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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte KEITH E. MATHENY[1]

Appeal 2018-004087
Application 13/679,978
Technology Center 3700

Before MICHAEL L. HOELTER, ANNETTE R. REIMERS, and LISA M. GUIJT, *Administrative Patent Judges*.

HOELTER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

This is a decision on appeal, under 35 U.S.C. § 134(a), from the Examiner's final rejection of claims 1, 3–6, 13, 16–20, 22–27, and 29–31, which constitute all the claims pending in this application. Final Act. 1 (Office Action Summary). We have jurisdiction under 35 U.S.C. § 6(b). For the reasons explained below, we do not find error in the Examiner's rejections of these claims. Accordingly, we AFFIRM the Examiner's rejections.

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[1] "The real part in interest is Matheny ENTerprises, assignee of record." App. Br. 2. We thus proceed on the basis that, for purposes of this appeal, Matheny ENTerprises is the "Appellant."

CLAIMED SUBJECT MATTER

The disclosed subject matter relates to "a biodegradable nasal splint, wherein the biodegradable nasal splint is configured for placement within a nasal passage so as to stabilize a surgically-corrected septum." Spec. ¶ 9. Claims 1, 13, and 22 are independent.

Claim 1 is illustrative of the claims on appeal and is reproduced below.

> 1. A biodegradable nasal splint comprising:
>
> a tubular component at least partially defining a hollow passageway and a flap extending outward from the tubular component, wherein the tubular component and the flap are formed from a degradable material, wherein the degradable material comprises at least 50% chitosan by weight of the degradable material, wherein the biodegradable nasal splint is configured for placement between a septum and an inferior turbinate so as to apply a horizontally opposing force between the nasal septum and the inferior turbinate.

REFERENCES

Eliachar	US 5,350,396	Sept. 27, 1994
Patterson	US 6,186,965 B1	Feb. 13, 2001
Eaton et al.	US 2007/0005094 A1	Jan. 4, 2007
Bradley	US 2008/0249428 A1	Oct. 9, 2008
Slager et al.	US 2008/0038354 A1	Feb. 14, 2008
Dubin	US 2010/0106255 A1	Apr. 29, 2010

Karatzanis, Alexander D., et al., *Septoplasty outcome in patients with and without allergic rhinitis*, 47 RHINOLOGY 444–49 (2009).

THE REJECTIONS ON APPEAL

Claims 29–31 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Final Act. 4.

Claims 1, 3–5, and 29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Dubin, Patterson, and Slager. Final Act. 4.

Claim 6 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Dubin, Patterson, Slager, and Eaton. Final Act. 6.

Claims 13, 16, 19, 20, 22, 23, 26, 27, 30, and 31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Eliachar, Patterson, and Slager.[2] Final Act. 7.

Claims 17 and 24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Eliachar, Patterson, Slager, and Karatzanis. Final Act. 9.

Claims 18 and 25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Eliachar, Patterson, Slager, and Bradley. Final Act. 10.

ANALYSIS

The rejection of claims 29–31 for failing to comply with the written description requirement

Each of claims 29–31 recites "the degradable material optionally further comprises chitin, and wherein the degradable material comprises at least 90% by weight of chitosan and chitin." App. Br. 24 (Claims App.). The Examiner determines that paragraph 63 of the Specification is "a 'laundry list' disclosure of every possible moiety [that] does not constitute a written description of every species in a genus because it would not 'reasonably lead' those skilled in the art to any particular species," and thus, "the limitations of claims 29–31 are considered to be new matter." Final Act. 4 (citing M.P.E.P. § 2163.05 II); Ans. 6–7.

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[2] The Examiner also listed claim 28, but claim 28 is canceled. *See* App. Br. 24 (Claims App.).

