

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LUCAS LATINI

Appeal 2007-4167
Application 10/406,647
Technology Center 3700

Decided: January 30, 2008

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, FRANCISCO
C. PRATS, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 1-6, 8,
9, and 11-15. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The claims are directed to microcatheter having a tip relief region with spiral cuts in its distal end. Claims 1-6, 8, 9, and 11-15 are pending (Appeal Br. 1). Appellant appeals the following rejections:

1) claims 1-4, 6, 8, 9, and 11-15 as obvious under 35 U.S.C. § 103(a) over Jones (U.S. Pat. No. 5,843,050, Dec. 1, 1998) (Answer 3); and

2) claims 1-6, 8, 9, and 11-15 as obvious under 35 U.S.C. § 103(a) over Okajima (U.S. Pat. No. 5,554,139, Sep. 10, 1996) in view of Griffin (U.S. Pat. No. 6,652,508 B2, Nov. 25, 2003) (Answer 3-4).

We select the following claims as representative of the appealed rejections:

1. A microcatheter having an elongate tubular body, a distal portion, a proximal portion, and a tip relief region within the distal end portion, wherein the tip relief region comprises one or more spiral cuts having a progressive pitch towards the distal end of the tip relief region, and wherein the pitch is between about 30 and 60 C/mm at the distal end of the tip relief region.

8. The microcatheter of claim 1, wherein the pitch of the one or more spiral cuts on the tip relief region ranges between about 0.05 and 60 C/mm.

9. The microcatheter of claim 1, wherein the pitch is between about 0.05 and 0.10 C/mm at the proximal end of the tip relief region.

12. The microcatheter of claim 1, wherein the tip relief region is coated.

13. The microcatheter of claim 12, wherein the tip relief region is coated by shrink wrapping.

14. A coaxial dual lumen microcatheter assembly formed by inserting the microcatheter of claim 1 coaxially within a second catheter.

15. The microcatheter of claim 1, having a size below about 1.5 Fr.

ISSUE ON APPEAL

The Jones, Okajima, and Griffin patents are cited by the Examiner for teaching microcatheters. These catheters differ from the claimed invention in the dimensions of the pitch of spiral cuts in the catheter's tip relief region and in the catheter diameter. The issue in this appeal is whether the claimed dimensional limitations distinguish the claimed invention over the prior art.

OBVIOUSNESS OVER JONES

Findings of Fact

Scope and contents of the prior art

1. Jones describes "a microcatheter for negotiating small tortuous vessels" (Jones, at col. 2, ll. 34-36).
2. The microcatheter has a distal section 32 of a tubular element 30 which is provided with a spiral cut to modify the flexibility of the catheter (Jones, at col. 5, ll. 19-21; at col. 6, l. 53 to col. 7, l. 2; Fig. 3; Answer 3). Thus, persons of skill in the art would have known from Jones that varying pitch adjusts the catheter's flexibility.
3. "The spiral cut generally has a pitch within the range of from about 0.01 inches to about 0.125 inches" (Jones, at col. 5, ll. 25-27).
4. In one embodiment, "the distal section 32 comprises a first spiral cut section having . . . a pitch of about 0.06, and a second, distal section having

. . . a pitch of about 0.030” (Jones, at col. 5, ll. 28-32).

5. “The precise pitch of the spiral cut and axial spacing of adjacent windings can be varied widely while still accomplishing the purposes . . . , and can be optimized for any particular application” (Jones, at col. 5, ll. 35-40).

6. Jones does not state that the disclosed pitch is critical to achieve the desired flexibility.

7. The pitch can be of continuous or variable spirals, or multizone spiral sections in which each zone has a unique pitch (Jones, at col. 7, ll. 35-41; Answer 3).

8. The microcatheter “will generally have an outside diameter within the range of from about 0.5 mm to about 1.5 mm” (Jones, at col. 3, ll. 60-62) which corresponds to 1.5 to 4.5 Fr (Appeal Br. 4).

9. “Other dimensions than these disclosed above and recited elsewhere herein can be readily utilized by those of ordinary skill in the art in view of the disclosure herein to suit particular intended uses of the microcatheter” (Jones, at col. 3, ll. 64-67).

10. The catheter can have a heat shrinkable outer jacket 42 which is “exposed to a source of heat to shrink the jacket” around the catheter body (Jones, at col. 7, ll. 48-53; at col. 6, ll. 35-40; Fig. 3; Answer 3).

11. The outer jacket 42 “preferably extends beyond the distal end of the . . . tubular element 30” (Jones, at col. 6, ll. 40-45; Fig. 3).

12. The microcatheter can have a balloon catheter placed around it (Jones, at col. 12, ll. 23-42; Fig. 14).

Differences between the prior art and the claimed invention

13. Jones describes a microcatheter having a tubular body 30, meeting the limitation of “an elongate tubular body” as recited in claim 1 (FF 1-2; Jones at col. 2, ll. 34-36; Jones, at col. 5, ll. 19-21; Fig. 3).

14. The distal section 32 of Jones’s microcatheter – which corresponds to the “tip relief region” of the microcatheter of claim 1 – has spiral cuts (FF 2; Jones, at col. 5, ll. 19-21; at col. 6, l. 53 to col. 7, l. 2; Fig. 3; Answer 3) as does the microcatheter of claim 1.

15. Jones states that its distal section can be continuous or variable (FF 7; Jones, at col. 7, ll. 35-41) – and thus teaches a “progressive pitch” as recited in claim 1.

16. The pitch of the cuts in Jones’s microcatheter is “generally . . . from about 0.01 inches to about 0.125 inches” (FF 3; Jones, at col. 5, ll. 25-27) which corresponds to about 0.254-3.175 mm per cut (Appeal Br. 4).

17. Claim 1’s microcatheter has a pitch “between about 30 and 60 C/mm at the distal end of the tip relief region” which corresponds to 0.017-0.333 mm per cut (Appeal Br. 3-4).

18. Thus, Jones does not describe a catheter having a pitch at its distal end of 0.017-0.333 mm per cut as required by claim 1 (FF 17; Appeal Br. 4), but its disclosed pitch of from about 0.254-3.175 mm per cut (FF 16; Appeal Br. 4) overlaps with the claimed pitch.

19. Claim 8’s microcatheter has a pitch at its tip relief region which “ranges between about 0.05 and 60 C/mm” which corresponds to 0.017-20 mm per cut (Appeal Br. 4).

20. Jones does not describe a catheter having a pitch at its distal end of 0.017-20 mm per cut as required by claim 1 (FF 17; Appeal Br. 4), but its

disclosed pitch of from about 0.254-3.175 mm per cut (FF 19; Appeal Br. 4) overlaps with the claimed pitch.

21. Claim 9's microcatheter has a pitch of claim 1 at its distal end and a pitch "between about 0.05 and 0.10 C/mm at the proximal end of the tip relief region" which corresponds to 10-20 mm per cut (Appeal Br. 4).

22. Jones does not describe a catheter with a pitch at its proximal end of 10-20 mm per cut (FF 21) as required by claim 9.

23. Jones describes a microcatheter which is coated by shrink wrapping as recited in claims 12 and 13 (FF 10; Jones, at col. 7, ll. 48-53; at col. 6, ll. 35-40; Answer 3).

24. Jones describes a balloon catheter around a microcatheter (FF 12; Jones, at col. 12, ll. 23-42; Fig. 14), meeting the limitations of claim 14 of a coaxial dual lumen catheter.

25. Jones describes a microcatheter having a diameter of about 1.5 to 4.5 Fr (FF 8; Appeal Br. 4), but not "having a size below about 1.5 Fr" as in the microcatheter of claim 15.

Level of ordinary skill in the art

26. Persons of ordinary skill in the art knew to optimize the pitch and diameter of Jones's microcatheter to make it suitable for its particular intended use (FF 5, 9; Jones, at col. 5, ll. 35-40; at col. 3, ll. 64-67).

Reason to modify the prior art

27. Persons of ordinary skill in the art would have been prompted to modify the dimensions of Jones's microcatheter to fit into a vessel of smaller size than could be reached with Jones's microcatheter and to achieve a different flexibility to optimize it for this particular intended use (*see* Answer 3; FF 24).

Analysis

In making an obvious determination, the Examiner must first identify the scope and contents of the prior art and then ascertain the differences between the prior art and the claimed invention. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The next step is to identify a reason why persons of skill in the art would have been prompted to combine the prior art to have made the claimed invention. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

In this case, Jones describes a microcatheter which meets all elements of claim 1 (and dependent claims 8 and 9) (FF 13-15), but not the specifically recited pitch of the spiral cuts at its distal end (see FF 16-20). However, Jones teaches that the pitch of the spiral cuts modifies the flexibility of the microcatheter (FF 2; Jones, at col. 5, ll. 19-21; col. 6, l. 53 to col. 7, l. 2). Jones also teaches that the “precise pitch of the spiral cut and axial spacing of adjacent windings can be varied widely while still accomplishing the purposes . . . , and can be optimized for any particular application” (FF 5; Jones, at col. 5, ll. 35-40). Thus, we agree with the Examiner that persons of ordinary skill in the art would have been prompted to modify the pitch of Jones’s catheter to vary the microcatheter’s flexibility (FF 25). Making such modifications to the pitch of Jones’s microcatheter would have been within the ordinary level of skill in the art (FF 24).

With respect to claims 1 and 8 which are directed to pitch ranges that overlap with the pitch of Jones (FF 18, 20), it is well-established that even a slight overlap in ranges establishes prima facie obviousness. *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003). In such cases, it must be shown “that the particular range is critical, generally by showing that the claimed range

achieves unexpected results relative to the prior art range.” *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990). Appellant has not provided rebuttal evidence of unexpected results.

While Jones does not specifically describe a range that overlaps with the pitch of claim 9 at the proximal end (FF 21), Jones does not limit the pitch to those which are disclosed (the “spiral cut generally has a pitch” (FF 3; Jones, at col. 5, ll. 25-27)) nor does it state that these ranges are critical (FF 6). To the contrary, Jones states that the pitch can be “varied widely while still accomplishing” its purpose to confer flexibility on the catheter (FF 5; Jones, at col. 5, ll. 35-40). Thus, while the claimed range differs from the range disclosed in Jones, it is reasonably suggested by Jones’s acknowledgement that pitch can be “varied widely.”

Jones’s microcatheter has a diameter of about 1.5 to 4.5 Fr (FF 7; Appeal Br. 4), but not “below about 1.5 Fr” as in the microcatheter of claim 15 (FF 25). However, persons of skill would have been motivated to reduce the catheter diameter to accommodate vessels of smaller size (FF 27) – a modification within the scope of ordinary skill in the art (FF 26).

In sum, we conclude that Examiner has provided sufficient evidence to establish that the claims are prima facie obvious over Jones. Once prima facie obviousness has been established, it is Appellant’s burden to provide rebuttal evidence or arguments. *Hyatt v. Dudas*, 492 F.3d 1365, 1369-70 (Fed. Cir. 2007).

Appellant argues that “there is no suggestion in Jones to modify the pitch to this extent Jones does say the pitch can be varied – but that should be interpreted to be within the range of pitches taught by Jones – 0.01

to 0.125 inches” (Appeal Br. 4). We are not persuaded by Appellant’s argument that the Examiner erred.

Firstly, as discussed above, Jones states that the pitch can be “varied widely” (FF 5; Jones, at col. 5, ll. 35-40), and varies it (FF 7; Jones, at col. 7, ll. 35-41), providing a reason to go outside the specifically disclosed range.

Secondly, absent unexpected results, we do not agree that the claimed dimensional limitations are sufficient to distinguish over the prior art. In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338 (Fed. Cir. 1984), cert. denied, 469 U.S. 830 (1984), the patentability of a device for drying ink was at issue. The differences between the prior art and the claimed invention were, *inter alia*, the distance between a suppression plate and a web, the nozzle slot width, and the width of the suppression plate. *Gardner*, 725 F.2d at 1345-46. The court held that such “dimensional limitations” did not distinguish the claimed invention over the prior art because they did not cause the device to perform any differently than the prior art device. *Gardner*, 725 F.2d at 1399.

Here, Appellant attempts to distinguish the claimed invention over the same type of dimensional limitation that the court in *Gardner* found inadequate by itself to establish a basis for patentability. Persons of skill in the art would have known from Jones that varying pitch adjusts the catheter’s flexibility (FF 2). There is no evidence that the claimed range of pitch does anything more than adjust the catheter’s flexibility as expected. Because Appellant has not shown that a microcatheter with the recited dimensions performs any differently than the prior art microcatheter, we conclude – based on the legal principles enunciated in *Gardner* – that claims 1, 8, and 9 are not patentably distinct from the cited prior art.

With regard to claim 15, Appellant argues that Jones does not suggest a microcatheter having a size less than about 1.5 Fr and that such catheter “would perform different from one above 1.5 Fr – for the simple reason that it can access smaller vessels” (Appeal Br. 4).

This argument is not persuasive. Jones explicitly suggests using dimensions other than those disclosed “to suit particular intended uses of the microcatheter” (FF 9; Jones, at col. 3, ll. 64-67). This reasonably suggests other diameters than those disclosed by Jones when the intended use would so demand it. A smaller diameter catheter performs the same way as any catheter – by having a size “for negotiating small tortuous vessels” (FF 1; Jones, at col. 2, ll. 34-36). Thus, we conclude that the diameter size of the microcatheter does not distinguish the claimed invention over the prior art – for similar reasons set forth above for the spiral cut.

Appellant also contends that Jones “does not teach that the spiral cut region specifically is coated” (Appeal Br. 5) as recited in claims 12 and 13. We do not agree. Jones states that the outer jacket 42 – which can be heat shrunk around the catheter body (FF 10; Jones, at col. 7, ll. 48-53; at col. 6, ll. 35-40; Fig. 3; Answer 3) – extends beyond the distal end of the catheter and shows it extending past the spiral cut region (FF 11; Jones, at col. 6, ll. 40-45; Fig. 3).

For the foregoing reasons, we affirm the rejections of claims 1, 8, 9, and 12-15. Claims 2-4, 6, and 11 were not argued separately and therefore fall with the other claims. *See* 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS OVER OKAJIMA IN VIEW OF GRIFFIN

Scope and contents of the prior art

28. Okajima describes an intravascular catheter (Okajima, at col. 1, ll. 5-10) which has spiral shaped slits that decrease gradually in the direction toward the distal tip portion to gradually reduce the rigidity of the metal to prevent it from kinking (Okajima, at col. 16, ll. 40-49; Answer 4).

29. The slits may change pitch continuously or step-wise (Okajima, at col. 7, ll. 35-37).

30. The distal region has the largest flexibility (Okajima, Abstract).

31. Griffin describes a catheter having helical or spiral slots 22 that are cut with a pitch which varies linearly from proximal to distal to gradually reduce the tube stiffness (Griffin, at col. 2, ll. 29-39; Fig. 2).

32. The slot can have a width of about 0.0002 inches or more and a pitch that gradually reduces from about 0.10 inches to about 0.0001 inches (Griffin, at col. 2, ll. 39-45).

33. “Those skilled in the art will recognize that the voids 22 may comprise a variety of geometries” (Griffin, at col. 2, ll. 49-51).

34. The flexibility of the distal portion allows it “to navigate through tortuous vasculature to remove vascular sites” (Griffin, at col. 1, ll. 32-34).

35. Neither Okajima nor Griffin describes the pitch as critical to achieve the purpose of the disclosed catheter (*see* FF 33).

Differences between the prior art and the claimed invention

36. Okajima and Griffin describe a microcatheter with a progressive pitch (FF 28-32) as recited in claim 1, but do not describe a microcatheter with a spiral cut having a pitch “between about 30 and 60 C/mm at the distal end of the tip relief region” as required by claim 1 (Appeal Br. 6).

Level of ordinary skill in the art

37. Okajima does not describe the particular pitch size necessary to achieve the desired flexibility, indicating that it was within the scope of ordinary skill in the art to make such a determination. *See* also FF 33, for Griffin’s teaching that the geometry of the catheter can be varied.

Reason to modify the prior art

38. Persons of ordinary skill in the art would have had reason to change the pitch of the spiral cuts in the distal end of the catheter to modify its flexibility to navigate remote vascular sites (*see* FF 34).

Analysis

In making an obvious determination, the Examiner must first identify the scope and contents of the prior art and then ascertain the differences between the prior art and the claimed invention. *Graham*, 383 U.S. at 17.

Here, Appellant acknowledges that the difference between the prior art and the claimed invention is that the prior art catheters do not disclose a microcatheter with a spiral cut having a pitch “between about 30 and 60 C/mm at the distal end of the tip relief region” as required by claim 1¹ (FF 34; Appeal Br. 6). Appellant contends that this difference in pitch makes the claimed invention patentable over the prior art (Appeal Br. 6). We do not agree.

¹ Appellant also takes the position that the Griffin’s use of the term “pitch” does not correspond to “pitch” as defined in the Specification and as instantly claimed (Appeal Br. 5). The Examiner does not respond to Appellant’s argument and thus we accept Appellant’s position as correct.

Appellant is distinguishing the claimed invention over the same type of dimensional limitation that the court in *Gardner* (*see supra* at p. 9) found inadequate by itself to establish a basis for patentability. Neither Okajima nor Griffin describes the pitch of the spiral cut as critical to achieve the purpose of the disclosed catheter (FF 35). Modifying the spiral cut was within the scope of ordinary skill in the art (FF 37) and there was reason to do it – to change its flexibility (FF 38). Thus, because Appellant has not shown that a microcatheter with the recited dimensions performs any differently than the prior art microcatheter, we conclude – based on the legal principles in *Gardner* – that claim 1 is not patentably distinct from the cited prior art.

For the foregoing reasons, we affirm the rejection of claim 1. Claims 2-6, 8, 9, and 11-15 fall with claim 1 because separate reasons for their patentability were not provided. *See* 37 C.F.R. § 41.37(c)(1)(vii).

CONCLUSION

We affirm the rejections of claims 1-4, 6, 8, 9, and 11-15 as obvious under 35 U.S.C. § 103(a) over Jones; and claims 1-6, 8, 9, and 11-15 as obvious over Okajima in view of Griffin.

TIME PERIOD

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

Appeal 2007-4167
Application 10/406,647

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