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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/043,021	03/08/2011	GAVIN Paul ANDREWS	ROVI-4-CIP	8070

24039 7590 08/20/2020

INNOVAR, LLC
P O BOX 250647
PLANO, TX 75025

EXAMINER	
BARHAM, BETHANY P	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
08/20/2020	ELECTRONIC

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte GAVIN PAUL ANDREWS, DAVID SIMON JONES, and SEAN PATRICK GORMAN

Appeal 2019-006212
Application 13/043,021
Technology Center 1600

Before JEFFREY N. FREDMAN, TAWEN CHANG, and JAMIE T. WISZ, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal[1,2] under 35 U.S.C. § 134 involving claims to a urinary catheter or stent composed of a multilayered device comprising plural coextensive and centrically arranged layers. The Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the Real Party in Interest as Laboratorios Farmaceuticos ROVI, S.A. (*see* Appeal Br. 2).

[2] We have considered and refer to the Specification of Mar, 8, 2011 ("Spec."); Final Action of Oct. 5, 2018 ("Final Act."); Appeal Brief of Mar. 4, 2019 ("Appeal Br."); Examiner's Answer of June 27, 2019 ("Ans."); and Reply Br. of Aug. 21, 2019.

Statement of the Case

Background

"[P]atients are often plagued by infection associated with the insertion of a medical device and this is seen to be one of the most critical disadvantages of an otherwise highly effective and beneficial medical treatment" (Spec. ¶ 3). "Bacteria and pathogens which typically colonize catheters produce urease which degrades urea in urine to form carbon dioxide and ammonia. At increased pH associated with such degradation/ contamination, minerals in urine precipitate leading to encrustation" (*id.* ¶ 4).

> Catheter encrustation can cause blockage of the catheter leading to an increase in the frequency with which the catheter must be removed and replaced. Encrustation also results in an increase in the pain of removal of the catheter. The tissue surrounding the catheter is also far more likely to become infected. This is particularly problematic for patients requiring long term catheterization. Serious consequences include septicemia, pyelonephitis and shock.

(*id.* ¶ 5). "The inventors have developed a device surface that is inherently resistant to infection through the use of intelligent *in vivo* reactions and preferably impregnation with antibiotics" (*id.* ¶ 12).

The Claims

Claims 1, 28, 63, 78, 79, 81, 82, 84–87, 90–95, and 97–109 are on appeal. Claim 1 is representative and reads as follows:

> 1. A multilayered device comprising plural coextensive and centrically arranged layers, said layers defining a lumen, wherein:
> a first coextensive layer is a structural layer that is substantially non-degradable or non-erodible under physiological conditions; and

at least one second coextensive layer that is interior to the first coextensive layer, defines a lumen, and is a pH sensitive layer comprising 0.5 to 50% wt of functional excipient, which is at least one organic acid, and one or more pH sensitive linear polymers having a water solubility that increases from a first water solubility to a second water solubility at a pH trigger ranging from pH ≥ 5 up to about pH 7, whereby the one or more pH sensitive linear polymers undergoes dissolution, degradation, or erosion in an aqueous environment at the second water solubility, and the at least one organic acid retards the rate of dissolution, degradation or erosion of the one or more pH sensitive linear polymers;

wherein the layers are centrically arranged; and

the device is a urinary catheter or urinary stent.

The Issues[3]

A. The Examiner rejected claims 1, 28, 63, 78, 79, 81, 82, 84, 87, 90–95, 97–100, and 102–109 under 35 U.S.C. § 103(a) as obvious over Hunter[4] and Sarangapani[5] (Final Act. 3–8).

B. The Examiner rejected claims 85 and 86 under 35 U.S.C. § 103(a) as obvious over Hunter, Sarangapani, and Hanselle[6] (Final Act. 8–9).

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[3] The Examiner required a species election on April 17, 2013. In the response filed July 9, 2013, Appellant elected silicone as the exterior structural layer of the device and hydroxypropylmethycellulose acetate succinate as the pH sensitive polymer. We limit our consideration of the merits of the appealed rejection to the elected species. *See Ex parte Ohsaka*, 2 USPQ2d 1460, 1461 (BPAI 1987).

[4] Hunter et al., US 2005/0191331 A1, published Sept. 1, 2005.

[5] Sarangapani, S., US 5,877,243, issued Mar. 2, 1999.

[6] Hanselle et al., WO 2008/080932 A1, published July 10, 2008.

A. 35 U.S.C. § 103(a) over Hunter and Sarangapani

The Examiner finds that Hunter suggests "urinary stents defining a lumen in the form of tubes in which the devices are coated with a pH sensitive layer comprising applicant's elected species, HPMCAS, and further coated with a structural layer comprising applicant's elected species, silicone" (Final Act. 4). The Examiner finds Hunter teaches "devices with a pH sensitive layer interior to a structural layer where the layers are centrically arranged on devices defining a lumen" (*id.* at 5).

The Examiner acknowledges that Hunter does "not teach a pH sensitive layer comprising 0.5 to 50 wt.% of functional excipient, which is at least one organic acid" (Final Act. 5).

The Examiner finds Sarangapani teaches "coatings and materials that resist bacterial colonization and encrustation for use in medical devices and urological applications" including "acidic chelating components, like organic acids, to provide a continuous antibacterial surface" (Final Act. 5). The Examiner finds "Sarangapani discloses incorporating EDTA and carboxylic acids, like citric acid into its coatings . . . as set forth in instant claims 98 and 105-109" (*id.* at 5–6).

The issue with respect to this rejection is: Does a preponderance of the evidence of record support the Examiner's conclusion that Hunter and Sarangapani render claim 1 obvious?

Findings of Fact

1. The Specification teaches the "device of the present invention may typically be a urinary catheter or urinary stent" (Spec. ¶ 17).

2. The Specification teaches "structural layers may be included in the device of the present invention to provide structural support to the device

and to provide a body (surface) upon which one or more layers of linear pH sensitive polymer can be applied or built. . . . A structural layer can comprise . . . silicone" (Spec. ¶ 23).

3. The Specification teaches a linear pH sensitive polymer layer comprising a "linear pH sensitive polymer . . . selected from the group consisting of hydroxypropyl methylcellulose acetate succinate (HPMC-AS[])" (Spec. ¶ 31).

4. The Specification teaches the "pH sensitive layer may comprise one or more functional excipients . . . The functional excipients may suitably be buffer groups (organic acids) such as citric acid, tartaric acid, succinic acid, and fumaric acid, EDTA" (Spec. 54).

5. Hunter teaches "drug-coated implants and medical devices that reduce the foreign body response to implantation" and that are "used to maintain body lumens or passageways such as . . . the urinary tract" (Hunter ¶ 15).

6. Hunter teaches "a method for inhibiting scarring comprising placing a genital-urinary stent implant and an antiscarring agent or a composition comprising an anti-scarring agent into an animal host, wherein the agent inhibits scarring" (Hunter ¶ 21).

7. Hunter teaches "genital-urinary (GU) stents that can benefit from being coated with . . . polyurethane, poly(ethylene terephthalate), PTFE or silicone" (Hunter ¶ 652).

8. Hunter teaches:

> Polymeric carriers for fibrosis-inhibiting agents can be fashioned in a variety of forms, with desired release characteristics and/or with specific properties depending upon the device, composition or implant being utilized. For example,

> polymeric carriers may be fashioned to release a fibrosis-inhibiting agent upon exposure to a specific triggering event such as pH.

(Hunter ¶ 417).

9. Hunter teaches:

> Representative examples of pH-sensitive polymers include poly (acrylic acid) and its derivatives (including for example, homopolymers such as poly(aminocarboxylic acid); poly(acrylic acid); poly(methyl acrylic acid), copolymers of such homopolymers, and copolymers of poly(acrylic acid) and/or acrylate or acrylamide Imonomers such as those discussed above. Other pH sensitive polymers include polysaccharides such as cellulose acetate phthalate; hydroxypropylmethylcellulose phthalate; **hydroxypropyl-methylcellulose acetate succinate**; cellulose acetate trimellilate; and chitosan. Yet other pH sensitive polymers include any mixture of a pH sensitive polymer and a water-soluble polymer.

(Hunter ¶ 417; emphasis added).

10. Hunter teaches "[n]umerous polymeric and non-polymeric delivery systems for use in GU stents have been described" and that "[f]or these devices, the coating process can be performed in such a manner as to (a) coat the external surface of the stent, (b) coat the internal (luminal) surface of the stent or (c) coat all or parts of both the internal and external surfaces of the stent" (Hunter ¶ 659).

11. Sarangapani teaches "medical devices that are resistant to bacterial growth or encrustation such as urological devices and more particularly to urinary catheters constructed of, or coated with, a material which enables the urinary catheters to inhibit urease, and to prevent calcium and magnesium phosphate deposits on the catheters" (Sarangapani 1:6–11).

12. Sarangapani teaches "[b]y providing a surface that kills harmful bacteria, devices such as catheters or self-administered urethral plugs, have a much lower probability of carrying line pathogenic bacteria to the bladder, thus lowering the incidence of UTI" (Sarangapani 6:34–37).

13. Sarangapani teaches "certain combinations of the above hydrophilic compounds with antibacterials, such as . . . EDTA, DPTA and carboxylic acids give surprising effects . . . to kill *E.coli* on contact" (Sarangapani 6:54–58).

14. Sarangapani teaches polymer additives for catheters comprising 1% and 2% citric acid (*see* Sarangapani 13:65–66) resulted in pH levels being reduced (*see* Sarangapani 14:25–28, Table III-B) and the "results showed that *E. coli* was consistently inhibited in synthetic and human urine by formulated discs (1 square centimeter) containing Citric acid and Phosphonic acids in combination with Silver" (Sarangapani 15:11–14).

15. Sarangapani teaches "a combination of acidifying chelating compounds that partition between the plastic and the body fluids such as urine, to provide an acidic pH on the surface" (Sarangapani 4:4–6).

16. Sarangapani teaches the "hydrophilic compounds not only make the surface attract water molecules but also render a low pH of 4-5, on the surface that discourages bacterial growth" (Sarangapani 6:47–50).

Principles of Law

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

Analysis

Prima facie obviousness

We adopt the Examiner's findings of fact and reasoning regarding the scope and content of the prior art (Final Act. 3–8; FF 1–16) and agree that Hunter and Sarangapani renders the claims obvious. We address Appellant's arguments below.

Appellant "submits Examiner appears to be over reading Hunter's disclosure . . . Hunter discloses literally tens of thousands to hundreds of thousands of different materials" (Appeal Br. 11). Appellant contends the "Examiner's reasoning above fails to **guide the artisan** toward the claimed invention and towards combination of its disclosure with Sarangapani, especially if Examiner is relying upon Sarangapani solely for its motivation to add organic acid to a polymeric coating that is already acidic" (*id.*).

We find this argument unpersuasive because "picking and choosing may be entirely proper in the making of a 103, obviousness rejection." *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972). Hunter teaches picking and choosing HPMC-AS coatings for urinary stents (FF 5, 6, 9) and teaches that silicone may also be selected (FF 7, 10), consistent with Appellant's elected species. We note that claim 1 broadly encompasses any non-degradable structural layer and any pH sensitive linear polymer, and therefore would encompass other layers and polymers disclosed by Hunter (FF 7, 9).

As to the argument regarding thousands of possible combinations, *Merck* found that prior art disclosing 1200 "effective combinations does not render any particular formulation less obvious." *Merck & Co., Inc. v. Biocraft Labs., Inc.,* 874 F.2d 804, 807 (Fed. Cir. 1989). Similarly, in *Corkill*, an obviousness rejection was affirmed in light of prior art teachings

that "hydrated zeolites will work" in detergent formulations, even though "the inventors selected the zeolites of the claims from among 'thousands' of compounds." *In re Corkill*, 771 F.2d 1496, 1500 (Fed. Cir. 1985).

Perricone explains that a "specific disclosure, even in a list, makes this case different from cases involving disclosure of a broad genus without reference to the potentially anticipating species." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1377 (Fed. Cir. 2005). In this case, Appellant's claim 1 "recites a combination of elements that were all known in the prior art, and all that was required to obtain that combination was to substitute one well-known . . . agent for another." *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1364 (Fed. Cir. 2012). Appellant provides no evidence that the selection of a combination of silicone polymers with HPMC-AS and citric acid or EDTA for use in urinary catheters results in any unexpected result or other secondary consideration.

Appellant contends "Examiner simply argues that Hunter's materials are likely to exhibit the same properties as Applicant's" (Appeal Br. 12). Appellant "wonders how such an assertion can be true if the vast majority of Hunter's materials do not exhibit the same properties, in particular the same combination of interdependent properties, as Applicant's instant claims" (*id.*).

We find this argument unpersuasive because the Examiner has demonstrated that Hunter and Sarangapani render obvious a composition identical in structure to that claimed by Appellant. The Examiner, in demonstrating identity of composition, reasonably presumes that "[p]roducts of identical chemical composition can not have mutually exclusive properties." *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990). Appellant

provides no evidence rebutting the position of the Examiner, and such a comparison is reasonably placed on Appellant. *See In re Best*, 562 F.2d 1252, 1255 (CCPA 1977).

Appellant cites Batich '147[7] and Batich '422[8] and asserts that these references are "more relevant than Hunter" but "preferably have a pH trigger of 8.5" and therefore "a patient using Batich's urinary device will experience a bacterial infection for an extended period of time before the device begins to release drug and treat the infection" (Appeal Br. 12). Appellant also asserts "Batich does not contemplate dissolution, erosion or degradation of the polymeric layer" and that "[i]nclusion of a functional excipient organic acid in Batich's device would delay swelling of the pH dependent layer and delay release of its antibiotic and urease inhibitor" (*id.* at 13). Appellant concludes the "combination of Hunter and Batich suggests the use of water swellable (not water soluble) pH dependent crosslinked (not linear) polymer having a pH trigger of 8.5 or higher. Hunter and Batich, thus, teach away from the claimed invention" (*id.* at 13).

We find this argument unpersuasive for several reasons. First, we agree with the Examiner that "Appellant's arguments regarding Batich or any hypothetical combinations with Hunter and/or Hanselle . . . are not relevant to the prior art currently of record" (Ans. 5). That is, Batich is not part of the rejection nor does Batich specifically address the identical polymers and pH sensitive layers disclosed by Hunter or the further coatings of Sarangapani. While we do agree with Appellant that prior art not part of the rejection might be relevant to teaching away concerns (*see* Reply Br. 3),

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[7] Batich et al., US 5,554,147, issued Sept. 10, 1996.
[8] Batich et al., US 6,306, 422 B1, issued Oct. 23, 2001.

we find the teaching away argument unpersuasive here for the reasons given below.

Second, while Appellant contends the art suggests a pH of 8.5, Sarangapani expressly teaches a desire for acidic pH (FF 15) and more particularly for a pH between 4 and 5 to discourage bacterial growth (FF 16). Thus, when selecting pH sensitive polymers from the disclosure of Hunter for use in urinary stents or catheters, Sarangapani would have provided reason to the ordinary artisan to select pH sensitive polymers in a range to discourage bacterial growth. As the Specification notes, this information is easily obtainable for commercially available HPMC-AS because "the pH value required for dissolution (the trigger pH) is as specified. The HPMC-AS grades LF/MF/HF, having an approximate molecular weight 18000 g/mol, are supplied by Shin-Etsu® Chemical Co. (Tokyo, Japan) under the brand name AQOAT®" (Spec. 9).

Third, Appellant identifies no teaching in Hunter, the reference actually relied upon by the rejection, that discourages, discredits, or otherwise teaches away from the use of the HPMC-AS polymer or silicone polymer in urinary stents or the use of acidic pH values. Indeed, Hunter suggests these structural components (FF 7–9) and Sarangapani suggests acidic pH values (FF 15–16). *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) ("The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed"). If a reference not of record, and not using the same components, teaches away from the use of those different components, that has little bearing on this obviousness rejection.

Appellant contends "contrary to Examiner's assertion, Sarangapani does not teach the addition of organic acid to an already acidic pH dependent layer. Instead, