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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* GEOFFREY C. GURTNER, MICHAEL T. LONGAKER, and  
VICTOR W. WONG<sup>1</sup>

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Appeal 2015-006004  
Application 13/706,186  
Technology Center 1600

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Before ERIC B. GRIMES, JOHN E. SCHNEIDER, and  
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a method for reducing scarring which have been rejected for failing to comply with the written description requirement, as anticipated, and as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

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<sup>1</sup> Appellants identify the Real Party in Interest as the Board of Trustees, Leland Stanford Junior University. Br. 1.

### STATEMENT OF THE CASE

The present invention is directed to a method for reducing the formation of scars at a wound site comprising administering an effective amount of an inhibitor of focal adhesion kinase (“FAK”). Spec. ¶ 13. The FAK inhibitor is administered at the wound site for a period of time sufficient to reduce scarring. *Id.*

Claims 1, 3–16, and 18–24 are on appeal. Claim 1 is illustrative and reads as follows:

1. A method of reducing scarring during healing of a skin wound, comprising: administering to a subject with a skin wound a pharmaceutical formulation comprising an effective dose of an inhibitor that specifically inhibits focal adhesion kinase (FAK), for a period of time sufficient to reduce scarring as compared to a healed wound of an untreated subject.

The claims stand rejected as follows:

Claims 1, 3–16, and 18–20 stand rejected under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement.

Claims 1, 3–7, 9–16, 19, and 20<sup>2</sup> stand rejected under 35 U.S.C. § 102(e) as anticipated by Rossini.<sup>3</sup>

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<sup>2</sup> The Examiner originally rejected claim 22 as anticipated by Rossini, but later withdrew that rejection. Ans. 9.

<sup>3</sup> Rossini, US 2011/0009332 A1, published Jan. 13, 2011 (“Rossini”).

Claims 1, 3–16, and 18–24 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Rossini in view of Klemm<sup>4</sup> in further view of Slack-Davis<sup>5</sup> and Jennings.<sup>6</sup>

## THE WRITTEN DESCRIPTION REJECTION

### *Issue*

In rejecting claims 1, 3–16, and 18–20 under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement, the Examiner finds that the claims recite subject matter that is not described in the Specification is such a way to convey to one skilled in the art that the inventors had possession of the claimed invention. Final Act. 3. The Examiner goes on to find that “[t]he metes and bounds of the genus have not been appropriately defined. The mere fact that Applicant may have discovered one type of drug to be an inhibitor of FAK in . . . reducing scarring during skin wound is not sufficient to claim the entire genus.” Final Act. 4. The Examiner also finds that

applicant has not described a reasonable number of members of the genus now claimed, but rather has presented the public with an idea of using an inhibitor that specifically inhibits FAK. Thus one would need to perform an assay that might identify some agents that fall within the scope of the claim. Of course, depending on what agents are used in the screening assay, it may well identify none.

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<sup>4</sup> Klemm et al., US 4,191,743, issued Mar. 4, 1980 (“Klemm”).

<sup>5</sup> Slack-Davis et al., *Cellular Characterization of a Novel Focal Adhesion Kinase Inhibitor*, 282 J. Bio. Chem. 14845–14852 (2007) (“Slack-Davis”).

<sup>6</sup> Jennings, US 2009/0214474 A1, published Aug. 27, 2009 (“Jennings”).

Final Act. 8. The Examiner concludes the claims do not comply with the written description requirement. *Id.*

Appellants contend the Specification teaches FAK's role in scar formation and that PF-573228 effectively inhibits FAK. Br. 3–4. Appellants go on to argue that FAK inhibitors are known in the art and that one skilled in the art could determine which compounds can be used in the claimed method. Br. 4–5.

The issue with respect to this rejection is whether the Examiner has established by a preponderance of the evidence that claims 1, 3–16, and 18–20 do not comply with the written description requirement.

*Findings of Fact.*

FF1. The Specification states:

A number of FAK inhibitors are known and used in the art. Nonlimiting examples include PF-573,228; PF-562,271; FAK Inhibitor 14, bortezomib; (for example see Cabrita et al. (2011) Mol. Oncol. 5(6):517-26; Ko et al. (2010) Anticancer Agents Med Chem 10(10):747-52; Li and Hua (2008) Adv. Cancer Res 101:45-61; WO 2008/115369 which describes inhibitors of FAK as derivatives of a 5-substituted 2,4-diaminopyridine; WO 2003/035621 which describes protein kinase inhibitors; and U.S. Patent no. 7,067,522 which describes 2,4,DI (hetero-) arylamino (-oxy)-5-substituted pyrimidines as inhibitors of FAK, each of which is herein individually and specifically incorporated by reference.) Inhibitors of interest include small molecule inhibitors, as well as biologicals such as antibodies, RNAi, antisense, peptide inhibitors and peptidomimetics, and the like.

