.C. § 103(a) over Seroff[2] and Dharmadhikari.[3] Final Action 2.

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. [Only once] that burden is met, [does] the burden of coming forward with evidence or argument shift[] to the applicant." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). "[O]bviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

The Examiner determined the claims would have been obvious over Seroff and Dharmadhikari. Final Action 2–3; *see also* Answer 5–7. The Examiner points to Seroff's Figure 3 as illustrating a tablet as claimed and determined the figure shows the claimed quick release layer as feature 16, the claimed modified release layer as feature 17, the claimed inert layer as

[2] US 6,387,403 B1 (issued May 14, 2002) ("Seroff").
[3] US 8,470,367 B2 (issued June 25, 2013) ("Dharmadhikari").

feature 18, and the claimed coating as feature 19. Final Action 2–3 (citing Seroff columns 12 and 13). In response to Appellant's argument that Seroff states layer 17 "does not contain drug," the Examiner asserted that Seroff's disclosed layer 17 is a drug layer because Seroff says as much at column 13, which the Examiner determined refers to "a lesser preferred embodiment[]." Answer 5.

Appellant presents several arguments, the first of which is that the prior art combination does not teach or suggest the claimed modified release API layer because Seroff's layer 17, identified by the Examiner as this claim element, is not a drug-containing layer, but is a push layer that facilitates drug release by swelling adjacent to Seroff's drug-containing layer 16. Appeal Br. 5. We find this argument persuasive.

Reading Seroff in its entirety, it is apparent that the portions of column 13 cited by the Examiner to support his determination that Seroff's layer 17 is a drug-containing modified release layer are errors within the reference. The Examiner is correct that Seroff's column 13 states twice, "drug layer 17." *See* Seroff 13:33 and 13:45–46. However, within the context of Seroff's disclosure as a whole, it is apparent that a person of ordinary skill in the art would have understood Seroff intends to discuss layer 16 at these portions, and we conclude that the identification of layer "17" instead is an apparent typographical error. *See In re Yale*, 434 F.2d 666, 668–69 (Fed. Cir. 1970) (when a prior art reference's typographical error, e.g., as exemplified by internal inconsistencies in the reference, would lead the skilled artisan to disregard the related disclosure, reliance on that

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