UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LIXIAO WANG

Appeal 2008-4008
Application 11/062,657
Technology Center 1700

Decided: September 30, 2008

Before BRADLEY R. GARRIS, CHUNG K. PAK, and
LINDA M. GAUDETTE, *Administrative Patent Judges*.

PAK, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on an appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1 through 4, 6, 7, 30 through 32, and 34 through 37, all of the pending claims in the above-identified application. We have jurisdiction pursuant to 35 U.S.C. § 6.

We AFFIRM.

STATEMENT OF THE CASE

The subject matter on appeal is directed to "medical devices made from thermoplastic polymers, especially devices inserted into the body, for instance tubular devices such as catheters and high strength balloons used thereon…" (Spec. 1, ll. 4-6). Details of the appealed subject matter are recited in representative claims 1, 6, and 32 reproduced below[1]:

1. A device article thermo formed from a composition comprising at least one condensable thermoplastic polymer selected from the group consisting of polycarbonate, (meth)acrylic polymers, polyol polymers, polysaccharides, and poly(meth)acrylamide polymers, wherein after thermoforming the article has been subjected to a solid state condensation polymerization reaction, which thereby increases the molecular weight of the polymer and provides the article with an improvement in at least one property selected from strength, fatigue resistance, rigidity, durability, impact resistance, puncture resistance and tubing kink-resistence.

6. A device article as in claim 1 wherein the polymer composition further comprises a solid state polymerization catalyst

32. A device article as in claim 1 wherein the said composition further comprises a small molecule plasticizer, polyol or polyacid compound having a functional group that can participate in said solid state polymerization reaction.

As evidence of obviousness of the appealed subject matter, the Examiner has proffered the following prior art references:

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[1] Appellant has presented substantive arguments for patentability of claims 1, 6, and 32 (App. Br. 9-15). Therefore, for purposes of this appeal, we select claims 1, 6, and 32 and decide the propriety of the grounds of rejection set forth in the Answer based on these representative claims consistent with 37 C.F.R. § 41.37(c)(1)(vii) (2005).

Pomeranz	EP 0 334 640 A2	Sep. 27, 1989
Weldon	US 5,088,991	Feb. 18, 1992
Dujari	US 5,955,569	Sep. 21, 1999
Day	US 6,222,001 B1	Apr. 24, 2001

The Examiner has rejected the claims on appeal as follows:

1) Claims 1 through 4, 7, 30, and 34 through 37 under 35 U.S.C. § 103(a) as unpatentable over the combined disclosures of Weldon and Pomeranz;

2) Claims 6 and 31 under 35 U.S.C. § 103(a) as unpatentable over the combined disclosures of Weldon, Pomeranz, and Dujari; and

3) Claim 32 under 35 U.S.C. § 103(a) as unpatentable over the combined disclosures of Weldon, Pomeranz, and Day.

Appellant appeals from the Examiner's decision rejecting the claims on appeal under 35 U.S.C. § 103(a).

RELEVANT FACTUAL FINDINGS (FF)

1. Weldon teaches a catheter having:

> desirable properties, especially including high tensile strength,…constructed from extrudable polymers that can be subjected to solid state polymerization such that its physical properties can be altered by exposing the extruded polymer to elevated temperature. A fuseless or seamless catheter is provided which exhibits a soft-walled tip portion by effecting solid state polymerization of only selected portions of the extruded polymer tube in order to thereby form a catheter which has a stiff, strong body and a pliable, atraumatic tip. The body and the tip are constructed of the same polymer but have differing physical properties (col. 2, l. 58 to col. 3, l. 3).

2. Weldon teaches that "[e]xtruded polymers include polyamides such as nylons, as well as polyurethanes, polyolefins, polyacetals, such as Delryn, polyvinyls such as polyvinyl chloride, and the like" (Col. 4, ll. 64-67).

3. Pomerantz teaches that thermoplastic materials, including polyacetals, polyamides, and polycarbonates, are used to construct the rigid structure of catheters (col. 3, ll. 20-27 and col. 4, ll. 55-65).