Spec. ¶ 31.

*Principles of Law*

A “sufficient description of a genus [] requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc).

*Analysis*

We agree with Appellants that claims 1, 3–16, and 18–20 satisfy the written description requirement. The present Specification demonstrates

far more than “an idea of using an inhibitor that specifically inhibits FAK” as stated in the Office Action. Rather, it is demonstrated by multiple approaches that FAK is involved in scar formation and that scar formation is reduced when the activity is specifically inhibited. These teachings, coupled with known specific inhibitors of FAK, provide one of skill in the art with ample evidence that Applicants were in possession of the invention.

Br. 4–5.

The Examiner contends that Appellants have not shown sufficient species to support the genus claims. Ans. 10–11. We are not persuaded. Appellants have disclosed a number of compositions that are known FAK inhibitors. FF1. This listing of known FAK inhibitors, coupled with the teachings of the Specification tying FAK to scar formation, would lead one skilled in the art to understand that Appellants had possession of the invention at the time the instant application was filed.

*Conclusion of Law*

We conclude that the Examiner has not established that claims 1, 3–16, and 18–20 do not comply with the written description requirement of 35 U.S.C. § 112, first paragraph.

THE ANTICIPATION REJECTION

*Issue*

In rejecting claims 1, 3–7, 9–16, 19, and 20 as anticipated by Rossini, the Examiner finds that Rossini teaches a method for treating a skin wound by administering an effective amount of a proteasome inhibitor such as bortezomib. Final Act. 9. The Examiner finds that bortezomib is the same compound as that taught by the instant Specification as being a FAK inhibitor. *Id.* Thus, Rossini anticipates the rejected claims. *Id.*

Appellants contend that bortezomib is not a specific inhibitor of FAK but rather is a general inhibitor of multiple proteins including proteasomes. Br. 5. Appellants go on to argue that proteasomes are structurally and functionally different from FAK and that there is no reason to extrapolate from one to the other. Br. 6–7.

The issue with respect to this rejection is whether the Examiner has established by a preponderance of the evidence that claim 1 is anticipated by Rossini under 35 U.S.C. § 102(e).

*Findings of Fact*

We adopt as our own the Examiner's findings and analysis. The following findings are included for emphasis and reference convenience.

FF2. Rossini teaches a method of treating a wound to control scarring by administering an effective amount of a proteasome inhibitor to the skin. Rossini, ¶ 8.

FF3. Bortezomib is a proteasome inhibitor which can be used in the method of Rossini. Rossini ¶ 47.

FF4. Rossini teaches administering bortezomib for up to 28 days so as to reduce scarring. Rossini ¶¶ 54, 69, 73, and 74.

FF5. The Specification teaches that bortezomib is a FAK inhibitor. Spec. ¶ 31.

### *Principles of Law*

“Anticipation requires that all of the claim elements and their limitations are shown in a single prior art reference.” *In re Skvorecz*, 580 F.3d 1262, 1266 (Fed. Cir. 2009).

Where . . . the claimed and prior art products are identical or substantially identical . . . the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . [The] fairness [of the burden-shifting] is evidenced by the PTO’s inability to manufacture products or to obtain and compare prior art products.

*In re Best*, 562 F.2d 1252, 1255 (CCPA 1977).

### *Analysis*

Claim 1 is representative of the rejected claims and is directed to a method for reducing scarring by applying an effective amount of a FAK inhibitor to a wound for a time sufficient to reduce scarring.

We agree with the Examiner that claim 1 is anticipated by Rossini. Rossini teaches applying bortezomib, a FAK inhibitor, to a skin wound in order to control scarring. FF2–5. Rossini teaches applying the bortezomib for a period of time sufficient to reduce scarring. FF4. *See also* Spec. ¶ 54 (sufficient time can vary from 1 day to 3 weeks). Thus, Rossini teaches all of the limitations of claim 1. *See Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997) (“Where . . . a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation.”).

