UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte EUGENE TEDESCHI

Appeal 2008-3144
Application 10/133,156
Technology Center 3700

Decided: August 28, 2008

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

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1-6 and 31-42. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to a stent delivery system. Claim 1 is representative of the claims on appeal, and reads as follows:

1. A stent delivery system comprising:
a catheter;
a balloon operably attached to the catheter; and
a stent disposed on the balloon;
wherein the stent further comprises a stent frame and a coating applied to the stent frame, the coating having at least one crimpable zone, at least one regular zone, and containing a therapeutic agent.

31. A stent delivery system comprising:
a catheter;
a balloon operably attached to the catheter; and
a stent disposed on the balloon;
wherein the stent further comprises a stent frame and a coating applied to the stent frame, the coating having at least one crimpable zone, at least one regular zone, and containing a therapeutic agent, the crimpable zone having sufficient hardness to maintain the coating on the stent frame after the stent is crimped on the balloon.

The Examiner relies on the following references:

Dinh	US 5,697,967	Dec. 16, 1997
Zhong	US 6,368,356 B1	Apr. 09, 2002

We reverse.

ISSUE (Obviousness)

The Examiner contends that claims 1-6 and 31-42 are obvious over the combination of Dinh and Zhong (Ans.[1] 3).

Appellant contends that there is no reason to combine the teachings of Dinh and Zhong. Specifically, Appellant contends that the alternating zones of the coating on the stent of Zhong is used in stents that are to be eventually expelled from the body, and thus one would not want to use a stent frame as taught by Dinh (App. Br. 12).

Thus, the issue on Appeal is: Does the combination of Dinh and Zhong teach a stent having a coating, wherein the coating has both a "crimpable" zone and a "regular zone"?

FINDINGS OF FACT

FF1. The Specification teaches:

> The expandable stent with a crimpable coating of the present invention provides an expandable stent with a coating containing a drug or therapeutic agent that can be crimped to a balloon according to conventional methods without damaging the coating. The stent comprises a stent frame, and a coating applied over the stent frame with the coating having at least one crimpable zone and containing a therapeutic agent. In one embodiment, the length of the crimpable zone can be much less than the length of the stent and the crimpable zone can have a higher durometer value than the remainder of the coating. In

[1] All references to the Answer (Ans.) are to the Supplemental Examiner's Answer mailed December 3, 2007.

> another embodiment, the coating in the crimpable zones can form rails to protect the coating in the regular coating zones.

(Specification 4).

FF2. According to the Specification, the crimpable zones may have a durometer value from about 90A to 70D, and more preferably in the range of 40D to 50D (Spec. 8).

FF3. The crimpable zones may be formed by uniformly coating the stent, and then exposing a portion of the coating to a treatment such as UV light or a photoinitiator, such that the polymer becomes cross-linked and hardens (Spec. 8-9). The treatment allows the polymer to become "strong enough in the crystalline state to withstand crimping without substantially cracking or deforming, so that the coating remains on the stent until the stent is deployed." (Spec. 8.) "[T]o . . . form the crimpable zones . . ., the polymer must be able to undergo a change from an amorphous state to a more durable crystalline state under a hardening treatment." (*Id.*).

FF4. In an alternative embodiment of forming crimpable zones, the stent may be coated with a uniform base coating layer and then coated with a second coating layer in the crimpable zone (Spec. 9).

FF5. The hardening of the crimpable zone can be made reversible so that the coating in the crimpable zone behaves like the coating in the regular zones (Spec. 11).

FF6. Claims 1-6 and 31-42 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Dinh and Zhong (Ans. 3).

FF7. Dinh is cited by the Examiner for teaching a balloon catheter with a coated stent, wherein the coating may include materials such as polyurethane and acrylate polymers, as well as therapeutic agents such as anti-inflammatory agents and anti-oxidants (Ans. 3-4).

FF8. According to the Examiner, "Dinh fails to form a zone of the coating to have a higher durometer value in the range of 40D-50D." (Ans. 4.)

FF9. Zhong is cited for teaching another type of implant, wherein the implant has a polymeric coating, wherein the polymer may be a coating on a stent and may include a drug (Ans. 4).

FF10. Zhong is further cited for teaching that cross-linking the polymer while the stent is compressed helps the stent to retain the conformation for insertion (Ans. 4 (citing Zhong col. 17, ll. 8-22)).

FF11. According to the Examiner, Zhong discloses that alternating different material properties along the length of the stent is helpful for obtaining desired shapes and functions (Ans. 4), and that the stent coating may be formed from zones of cross-links and non-cross-linked polymer (Ans. 5 (citing Zhong col. 3, ll. 32-45)).

