

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KEIJI IGAKI and HIDEKI YAMANE

Appeal 2007-4138
Application 10/182,271
Technology Center 1600

Decided: March 25, 2008

Before DEMETRA J. MILLS, LORA M. GREEN,
and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 1-33.
We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

The claims are directed to stents which are formed of a biodegradable polymer. Claims 1-33 are pending and appealed. Appellants request review of the following rejections:

1) Claims 1-9, 14-17, 20-29, and 31-33 as anticipated under 35 U.S.C. § 102(b) by Igaki (U.S. Pat. No. 5,733,327, Mar. 31, 1998) (Ans. 3); and

2) Claims 1, 5-21, and 24-30 as anticipated under 35 U.S.C. § 102(b) by Hossainy (U.S. Pat. No. 6,153,252, Nov. 28, 2000) (Ans. 4).

Claims 1, 11, 20, 31, 32, and 33, which are representative of the appealed subject matter, read as follows:

1. A luminal stent, inserted into a blood vessel, wherein said stent is formed of a biodegradable polymer material to a shape of a tube; and

wherein said biodegradable polymer material becomes swollen to be impregnated with a drug.

11. A method for manufacturing a luminal stent comprising:
permitting swelling of a stent formed of a biodegradable polymer material by a supercritical fluid in a pressurized vessel to allow impregnation of said biodegradable polymer material with a drug.

20. A stent material for forming a luminal stent introduced into a blood vessel, wherein

said stent material is a biodegradable polymer material which is swollen and impregnated with a drug and on the surface of which a biodegradable polymer layer is layered.

31. The luminal stent according to claim 1 wherein said biodegradable polymer material is composed of one or more high-melting point polymers or copolymers selected from a group comprising poly-L-lactic acid, polyglycolic acid, polyglactin, polydioxanone, polyglyconate.

32. The stent material for forming a luminal stent according to claim 20 wherein said biodegradable polymer material is composed of one or more high-melting point polymers or copolymers selected from a group comprising poly-L-lactic acid, polyglycolic acid, polyglactin, polydioxanone, polyglyconate.

33. The stent material for forming a luminal stent according to claim 20 wherein the biodegradable polymer layered on the surface of said biodegradable polymer material is composed of one or more high-melting point polymers or copolymers selected from a group comprising poly-L-lactic acid, polyglycolic acid, polyglactin, polydioxanone, polyglyconate.

FINDINGS OF FACT

The Igaki Patent

1. Igaki describes a stent to be introduced into a blood vessel (Igaki, at col. 2, ll. 63-65; Ans. 3).
2. The stent is “formed by weaving or knitting a fiber which contains a drug and is made of a biodegradable polymer” (*id.* at col. 2, l. 65 to col. 3, l. 1; *see* Ans. 3).
3. “The drugs as a solute are dissolved in the biodegradable polymer as a solvent to form a solution” (*id.* at col. 3, ll. 18-19).
4. The solution may also be coated on a rigid stent, including a knitted stent body made of a biodegradable polymer of a high melting point, such as poly-lactic or poly-glycolic acid which have a melting point ranging from about 220-240°C (*id.* at col. 3, ll. 22-25 and ll. 31-36; Ans. 3, 5).
5. “In this case, when heated to an elevated temperature, the drug is susceptible to undesired change in its molecular structure, which leads to loss of the aimed effect or conversion to a toxic substance. . . .
Consequently, there might occur an inconvenience that the drugs added

thereto is subjected to undesired chemical conversion, when heated to such elevated temperature” (*id.* at col. 3, ll. 26-36).

6. “Accordingly, it is required that the biodegradable polymer have a low me[l]ting point at which the drug added can be present without loss of the pharmacological effects. For example, it is desirable to have the melting point of the biodegradable polymer at 80°C or lower” (*id.* at col. 3, ll. 37-41).

7. In Example 5, Igaki describes a high-melting biodegradable polymer fiber coated with a solution of a drug-containing low-melting biodegradable polymer (*id.* at col. 7, ll. 15-20).

8. The fiber is knitted to form a stent body 40 (*id.* at col. 7, ll. 36-38).

9. The “knitted stent body 40 may be further coated with the low-melting biodegradable polymer solution . . . so that the amount of . . . drug coated on the stent body 40, can be adjusted to a proper level” (*id.* at col. 7, ll. 54-61).

The Hossainy Patent

10. Hossainy describes stents made of bioabsorbable polymers, such as aliphatic polyesters, lactic acid and glycolic acid (Hossainy, at col. 3, ll. 18-20; Ans. 4).