4. Appellant acknowledges that solid state polymerization catalysts, such as Lewis acid and bases, for polycarbonates are well known (Spec. 6).

5. Dujari teaches the employment of a particular Lewis acid condensation catalyst in polyamide polymer to improve solid state polymerization of the same (col. 1, ll. 5-15).

6. Dujari teaches various conventional solid state Lewis acid or base condensation catalysts, such as phosphoric acid, phenyl phosphinic acid, and sodium hypophospite, are known to be used in conventional solid state polymerization of polyamide polymers (col. 16-25).

7. Day teaches that solid state polymerization of polycarbonates is well known (col. 1, ll.16-28).

8. Day teaches that additives such as plasticizers, ketones, and mold release, and alcohol, produce an increase in the rate of subsequent solid state polymerization of polycarbonates (col. 13, ll. 43-46).

PRINCIPLES OF LAW

Under 35 U.S.C. § 103, the factual inquiry into obviousness requires a determination of: (1) the scope and content of the prior art; (2) the

differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). "[A]nalysis [of whether the subject matter of a claim would have been prima facie obvious] need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l Co., v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740-41 (2007); *see also DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006) ("The motivation need not be found in the references sought to be combined, but may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself…."); *In re Bozek*, 416 F.2d 1385, 1390 (CCPA 1969) ("Having established that this knowledge was in the art, the examiner could then properly rely, as put forth by the solicitor, on a conclusion of obviousness 'from common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference.'"). The common knowledge imputed to the level of one of ordinary skill in the art includes Appellant's admission regarding what was known at the time of the invention. *See In re Nomiya*, 509 F.2d 566, 570-71 (CCPA 1975) (the admitted prior art in an Applicant's Specification may be used in determining the patentability of a claimed invention); *see also In re Fout*, 675 F.2d 297, 301 (CCPA 1982) ("[i]t is not unfair or contrary to the policy of the patent system that appellants' invention be judged on obviousness against their actual contribution to the art").

"[W]here the prior art gives reason or motivation to make the claimed [invention]…the burden (and opportunity) then falls on an applicant to rebut that prima facie case. Such rebuttal or argument can consist of … any other argument or presentation of evidence that is pertinent." *In re Dillon*, 919 F.2d 688, 692-93 (Fed. Cir. 1990)(*en banc*). Appellant's mere arguments in the Brief or conclusory statements in the Specification cannot supplant objective evidence. *See, e.g., In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984); *In re Lindner*, 457 F.2d 506, 508 (CCPA 1972).

It is well settled that arguments not raised in the opening Brief are considered waived. *See Cross Med. Prods., Inc. v. Medtronics Sofamor Danek, Inc.*, 424 F.3d 1293, 1320-21 n.3 (Fed. Cir. 2005).

ANALYSES AND ISSUES

Claims 1 through 4, 7, 30, and 34 through 37

Appellant does not dispute the Examiner's finding that:

> Weldon discloses a catheter thermoformed, extruded, wherein after thermoforming, the article has been subjected to solid state polymerization reaction (column 2, lines 58-68) which thereby increases the molecular weight of the polymer (since the material is subjected to solid state polymerization) and provides the article with an improvement in at least one property selected from tensile strength, fatigue resistance, rigidity, durability, impact resistance, puncture resistance and tubing kink-resistance (abstract, column 4, lines 40-68). [*Compare* Ans. 3-4 *with* App. Br. 9-13; compare also FF 1 with claims 1 and 2 on appeal.]

Rather, Appellant contends that one of ordinary skill in the art would not have been led to employ the claimed polymers, such as polycarbonates, in making Weldon's catheter (App. Br. 11-12).

Therefore, the dispositive question is: Would one of ordinary skill in the art have been led to employ the claimed polymer, such as polycarbonates, in constructing Weldon's catheter? On this record, we answer this question in the affirmative.