FF12. The Examiner notes that Zhong teaches that the initial durometer value for the polymer is between 50-100 Shore A, and the Examiner finds that 90 Shore A roughly corresponds to a 40-50 Shore D durometer value (Ans. 4).

FF13. The Examiner concludes that it "would have been obvious to one of ordinary skill in the art at the time the invention was made to include cross-linked zones in the Dinh coating that have a durometer value of about 40D-

50D, as Zhong teaches that the harder zones help to maintain a compressed configuration of the stent and the mechanical properties of the stent can be altered for various functions." (Ans. 4.) The Examiner concludes further that since "the cross-linked segments have a higher durometer value, thay are considered to meet the limitation 'crimpable zone.'" (*Id.*)

FF14. Zhong teaches "a means of boosting the mechanical performance of shaped . . . medical devices comprising polymer hydrogels, such as stents, so that they may be more easily inserted into or removed from the body (Zhong Abstract).

FF15. Zhong teaches further:

> Crosslinks may be distributed homogeneously or heterogeneously throughout polymer that forms the shaped medical device. In one embodiment of the invention, a shaped medical device comprises a polymer having a heterogeneous distribution of non-ionic and ionic crosslinks and a variable dissolution or degradation rate along its length. In another embodiment of the invention, the shaped medical device comprises alternating segments of ionically crosslinked and non-ionically crosslinked polymer. The length of a segment may be varied to adapt the shaped medical device to a pre-selected dissolution and/or degradation rate. In still a further embodiment of the invention, segments of non-dissolvable polymer are included. In this embodiment, the non-dissolvable polymer may be in the form of a string or a mesh.

(Zhong col. 3, ll. 32-45).

FF16. As to heterogenous polymers, Zhong teaches:

> In one embodiment of the invention, the crosslinkable polymer is also combined with short segments of non-

> dissolvable, non-disintegratable polymer(s), or biodegradable suture material to increase the versatility of the shaped medical device. The segments may be spaced at regular or irregular intervals. . . . . Suitable non-dissolvable polymers include, but are not limited to, silicones, and the like . . .
>
> In further embodiments of the invention, short or thin portions of non-dissolvable polymer, such as strings . . . or meshes. . ., are used because they generally are more easily eliminated from the body without creating obstructions. In another embodiment of the invention, a shaped medical device is provided which comprises a relatively straight section (e.g., the tubular body of a stent) which is reinforced with a biodegradable suture or braid, and a curved portion (e.g., the pigtail end of a stent) which is not reinforced. The curved portion anchors the shaped medical device at a particular location within the body. In this embodiment, the non-reinforced curved portion of the device weakens or degrades first. This allows the relatively straight section of the device to migrate to a point of egress (e.g., in the case of a ureteral stent, to the bladder).
>
> Alternatively, the shaped medical device according to the present invention includes a weak point, or break point, in a relatively straight section of the device proximal to a curved section of the device.

(Zhong col. 9 l. 58-col. 10 l. 20).

FF17. In the embodiment relied upon by the Examiner for teaching that cross-linking the polymer while the stent is compressed helps the stent to retain the conformation for insertion, Zhong teaches:

> In another aspect of the invention, an ionically crosslinkable polymer is formed into a primary shape and subjected to both non-ionic and ionic crosslinking conditions to form a crosslinked polymer having the primary shape and

> containing both ionic and non-ionic crosslinks. In this embodiment, an ionically and non-ionically crosslinked shaped polymer is prepared . . . . Then, the shaped polymer is selectively stripped ex vivo of at least a portion or essentially all of the crosslinking ions; the shaped polymer is then conformed to a secondary shape, e.g., bent around a wire, stretched, compressed, or the like. The shaped polymer is subsequently ionically re-crosslinked while retained in the secondary shape. Release of the crosslinking ions in vivo will cause the implanted device to revert substantially to the original primary, non-ionically crosslinked shape. . . .
>
> This embodiment is particularly useful where the shaped medical device is of hollow, tubular configuration, such as a stent. Where the stent is both ionically and non-ionically crosslinked, it may be selectively stripped of crosslinking ions. In one embodiment, the stent is stretched to form a narrower stent which facilitates insertion into the body, ionically crosslinked or re-crosslinked in the stretched state to fix the stent in the stretched state, implanted in the body and then re-stripped in vivo of the ionic crosslinks to produce a softer shaped device having a wider lumen.

(Zhong col. 16 l. 56-col. 17 l. 22.)

FF18. As to the hardness of the crimpable zone relied upon by the Examiner, Zhong teaches that in the context of a ureteral stent (Zhong col. 12, l. 58-col. 13, l. 30). The stent initially has a higher durometer for ease of placement, and the durometer is reduced after placement to enhance patient comfort while it is used as a stent (*id.*).

FF19. Finally, Zhong provides an example of an ureteral stent having segments of varying polymer types. Specifically, Zhong teaches:

> In FIG. 1, a shaped medical device in the form of a ureteral stent 10 is shown having a pigtail end 16 for positioning into the kidney of a patient, a tubular elongate body 12 for positioning into the ureter, and a second pigtail end 17 for positioning into the bladder. The stent 10 optionally comprises drainage holes 14, throughout the elongate body 12 and the pigtail ends 16 and 17. The stent 10 is molded or extruded from at least two different materials arranged in segments 18 and 20. Each segment may comprise: (1) an entirely ionically crosslinked hydrogel; (2) an entirely non-ionically crosslinked hydrogel; (3) a mixture of non-ionically and ionically crosslinked hydrogels; or (4) non-dissolvable polymer. In the embodiment shown in FIG. 1, segment 18 is a non-dissolvable polymer while segment 20 comprises at least ionic crosslinks. In this embodiment, segments 18 and 20 are alternatively distributed along the length of the stent body at regular intervals. The length of segment 18 is short relative to the length of segment 20 to facilitate removal of the non-dissolvable portion of the stent from the body.

(Zhong col. 20, ll. 48-67.)

PRINCIPLES OF LAW

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has recently emphasized that "the [obviousness] analysis 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 v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). In assessing the prior art, each prior art reference must be considered in its entirety in an obviousness determination. *In re Wesslau*, 353 F.2d 238, 241 (CCPA 1965). Moreover, in order to facilitate review of the obviousness determination, the "analysis should be made explicit." *KSR,* 127 S.Ct. at 1741.

ANALYSIS

Claims 1 and 31, the independent claims on appeal, both require that the stent coating have at least one "crimpable zone" and at least one "regular zone." The Examiner interpreted the "crimpable zone" as being a zone of the coating on the stent that is harder that the "regular zone." (Ans. 5; *see also* App. Br. 10.) We agree with that interpretation, as the Specification teaches that crimpable zone have a higher durometer value than the remainder of the coating (Spec. 4), wherein the crimpable zones may have a durometer value from about 90A to 70D, and more preferably in the range of 40D to 50D (Spec. 8)

We do not agree, however, that the combination of Dinh and Zhong renders such a stent obvious. While Zhong teaches that crosslinks may be distributed homogeneously or heterogeneously throughout polymer that forms the shaped medical device (FF15), when teaching the heterogenous polymers, Zhong teaches that the crosslinkable polymer is combined with short segments of non-dissolvable, non-disintegratable polymers, or

biodegradable suture material, wherein the non-dissolvable, non-disintegratable polymers may be a silicone, or may be a mesh or string which are more easily eliminated from the body without creating an obstruction (FF16).

The Examiner finds that Zhong teaches cross-linking the polymer while the stent is compressed helps the stent to retain the conformation for insertion (FF11). However, the section of Zhong relied upon is drawn to ionically crosslinking the stent as a whole, and then removing the crosslinking *in vivo* to make the stent more comfortable to the patient (FF17). Finally, as to Example 7 of Zhong, the example is drawn to a ureteral stent, wherein the alternatively distributed segments of differently cross-linked gels are to facilitate removal from the body (FF18 and FF19).

Thus, to summarize, while Zhong teaches "a means of boosting the mechanical performance of shaped . . . medical devices comprising polymer hydrogels, such as stents, so that they may be more easily inserted into or removed from the body" (FF14), that teaching must be considered in the context of the teachings of the reference as a whole. However, when Zhong crosslinks the polymer coating of the medical device, an ionic crosslinking is added to the entire device, and then removed *in vivo* for patient comfort (FF17) and thus does not meet the limitations of claims 1 of a crimpable and regular zone. As to using heterogenous crosslinking, Zhong teaches that in the context of a device wherein the second polymeric material is a biodegradable suture, string, or mesh (FF16), or in the context of a stent that naturally degrades and is excreted from the body, such as a ureteral stent

(FF17-FF19). As the Examiner has not provided any reason as to why the ordinary artisan would use a heterogenous polymer coating wherein a portion of the coating is biodegradable suture, string, or mesh, or wherein the coating is used in the context of a stent that degrades and is excreted from the body, for the coating of the balloon stent taught by Dinh, we are compelled to reverse the rejection.

CONCLUSIONS OF LAW

We conclude that the Examiner has not set forth a prima facie case that the combination of Dinh and Zhong teaches a stent having a coating, wherein the coating has both a "crimpable" zone and a "regular zone" as required by claims 1 and 31, the independent claims on appeal. Thus, the Examiner has not set forth a prima facie case of obviousness, and we are compelled to reverse the rejection of claims 1-6 and 31-42 under 35 U.S.C. § 103(a) as being obvious over the combination of Dinh and Zhong.

REVERSED

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