11. The stents can be coated with film-forming bioabsorbable polymers that can comprise a pharmaceutical agent (*id.* at cols. 3-6, particularly, col. 6, ll. 45-48; at col. 7, ll. 10-17; Ans. 4).

12. A solution of a polymer and solvent is prepared with a solvent chosen such that the pharmaceutical agent and polymer are soluble in it (*id.* at col. 6, ll. 35-52).

13. The stent can be coated with multiple polymer coatings or layers, including polymer layers containing different drugs to provide for sequential drug delivery (*id.* at col. 7, ll. 3-55) in which the polymer is a biodegradable ϵ -caprolactone (*id.* at cl. 7, ll. 35-45; at col. 3, ll. 18-21; Ans. 5).

14. Hossainy does not describe a method of permitting swelling of a stent formed from a biodegradable by a supercritical fluid in a pressurized vessel.

CLAIM INTERPRETATION

Claim interpretation is at the heart of patent examination because the language of the claim defines its scope. Only when claim scope has been determined by interpreting the words in a claim, can the claim be properly compared to the prior art.

During patent examination, the PTO is permitted to adopt “the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.” *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997); *In re Crish*, 393 F.3d 1253, 1256 (Fed. Cir. 2004). With these as guiding principles, we turn to the claims.

Claim 1 is directed to a luminal stent “formed of a biodegradable polymer to a shape of a tube.” The claim states that the “biodegradable polymer becomes swollen to be impregnated with a drug” but does not positively recite that the polymer as present in the claimed stent is swollen. Consequently, we interpret this limitation to mean that the polymer is

capable of becoming “swollen,” but not to require it to be in the swollen state.

Claim 20 is directed to a “stent material” which is a “biodegradable polymer.” The biodegradable polymer is “swollen and impregnated with a drug.” A layer of “biodegradable polymer” is on the surface of the stent material. The preamble of the claim states that the stent material is “for forming a luminal stent introduced into a blood vessel”, but we interpret this to be an intended use of the stent material because there is no language in the claim which requires the material to have been formed into a luminal stent.

DISCUSSION

Anticipation by Igaki

Claims 1-9, 14-17, 20-29, and 31-33 stand rejected as anticipated under 35 U.S.C. § 102(b) by Igaki.

Claims 1-9 and 14-17

Appellants argue claims 1-9 and 14-17 as a group (App. Br. 6). Therefore, we have selected claim 1 as representative of the group for the purpose of deciding the rejection. Claims 2-9 and 14-17 were not separately and thus fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Claim 1 is directed to a luminal stent “formed of a biodegradable polymer to a shape of a tube.” The claim states that the “biodegradable polymer becomes swollen to be impregnated with a drug”; we have interpreted this limitation to mean that the polymer is capable of becoming “swollen,” but not to require it to be in the swollen state.

The Examiner finds that Igaki describes a stent made of biodegradable polymer (FF 1; Ans. 3) and that the polymer would be capable of swelling to

become impregnated with a drug (Ans. 5) – and thus meets all the limitations of claim 1, anticipating it. (Anticipation requires a showing that each element of the claim is identifiable in a single reference. *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005).)

Appellants argue that Igaki “does not disclose a polymer which is swollen to be impregnated with a drug. In claim 1 the drug is not dissolved in the polymer, as is the case in Igaki . . . ; rather, the polymer in claim 1 becomes swollen” (App. Br. 6).

The Examiner has the better argument. Claim 1, as we have interpreted it, does not require the biodegradable polymer to be swollen and impregnated with drug; only that it be capable of achieving this state. As the claimed stent may be comprised of the same biodegradable polymers disclosed in Igaki,¹ the Examiner had sound basis for presuming that such polymers would also be capable of becoming swollen and impregnated with drug as in claim 1. “[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990). Appellants do not provide adequate arguments or evidence to rebut the Examiner’s reasonable presumption. Accordingly, we affirm the rejection of claim 1. Claims 2-9 and 14-17 fall with claim 1.

Claims 20-29

Claims 20-29 are argued as a group (App. Br. 6). We have selected claim 20 as representative of the group for the purpose of deciding the

¹ Compare instant claim 32 reciting that the polymer can be poly L-lactic acid and polyglycolic acid with Igaki’s teaching that polymer can be poly-lactic or poly-glycolic acid (FF 4; Ans. 5).

rejection. Claims 21-29 fall with claim 20 because separate arguments for their patentability were not provided. 37 C.F.R. § 41.37(c)(1)(vii).

Claim 20 is directed to a “stent material” of a “biodegradable polymer.” The biodegradable polymer is “swollen and impregnated with a drug.” A layer of “biodegradable polymer” is on the surface.

Example of 5 of Igaki describes a stent body made of a high-melting biodegradable polymer fiber coated with a solution of a drug-containing low-melting biodegradable polymer which is knitted to form a stent body (FF 7, 8). The drug is dissolved in a solution comprising the low-melt polymer and solvent (FF 3). Dissolving the polymer in a solvent would swell it; the drug, when dissolved in the solution of swelled polymer, would diffuse and permeate into it – and therefore would impregnate the polymer. Thus, the stent body described by Igaki in Example 5 is comprised of a biodegradable material “swollen and impregnated with drug” as recited in claim 20. Furthermore, the stent body comprising drug can be “coated with the low-melting biodegradable polymer solution” (FF 9), and thus meets the claim limitation that the stent has a “biodegradable polymer layer” on its surface. In sum, Igaki describes a stent which meets all the limitations of claim 20, anticipating it.

Appellants contend that claim 20 is not anticipated by Igaki for the same reasons as claim 1 (Reply Br. 3). We are not persuaded by this argument. As discussed above for claim 1, there is sound basis for believing that a biodegradable polymer prepared in accordance with Igaki (*see* FF 3, 8) would be “swollen” and “impregnated with a drug” as required by claim 20, shifting the burden to Appellants to provide rebuttal evidence or arguments. Since Appellants have not provided any reason to doubt this reasonable

presumption, we affirm the rejection of claim 20. Claims 21-29 fall with claim 20.

Claim 31

Claim 31 is dependent on claim 1, and further requires that the polymer is selected from a list of high-melting point polymers, including poly L-lactic acid and polyglycolic acid. These polymers are disclosed by Igaki (FF 4). Thus, the Examiner finds that all elements of claim 31 are described by Igaki (Ans. 3, 5).

Appellants argue that Igaki does not describe a high-melting point polymer, such as those recited in claim 31, impregnated with drug (App. Br. 4; Reply Br. 4).

We are not persuaded by this argument. Claim 1, as we have interpreted it, does not require the polymer to be impregnated with drug – only that it be capable of becoming swollen and impregnated. Consequently, we affirm this rejection for the same reasons as for claim 1.

Claim 32

Claim 32 is dependent on claim 20, and further requires that the polymer is selected from a list of high-melting point polymers, including poly L-lactic acid and polyglycolic acid. The high-melting polymer is required by the claim to be “swollen and impregnated with drug.”

Appellants argue that the Igaki does not describe the claimed high melting point polymers combined with drug (App. Br. 7-8) and that Igaki “teaches against the use of high point polymers . . . since they might negatively affect the drugs to be dissolved in the melted polymer to form the stent (*id.* at 8).

We agree with Appellants. Igaki specifically states that the drugs are required to be in a low melting polymer (FF 5, 6); these polymers are not the same as those which are recited in claim 32. Thus, Igaki does not meet all the limitations of the claimed invention. Accordingly, we reverse the rejection of claim 32.

Claim 33

Claim 33 is dependent on claim 20, and further requires that the biodegradable polymer layer on the surface of the biodegradable polymer material is selected from a list of high-melting point polymers, including poly L-lactic acid and polyglycolic acid.

Appellants argue that Igaki does not describe a high melting point polymer layered on a biodegradable polymer (App. Br. 8).

We agree with Appellants. In each case where Igaki describes a polymer coating layered on another biodegradable polymer, the coating is of a low-melting point polymer, none of which are disclosed to be those recited in claim 33 (*see e.g.*, FF 7, 9). Thus, Igaki does not meet all the limitations of the claimed invention. Accordingly, we reverse the rejection of claim 33.

Anticipation by Hossainy

Claims 1, 5-21, and 24-30 stand rejected as anticipated under 35 U.S.C. § 102(b) by Hossainy.

Claims 1, 5-10, and 14-19

Claims 1, 5-10, and 14-19 are argued as a group (App. Br. 8). We have selected claim 1 as representative of the group for the purpose of deciding the rejection. Claims 5-10 and 14-19 fall with claim 1 because separate reasons for their patentability were not provided. 37 C.F.R.

§ 41.37(c)(1)(vii).

Claim 1 is directed to a luminal stent “formed of a biodegradable polymer material to a shape of a tube.” The claim states that the “biodegradable polymer material becomes swollen to be impregnated with a drug” but does not require it be in this state when formed into a stent.

The Examiner finds that Hossainy describes a stent comprising a biodegradable polymer which includes the same polymers – including aliphatic polyesters – which are disclosed as suitable for the stent of claim 1 (FF 10; Ans. 4; compare instant claim 6 which states that the “biodegradable polymer material is an aliphatic polyester”). The Examiner also finds that when the drug particles are dissolved in a solution of the polymer, the polymer become “swollen to be impregnated with a drug” (Ans. 4-6).

Appellants argue that “Hossainy makes no mention of a ‘swollen’ polymer, but only speaks of a polymer and a drug dissolved in a common solvent to form a wet solution coating a stent (see Hossainy at column 8, lines 58-60). Hossainy does not even suggest that the material forming the stent itself might be swollen” (App. Br. 9).

We are not persuaded by Appellants’ argument. Claim 1, as we have interpreted it, does not require the biodegradable polymer to be swollen and impregnated with drug; only that it be capable of achieving this state. As the claimed stent may be comprised of the same biodegradable polymers disclosed in Hossainy (*see* FF 10; instant claim 6), the Examiner had sound basis for presuming that such polymers would be capable of becoming swollen and impregnated with drug as in claim 1. “[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In*

re Spada, 911 F.2d 705, 708 (Fed. Cir. 1990). Appellants have not provided adequate arguments or evidence to rebut the Examiner's reasonable presumption. Accordingly, we affirm the rejection of claim 1. Claims 5-10 and 14-19 fall with claim 1.

Claims 11-13

Claim 11 is directed to a method for manufacturing a luminal stent comprising "permitting swelling of a stent formed of a biodegradable polymer material by a supercritical fluid in a pressurized vessel to allow impregnation of said biodegradable polymer material with a drug."

The Examiner has not pointed to any disclosure in Hossainy which describes the process steps recited in claim 11. Because we agree with Appellants that the claimed process is not described in Hossainy (FF 13), we reverse the rejection of claims 11-13.

Claims 20, 21, and 24-30

Claims 20-29 are argued as a group (App. Br. 11). We have selected claim 20 as representative of the group for the purpose of deciding the rejection. Claims 21-29 fall with claim 20 because separate arguments for their patentability were not provided. 37 C.F.R. § 41.37(c)(1)(vii).

Claim 20 is directed to a stent of a "biodegradable polymer." The biodegradable polymer is "swollen and impregnated with a drug." A layer of "biodegradable polymer" is on the surface.

The Examiner finds that

discloses a luminal vascular implant comprising biodegradable polymers impregnated with drugs (abstract). The woven polymers include aliphatic polyesters (col. 3, lin.3-21), and the drugs include well know anti-thrombogenic agents (col. 7, lin. 56-col. 8, lin. 57). The coatings can be additive along with the

active agents, having separate polymers and separate drugs in each successive layer (col. 7, lin. 10-17; col. 8, lin. 35-57).

(Ans. 4.)

Appellants argue

Hossainy at most teaches that a film forming polymer coating containing a pharmaceutic[al] agent may be coated on the outside of the material forming a stent (see Hossainy at column 5, lines 39-40 and column 8, lines 36-38). Hossainy, however, fails to even suggest that a polymer material forming a stent itself might be impregnated with a drug rather than just coated with a drug containing coating. The Examiner is of the opinion that impregnation means “To fill throughout; saturate” (see the Final Office Action at page 3, paragraph 7) (a full citation is not provided by the Examiner for the suggested definition). Even in view of the definition of “impregnation” suggested in the Final Office Action, Hossainy fails to disclose a stent impregnated with a drug, since a mere drug-containing coating on the outer surface of a biodegradable polymer material forming a stent does not equate to a biodegradable polymer material forming a stent which is “filled throughout or saturated” with a drug.

(App. Br. 11-12).

This argument is not persuasive. Appellants state that Hossainy does not describe “a stent impregnated with a drug” (*id.* at 12). However, claim 20 is not directed to a stent, but a “stent material” (*see supra* at p. 5, “Claim Interpretation”). Appellants concede that Hossainy teaches a polymer coating containing a drug (*id.* at 11). The Examiner finds that dissolving the drug in a solvent containing a polymer would result in the polymer becoming swollen and impregnated with drug (*see* Ans. 4; *see* FF 12). Given this logic and the finding that Hossainy describes coating polymers which are the same as those which are claimed (*see* FF 10; instant 31), the Examiner had sound basis for presuming that such polymers would also be capable of becoming swollen and impregnated with drug as in claim 20.

Appeal 2007-4138
Application 10/182,271

“[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *Spada*, 911 F.2d at 708 (Fed. Cir. 1990). Appellants do not provide adequate arguments or evidence to rebut the Examiner’s reasonable presumption. Accordingly, we affirm the rejection of claim 20. Claims 21 and 24-30 fall with claim 20.

CONCLUSION

In summary, we affirm the rejections of claims 1-10 and 14-31. We reverse the rejections of claims 11-13, 32, and 33.

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

Ssc:

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