The written description requirement is satisfied when the disclosure of the application reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. *Ariad Pharmaceuticals v. Eli Lilly*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). Here, the Examiner recognizes, "the specification discloses the use of chitosan and chitin in constructing the nasal splint and further discloses the nasal splint can be at least 90% by weight degradable material." Final Act. 4; *see also* Spec. ¶¶ 62–63. Thus, Appellant has shown possession of the subject matter of claims 29–31. Although paragraph 63 of the Specification lists a number of degradable polymers that may be used for a BSS/BAIESS (biodegradable structural support/biodegradable, active ingredient-eluting structural support), contrary to the Examiner's assertion, nothing in this paragraph implies that the list is intended to represent a "laundry list" of every possible degradable polymer, or is a reference to "every species in a genus." Final Act. 4; Ans. 7.

For these reasons, we do not sustain the rejection of claims 29–31 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

The rejection of claims 1, 3–5, and 29 as being obvious over Dublin, Patterson, and Slager

Appellant argues claims 1, 3–5, and 29 together. App. Br. 5–18; Reply Br. 2–7. We select claim 1 for review, with claims 3–5 and 29 standing or falling therewith. *See* 37 C.F.R. § 41.37(c)(1)(iv).

The Examiner finds that Dubin discloses a nasal splint comprising a tubular component (body 12) defining a hollow passageway 36 and a flap (retention member 20). Final Act. 5 (citing Dubin Fig. 4; ¶ 1); *see also*

Dubin Fig. 2. The Examiner acknowledges that Dubin "fails to disclose the splint is made of a degradable material." Final Act. 5. The Examiner relies on Patterson as disclosing a nasal splint constructed out of a biodegradable material.[3] Final Act. 5 (citing Patterson 1:5–10). The Examiner concludes that it would have been obvious to modify the nasal splint of Dubin to be constructed of an absorbable material, as taught by Patterson, to "eliminate[] the need for a patient to have a follow-up visit with a doctor for splint removal and because removal can be sometimes be difficult and painful." Final Act. 5 (citing Patterson 1:38–50).

The Examiner also acknowledges that "Dubin '255 and Patterson '965 fail to disclose the splint is constructed from chitosan." Final Act. 5. The Examiner, however, concludes that it would have been obvious as a matter of design choice, to modify the nasal splint of Dubin and Patterson to be made of chitosan "because [Appellant] has not disclosed that this particular absorbable material provides an advantage, is used for a particular purpose, or solves a stated problem" and because an ordinary artisan would have expected the nasal splint, made from materials disclosed in Patterson, "to perform equally [as] well" as a nasal splint made of chitosan. Final Act. 5–6.

Alternatively, the Examiner finds that Slager discloses "an absorbable nasal splint (paragraph [0170]) and teaches [that] the splint can be made of chitosan (paragraph [0108])." Final Act. 6. The Examiner concludes that it would have been obvious to modify the nasal splint of Dubin and Patterson

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[3] The Examiner points out that Patterson discloses that its nasal splint can be completely made of a biodegradable material, and thus, its nasal splint is at least 50% by weight of a degradable material, as claimed. *See* Ans. 5.

to be made of chitosan, as taught by Slager, "since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice." Final Act. 6 (citing *In re Leshin* 277 F.2d 197 (CCPA 1960)).

Appellant seems to agree with both of the above "design choice" rationales because when addressing the written description issue, Appellant states "that the skilled artisan would have been 'reasonably led' to a degradable material that includes both chitosan and chitin." App. Br. 19. However, Appellant contends, "*Patterson's* disclosure would not have caused the skilled artisan to believe that [] the device disclosed by *Dubin* [] might be improved by making [Dubin's] device[] degradable." App. Br. 8. As support, Appellant argues that Patterson's device has a different shape and that Dubin's design "must have sufficient mechanical activity to" remain operational. App. Br. 9 (referencing Patterson 3:52–4:20). According to Appellant, "[t]he skilled artisan would appreciate that the materials employed in making *Dubin's* stent [] biodegradable are critical to the way in which those device[s] perform" and "[t]he fact that *Patterson* might disclose a biodegradable nasal splint ***does not*** demonstrate the obviousness of making [] *Dubin's* stent [] biodegradable." App. Br. 10; *see also* Reply Br 2–7. To be clear, Appellant contends that based on Patterson's disclosure, there is no "reasonable expectation of success in attempting to make [Dubin's] device[] biodegradable." Reply Br. 3.

These arguments are unpersuasive. Appellant does not provide evidence or persuasive argument to show that the shape of, or the mechanical activity relating to Dubin's nasal splint, would preclude the use of a degradable material since Patterson clearly discloses that a degradable

material is suitable for use in making nasal splints. *See* Patterson Abstract. Further, "attorney argument [is] not the kind of factual evidence that is required to rebut a prima facie case of obviousness." *In re Geisler,* 116 F.3d 1465, 1470 (Fed. Cir. 1997).

Appellant also argues that modifying Dubin's device to be made of chitosan would not have been a design choice because "the skilled artisan must first have recognized that a nasal splint formed from a degradable material including chitosan would be functionally equivalent to known nasal splints" and that "the Examiner has not demonstrated the suitability of chitosan for making an absorbable nasal splint." App. Br. 10–11. This argument is also unpersuasive. The Examiner points to paragraphs 108 and 170 of Slager which disclose that "degradable polymers can include modified polysaccharides such as . . . chitosan" and that the devices contemplated by Slager include "ear[,] nose[,] and throat devices such as[,] nasal buttons [and] nasal and airway splints." *See* Final Act. 6; Slager ¶¶ 108, 170. Accordingly, the Examiner has demonstrated the suitability of using chitosan in making nasal splints.

Further, we note that Appellant discusses "a biodegradable, active ingredient-*eluting* structural support (BAIESS)" (Spec. ¶ 42) and that Slager similarly discloses "polymeric matrices for the controlled release of a hydrophilic bioactive agent" or an "*elution* control matrix" (Slager Abstract (emphasis added)). Such common functionality of Appellant's and Slager's devices, and Appellant's earlier statement regarding how a "skilled artisan would have been 'reasonably led'" to chitosan (App. Br. 19), further support the Examiner's position that it would have been obvious to modify the device of Dubin to be made of chitosan.

Appellant next contends that "Slager does not disclose an absorbable nasal splint made from chitosan and, therefore, does not demonstrate the suitability of chitosan for making a biodegradable nasal splint." App. Br. 12; emphasis omitted. Appellant argues that Slager only discloses that some devices might be "composed of the matrix itself" and "only some of the multitude of devices listed in" Slager's paragraph 170 might be formed from the elution controlled matrix because "the skilled artisan would not read Slager to suggest that a pace-maker or battery [which are disclosed in paragraph 170] might be formed from chitosan" or because "the disclosed matrix-forming composition may [only] be used as a coating applied to these devices." App. Br. 13; emphasis omitted. As such, Appellant argues that the rejection is based on impermissible hindsight reconstruction. *See* App. Br. 13–15.

Appellant's arguments ignore the explicit disclosure in Slager's paragraphs 108 and 170 as reproduced above. Contrary to Appellant's contention, the Examiner's rationale for modifying the device of Dubin is based on evidence and sound technical reasoning rather than impermissible hindsight reconstruction.

We also note that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). "If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *KSR*, 550 U.S. at 417. In this case, we find that the strong evidence demonstrating that the claimed subject matter is nothing more than the application of a known technique to a known device

ready to yield predictable results, and that there is reasonable expectation of success in making Dubin's device biodegradable. *See also* Ans. 4.

Lastly, Appellant argues that "[t]he *Matheny Declaration*[4] demonstrates that the claimed biodegradable nasal splint formed from a degradable material that comprises chitosan meets a long-felt, unresolved need in the art." App. Br. 16. Appellant contends that the Declaration shows that there are "numerous problems associated with conventional nasal splints, like the Doyle Splint, for which a patent application was filed over 40 years ago," "[t]hese problems have existed for a substantial period of time and continue to the present," and "[t]hus, there is clearly a 'long-felt' and continuing need to overcome the problems associated with conventional nasal splints." App. Br. 17; *see also* Reply Br. 5–6.

Establishing long-felt need requires objective evidence that an art-recognized problem existed in the art for a long period of time without a solution. In particular, the evidence must show that the need was a persistent, yet unfulfilled one that was recognized by those of ordinary skill in the art. *In re Gershon*, 372 F.2d 535, 539 (CCPA 1967). "[L]ong-felt need is analyzed as of the date of an articulated identified problem and evidence of efforts to solve that problem." *Texas Instruments, Inc. v. ITC*, 988 F.2d 1165, 1178 (Fed. Cir. 1993).

The Declaration addresses a 40 year old Doyle device and does not take into consideration the more current teachings of Patterson and Slager, as discussed above. Further, Appellant does not present evidence that others considered the lack of a chitosan nasal splint as undesirable, or as presenting

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[4] Declaration of inventor Keith E. Matheny filed on June 3, 2016.

a problem in need of a solution. As such, Dr. Matheny's testimony is not sufficient to establish that an industry-recognized problem existed in the art. Thus, we agree with the Examiner that the Declaration is unpersuasive in that it does not cite sufficient objective evidence. *See* Ans. 6.

Accordingly, and based on the record presented, we are not persuaded the Examiner erred in rejecting claims 1, 3–5, and 29 as being obvious over Dubin, Patterson, and Slager. We thus sustain the rejection of these claims.

The rejection of claim 6
as being obvious over Dubin, Patterson, Slager, and Eaton

Appellant does not present substantive arguments regarding the rejection of claim 6, which depends from claim 1. App. Br. 5–18; Reply Br. 2–7. We thus sustain the rejection of claim 6 for the same reasons as discussed above for claim 1.

The rejection of claims 13, 16, 19, 20, 22, 23, 26, 27, 30, and 31
as being obvious over Eliachar, Patterson, Slager, and Karatzanis

Appellant argues all these claims together. App. Br. 5–18; Reply Br. 2–7. We select claim 13 for review, with claims 16, 19, 20, 22, 23, 26, 27, 30, and 31 standing or falling therewith.

In regard to claim 13, the Examiner finds that Eliachar discloses "a method of performing a corrective procedure with respect to a patient's nasal passage and positioning a splint between the patient's septum and the inferior turbinate." Final Act. 7–8 (citing Eliachar Fig. 1; 1:10–25). The Examiner acknowledges Eliachar "fails to disclose the splint is biodegradable" and "fail[s] to disclose [a] biodegradable material [made of] chitosan." Final Act. 8. Similar to the rejection of claim 1 as discussed

above, the Examiner relies on Patterson and Slager as disclosing these missing limitations, respectively. *See* Final Act. 8–9.

Appellant's arguments parallel those presented above regarding claim 1. *See* App. Br. 5–18; Reply Br. 2–7. Because we find no deficiencies in the Examiner's rejection of claim 1 as being obvious over Dubin, Patterson, and Slager (*see supra*), for similar reasons, we likewise sustain the Examiner's rejection of claims 13, 16, 19, 20, 22, 23, 26, 27, 30, and 31 as being obvious over Eliachar, Patterson, and Slager.

The rejection of claims 17 and 24
as being obvious over Eliachar, Patterson, Slager, and Karatzanis

The rejection of claims 18 and 25
as being obvious over Eliachar, Patterson, Slager, and Bradley

Appellant does not present substantive arguments regarding the rejections of claims 17, 18, 24, and 25, which depend either from claim 13 or claim 22. App. Br. 5–18; Reply Br. 2–7. Accordingly, we sustain the rejections of claims 17, 18, 24, and 25 for the same reasons discussed above.

DECISION

The Examiner's rejection of claims 29–31 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement is reversed.

The Examiner's art rejections of claims 1, 3–6, 13, 16–20, 22–27, and 29–31 under 35 U.S.C. § 103(a) are affirmed.

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)(iv).

AFFIRMED