Appellants argue that bortezomib is not a specific inhibitor of FAK; thus, Rossini does not anticipate the claims. We are unpersuaded. Appellants’ Specification specifically lists bortezomib as a FAK inhibitor that can be used in the practice of the invention. FF5. Appellants have offered no persuasive evidence to show that claim 1 does not encompass the use of bortezomib as an FAK inhibitor. *In re Best*, 562 F.2d at 1255.

### *Conclusion of Law*

We conclude that the Examiner has established by a preponderance of the evidence that claim 1 is anticipated by Rossini under 35 U.S.C. § 102(e).

Claims 3–7, 9–16, 19, and 20 have not been argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

## THE OBVIOUSNESS REJECTION

### *Issue*

In rejecting claims 1, 3–16, and 18–24 as obvious, the Examiner finds that Rossini teaches reducing of scarring by treating a wound with an

effective amount of bortezomib, a FAK inhibitor. Final Act. 11. The Examiner also finds that Slack-Davis teaches the use of PF-573228 for wound healing. Final Act. 12. The Examiner concludes that it would have been obvious to one skilled in the art to substitute PF-573228 for bortezomib as they both are used for wound healing. Final Act 12–13.

Appellants contend that Rossini does not teach FAK inhibition but looks to a different protein for a different purpose. Br. 8. Appellants argue that Rossini does not teach the specific agents other than bortezomib. *Id.* With respect to claims 22–24, Appellants argue that Slack-Davis does not teach the use of PF-573228 to reduce scar formation and that the other references do not teach the use of a specific inhibitor of FAK. *Id.*

The issue with respect to this rejection is whether the Examiner has established by a preponderance of the evidence that claims 1, 3–16, and 18–24 would have been obvious over Rossini combined with Klemm, Slack-Davis, and Jennings under 35 U.S.C. § 103(a).

#### *Findings of Fact*

The following findings are included for emphasis and reference convenience.

FF6. Slack-Davis teaches that PF-573228 is a FAK inhibitor. Slack-Davis 14845.

*Principles of Law*

A proper § 103 analysis requires “a searching comparison of the claimed invention—including all its limitations—with the teaching of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995).

“Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination.” *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011). “Rather, obviousness requires the additional showing that a person of ordinary skill at the time of the invention would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention.” *Id.*

*Analysis*

We agree with the Examiner that the subject matter of claim 1 would have been obvious to one skilled in the art at the time the invention was made. As discussed above, Rossini teaches the use of bortezomib to treat wounds, as required by claim 1. FF2–3. Claims 3–16 and 18–20 were not argued separately and fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

Appellants argue that Rossini does not teach the use of a FAK inhibitor and is directed to a different protein. Br. 7. We are unpersuaded. As discussed above, Appellants have specifically identified bortezomib as an FAK inhibitor. Appellants have offered no persuasive evidence that bortezomib does not act as a FAK inhibitor.

With respect to claims 22–24, Appellants have the better position. While Slack-Davis teaches that PF-573288 is a FAK inhibitor, there is not a

teaching of its use to treat wounds. The passage cited by the Examiner references an in vitro wound healing assay, however, on closer examination, the assay used in Slack-Davis is related to cell migration and not the healing of wounds. Thus we agree with Appellants that the Examiner has not pointed to any persuasive evidence that one skilled in the art would have been motivated to substitute PF-573228 for bortezomib in the method taught by Rossini.

*Conclusion of Law*

We conclude that the Examiner has established by a preponderance of the evidence that claims 1, 3–16, and 18–20 would have been obvious over Rossini combined with Klemm, Slack-Davis, and Jennings under 35 U.S.C. § 103(a).

We conclude that the Examiner has failed to establish that claims 22–24 would have been obvious over Rossini combined with Klemm, Slack-Davis, and Jennings under 35 U.S.C. § 103(a).

SUMMARY

We reverse the rejection of claims 1, 3–16, and 18–20 under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement.

We affirm the rejection of claims 1, 3–7, 9–16, 19, and 20 under 35 U.S.C. § 102(e) as anticipated by Rossini.

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We affirm the rejection of claims 1, 3–16, and 18–20 under 35 U.S.C. § 103(a) as unpatentable over Rossini in view of Klemm in further view of Slack-Davis, and Jennings.

We reverse the rejection of claims 22–24 under 35 U.S.C. § 103(a) as unpatentable over Rossini in view of Klemm in further view of Slack-Davis, and Jennings.

#### TIME PERIOD FOR RESPONSE

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

AFFIRMED-IN-PART