

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte MARLENE SCHWARZ and ROBERT RICHARD

Appeal 2008-2442
Application 10/174,286
Technology Center 1600

Decided: June 17, 2008

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and JEFFREY
N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a therapeutic agent releasing medical device which the Examiner has rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Background

“Numerous medical devices have been developed for the delivery of therapeutic agents to the body” (Spec. 1). The Specification notes that “[o]nce the medical device is placed at the desired location within a patient, the therapeutic agent is released from the medical device at a rate that is dependent upon the nature of the polymeric carrier and/or barrier layer” (Spec. 1). The Specification indicates that “there is a continuing need for polymeric layers, including polymeric barrier layers and carrier layers, which are able to provide a broad range of therapeutic agent release rates” (Spec. 1).

Statement of the Case

The Claims

Claims 1-34 are on appeal.¹ We will focus on claim 1, which is representative and reads as follows:

1. A therapeutic-agent-releasing medical device comprising:
 - (a) an implantable or insertable medical device;
 - (b) a release layer disposed over at least a portion of the implantable or insertable medical device, said release layer comprising (i) a first polymer comprising one or more polymer chains that form one or more polymer phase domains when the first polymer is in a pure solid-state form; and (ii) a second polymer comprising two or more polymer chains that form two or more phase domains when the second polymer is in a pure solid-state form, wherein at least one polymer chain in the second polymer is compatible with at least one polymer chain in the first polymer; and

¹ Appellants acknowledge that claims 1-34 are under appeal in the Reply Brief filed May 10, 2007.

(c) a therapeutic agent, wherein said release layer regulates the rate of release of the therapeutic agent from the medical device upon implantation or insertion of the device into a patient

The prior art

The Examiner relies on the following prior art reference to show unpatentability:

Samson	US 5,827,201	Oct. 27, 1998
Schwarz	US 6,368,658 B1	Apr. 9, 2002

The issues

The rejections as presented by the Examiner are as follows:

Claims 1-34 stand rejected under 35 U.S.C. § 103(a), as being obvious over Samson and Schwarz (Ans. 3).

35 U.S.C. § 103(a) rejection over Samson and Schwarz

The Appellants argue that

The concept of miscibility of (a) at least one polymer chain of a first polymer that comprises one or more polymer chains with (b) at least one polymer chain of a second polymer that comprises two or more polymer chains, in a single release layer, however, is not taught or suggested in Samson.

(App. Br. 6). Appellants then contend that “Schwarz is directed to a coating process, as opposed to the composition of the coatings so formed. Numerous polymers are disclosed, but only generally. There is no specific disclosure that would suggest a combination of first and second polymers as recited in the present claims” (App. Br. 6).

Appellants also argue that “it is exceedingly unlikely that the selection and combination of any two polymers will lead to a situation in which at least one polymer chain in the first polymer is compatible with at least one polymer chain in the second polymer, as presently claimed in claims 1 and 16” (App. Br. 7).

The Examiner responds that the “201 [Samson] patent provides an implantable device with a polymeric coating comprised of two polymers, where the first and/or second polymer can be copolymers, homo-polymers etc.” (Ans. 6). The Examiner then argues that “selection of particular polymers is well within the level of skill in the art, as shown in the [Schwarz] '658 [patent]” (Ans. 6).

In view of these conflicting positions, we frame the obviousness issues before us as follows:

Would it have been obvious to a person of ordinary skill to utilize the drug releasing polymers of Schwarz on the device of Samson where the coating is composed of multiple layers of polymers?

Findings of Fact

1. Samson teaches an insertable medical device which is a “guidewire suitable for introduction into the vasculature of the brain” (Samson, col. 4, ll. 9-10). Sampson teaches that the guidewire is “a catheter guidewire” (Samson, col. 1, ll. 24-25).

2. Samson teaches that the device includes “a polymeric layer placed over some or all of the assembled metallic components which layer may be coated with an additional lubricious polymer coating” (Samson, col. 4, ll. 19-21).

3. Samson teaches multiple polymer layers, noting that “[a]ll or part of the guidewire core and braid may be covered or coated with one or more layers of a polymeric material” (Samson, col. 11, ll. 49-50).

4. Samson teaches that the polymers may include a first polymer with two domains such as “block or random copolymers” (Samson, col. 12, l. 18).

5. Samson discloses that “[s]uitable monomers include ethylene, propylene, styrene, styrene derivatives, alkylmethacrylates, vinylchloride, vinylidenechloride, methacrylonitrile, and vinyl acetate” (Samson, col. 12, ll. 30-33).

6. Schwarz teaches that the “medical devices used in conjunction with the present invention include any device amenable to the coating processes described herein” (Schwarz, col. 3, ll. 41-43).

7. Schwarz teaches that the medical devices include a variety of implantable devices including “catheters, needle injection catheters” (Schwarz, col. 3, ll. 52-53).

8. Schwarz teaches coating the devices, where “the coating materials comprise therapeutic agents, applied to the medical devices alone or in combination with solvents in which the therapeutic agents are at least partially soluble or dispersible or emulsified, an/or in combination with polymeric materials as solutions, dispersions, suspensions, latices” (Schwarz, col. 4, ll. 1-6).

9. Schwarz teaches “polymeric materials employed as, for example, primer layers for enhancing subsequent coating applications . . . layers to control the release of therapeutic agents” (Schwarz, col. 6, ll. 6-13).

10. Schwarz teaches additional layers in which polymeric materials may also be used including “protective layers for underlying drug layers . . . biodegradable layers, biocompatible layers . . . layers to facilitate device delivery . . . drug matrix layers (i.e., layers that adhere to the medical device and have therapeutic agent incorporated therein or thereon for subsequent release into the body)” (Schwarz, col. 6, ll. 17-31).

11. Schwarz discloses a very large variety of polymers for use in drug matrix layers (*see* Schwarz, col. 6, ll. 32-67).

12. Schwarz teaches that “[i]t is also within the scope of the present invention to apply multiple layers of the same or different coating materials, which may perform identical or different functions” (Schwarz, col. 7, ll. 28-30).

13. Schwarz discloses an example in which stents are coated with multiple layers of a copolymer of polylactic acid and polyglycolic acid with differing concentrations of the polymers in different layers (*see* Schwarz, col. 14, ll. 41-55).

14. Schwarz teaches a large variety of therapeutic agents noting “therapeutic or bioactive agents used in conjunction with the present invention include, for example, pharmaceutically active compounds, proteins, oligonucleotides, ribozymes, anti-sense genes, DNA compacting agents, gene/vector systems)” (Schwarz, col. 4, ll. 15-19). Schwarz continues to disclose a variety of general and specific therapeutic agents (*see* Schwarz, col. 4, l. 20 to col. 5, l. 61).

15. Schwartz teaches that the “suspended medical devices to be coated could be sprayed first with a polyfunctional condensation monomer

followed by spraying with a complementary condensation polyfunctional monomer to provide a polymer coating by *interfacial* polymerization” (Schwartz, col. 10, ll. 4-8, emphasis added).

Discussion of 35 U.S.C. § 103(a) over Samson and Schwarz

Claim 1 is drawn to a device with a release layer disposed over “a portion of the implantable or insertable device” where the release layer comprises “a first polymer comprising one or more polymer chains that form one or more polymer phase domains” and “a second polymer comprising two or more polymer chains that form two or more phase domains” and where “at least one polymer chain in the second polymer is compatible with at least one polymer in the first polymer” (*see* Claim 1).

In analyzing claim 1, our mandate is to give claims their broadest reasonable interpretation.

Giving claims their broadest reasonable construction “serves the public interest by reducing the possibility that claims, finally allowed, will be given broader scope than is justified.” *Yamamoto*, 740 F.2d at 1571; accord *Hyatt*, 211 F.3d at 1372; *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989) (“An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.”).

In re American Academy of Science Tech Center, 367 F.3d 1359, 1364, (Fed. Cir. 2004).

Appellants Specification defines a release layer as “a layer that regulates the release of at least one therapeutic agent” (Spec. 4, ¶ 0022). The Specification identifies a wide variety of polymers which can be used in the release layer (*see* Spec. 5-6, ¶ 0027). The Specification notes the first polymer can be “a homopolymer, a random copolymer, or an alternating copolymer” while the second polymer can be a “block copolymer or graft copolymer, in which case multiple phase domains are typically formed”. The Specification indicates that the polymers should be “compatible” (*see* Spec. 5, ¶ 0026), and states that “[t]wo polymer chains are said to be compatible when the phases that correspond to these chains exhibit at least some degree of interfacial mixing” (Spec. 2, ¶ 0006).

We therefore interpret the term “compatible” as simply requiring that the polymers can be placed in layers adjacent to one another with some “interfacial mixing”. Consequently, we interpret the requirement of claim 1 for a first and second compatible polymer as broadly encompassing the situation where multiple polymer layers comprise the “release layer” and where these multiple layers may be “compatible” with one another where some “interfacial mixing” may occur.

Samson teaches an insertable medical device which is a guidewire in a catheter (FF 1). Samson teaches that the device may be coated in multiple polymeric layers (FF 2-3). Samson teaches that these polymeric layers may include polymers with one polymer chain and block copolymers with two phase domains (FF 4-5). The Examiner acknowledges that Samson does not teach inclusion of a therapeutic agent into the polymeric layers (Ans. 4).

The Examiner relies upon Schwarz for the disclosure that therapeutic agents may be incorporated into polymeric layers on insertable and implantable medical devices, including catheters (FF 6-8). Schwarz teaches that the release layer may be composed of multiple polymeric layers and may also be placed between multiple polymeric layers (FF 9-13). Schwarz teaches a variety of different polymeric materials including copolymers which may be used to form the multiple layers (FF 11-13). Schwarz teaches therapeutic agents which may be subjected to regulated rates of release by the polymeric layers (FF 13-14). Schwarz also teaches that the polymer layers may be laid down to permit interfacial polymerization, rendering the polymers “compatible” as discussed above (FF 15).

The obviousness case rests on whether a person of ordinary skill in the art would have considered it obvious to coat the catheter device of Samson with multiple polymeric layers, including a release layer with polymer and copolymer layers to release therapeutic agents as disclosed by Schwarz in insertable medical devices such as catheters (*see* FF 1-14).

We conclude that the Examiner has set forth a prima facie case that claim 1 would have been obvious to the ordinary artisan in view of Samson and Schwarz. In *KSR*, the Supreme Court indicated that “[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability.” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007). In the instant case, using the multiple polymeric layers of Schwarz with therapeutic agents in the guide wire and catheter of Samson would have

been a known and predictable way to incorporate drug release into an insertable medical device (*see* FF 1-3, 6-10, 15).

We are not persuaded by Appellants' arguments that there is "no specific disclosure that would suggest a combination of first and second polymers as recited in the present claims" (App. Br. 6). In fact, Schwarz expressly teaches combinations of polymer layers, where the layers may involve the same or different functions, including drug release, lubricity, and biocompatibility (FF 9-11). There is immense disclosure in Schwarz to combine polymers into multiple layers to achieve goals including release rates (FF 12). As Schwarz states "[i]t is also within the scope of the present invention to apply multiple layers of the same or different coating materials, which may perform identical or different functions" (Schwarz, col. 7, ll. 28-30). Schwarz expressly teaches that monomers may be selected which have some "interfacial polymerization" and are therefore "compatible" (FF 15).

We are also not persuaded by Appellants' argument that "[t]here is no disclosure, however, of *how* one is to vary the polymer structure and formulation to control release rate or profile, much less how one of ordinary skill would go about selecting specific combinations of polymers for use within a release layer (App. Br. 6). Schwarz exemplifies a situation in which multiple layers of different polymer composition are sequentially coated onto a device in order to result in different release rates (FF 12).

Additionally, Schwarz recognizes that the

release rate of drugs from drug matrix layers is largely controlled, for example, by variations in the polymer structure and formulation, the diffusion coefficient of the matrix, the solvent composition, the ratio of drug to polymer, potential chemical reactions and interactions

between drug and polymer, the thickness of the drug adhesion layers and any barrier layers, and the process parameters.

(Schwarz, col. 7, ll. 3-9.) Thus, Schwarz is expressly teaching the variables involved in controlling the release rate of drugs from the drug matrix layers. Given Schwarz's extensive discussion of polymeric drug matrix layers and teaching to use such layers on catheters (FF 7-13), where the Samson device is a catheter with a guidewire (FF 1-2), we conclude that such a combination is merely a "predictable use of prior art elements according to their established functions." *KSR*, 1727 S. Ct. at 1740.

We disagree with Appellants' conclusion that the prior art teaches that "one cannot combine two different polymers and readily achieve compatibility between the chains of the polymers" (App. Br. 7). While the Kumar article states that blending polymers is a "tricky business," solutions to this problem are known to the skilled artisan, including the use of copolymers (*see* Kumar 2-3), which are taught by both Schwarz and Samson (FF 4, 13, 15). In fact, Schwarz exemplifies such a situation (*see* Schwarz, col. 10, ll. 4-15). This supports a conclusion that the ordinary artisan would have had a reasonable expectation of success. *See In re O'Farrell*, 853 F.2d 894, 903-04, (Fed. Cir. 1988) ("Obviousness does not require absolute predictability of success. . . . For obviousness under § 103, all that is required is a reasonable expectation of success.")

We are also not persuaded by Appellants' arguments that "the present specification demonstrates unobvious results adequate to rebut any possible *prima facie* case". All of Appellants' examples in the Specification use the present tense. Example 1 begins "[s]olutions are provided that contain

99wt% chloroform . . . One solution is prepared . . . A second solution is prepared” (Spec. 20). Since the examples were written in the present tense, they are presumed prophetic and do not represent actual evidence. *See Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1578 (Fed. Cir. 1984)(“the examples were written in the present tense to conform with the PTO requirements on prophetic examples.) Consequently, Appellants’ “results” are not actually data or factual evidence. “It is well settled that unexpected results must be established by factual evidence. Mere argument or conclusory statements in the specification does not suffice.” *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984).

Finally, regarding Appellants’ comments on the dependent claims, we note that pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), “[a] statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim.”

We affirm the rejection of claim 1 as obvious over Samson and Schwarz. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 2-34 as these claims were not argued separately.

CONCLUSION

In summary, we affirm the rejection of claim 1 under 35 U.S.C. § 103(a). Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 2-34 as these claims were not argued separately.

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)(2006).

AFFIRMED

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