As indicated *supra*, Weldon clearly teaches employing any extrudable polymer, inclusive of polyamides, polyurethanes, polyolefins, polyacetals, polyvinyls, and *the like*, in constructing its catheter (FF. 1-2). Weldon indicates that such extrudable polymer can be strengthened by subjecting it to solid state polymerization after it is extruded (thermoformed) into a catheter (FF. 1). Although Weldon does not specifically mention the claimed extrudable thermoplastic polycarbonates, Pomerantz teaches that thermoplastic materials, such as polyacetals, polyamides, and polycarbonates, are known to be used in constructing structures of catheters (FF. 3). In other words, Pomerantz teaches that polyacetals, polyamides, and polycarbonates are interchangeable materials in constructing catheters. Thus, we concur with the Examiner that one of ordinary skill in the art would have been led to employ known extrudable polymers for constructing catheters, such as polycarbonates, in constructing Weldon's catheter, with a reasonable expectation of successfully strengthening it upon subjecting it to solid state polymerization.

Appellant separately argues the limitation of claims 34 through 37 for the first time in the Reply Brief. (See App. Br. and Reply Br. in their

entirety). However, it is well settled that arguments not raised in the opening Brief are considered waived. In any event, Appellant has not demonstrated any reversible error in the Examiner's determination that the selection of appropriate known extrudable polymers, such as those recited in claims 34 through 37, via routine experimentation in forming Weldon's catheter is well within the ambit of one of ordinary skill in the art. Implicit in Weldon's disclosure relating to the employment of any extrudable polymers is that it is well within the skill of one of ordinary skill in the art to select appropriate extrudable polymers useful for forming Weldon's catheter.

Claims 6 and 31

Appellant contends that one of ordinary skill in the art would not have been led to employ a solid state polymerization catalyst, such as a Lewis acid or base catalyst, in Pomeranz's polycarbonates material used in Weldon's extrudable polymer-based catheter (App. Br. 13-14).

Thus, the dispositive question is: Would one of ordinary skill in the art have been led to employ a solid state polymerization catalyst, such as a Lewis acid or base catalyst, in Pomeranz's polycarbonates material used in forming Weldon's extrudable polymer-based catheter within the meaning of 35 U.S.C. § 103? On this record, we answer this question in the affirmative.

As pointed out by the Examiner (Ans. 4 and 9), Dujari teaches the concept of employing a solid state catalyst, such as a Lewis acid catalyst, in a polymer to improve its solid state polymerization (FF. 5-6). Indeed, Appellant acknowledges that the use of such solid state polymerization

catalysts (Lewis acid or Base catalyst) in solid state polymerization of poly carbonates is well known (FF. 4).

Given the above knowledge, we concur with the Examiner that one of ordinary skill in the art would have been led to employ known solid state polymerization catalysts (claimed catalysts) in preparing Weldon's extrudable polycarbonate polymer based catheter, with a reasonable expectation of improving the formation of Weldon's catheter during its exposure to solid state polymerization.

Claim 32

Appellant contends that one of ordinary skill in the art would not have been led to employ a plasticizer in polycarbonates used in forming Weldon's extrudable polymer-based catheter (App. Br. 14-15).

Thus, the dispositive question is: Would one of ordinary skill in the art have been led to employ a plasticizer in Pomeranz's polycarbonates used in forming Weldon's extrudable polymer-based catheter within the meaning of 35 U.S.C. § 103? On this record, we answer this question in the affirmative as well.

As indicated *supra*, Day teaches that solid state polymerization of polycarbonates is well known (FF. 7). Day also teaches that additives, such as plasticizers, produce an increase in the rate of subsequent solid state polymerization of polycarbonates (FF. 8).

Given the above teachings, we concur with the Examiner that one of ordinary skill in the art would have been led to employ such additives in preparing Weldon's extrudable polycarbonate polymer based catheter, with a

reasonable expectation of improving the formation of Weldon's catheter during its exposure to solid state polymerization.

CONCLUSION

Accordingly, based on the totality of record relied upon by the Examiner and Appellant, we determine that the preponderance of evidence weighs most heavily in favor of obviousness of the subject matter recited in the claims on appeal within the meaning of 35 U.S.C. § 103 (a).

ORDER

In view of the foregoing, the decision of the Examiner is affirmed.

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

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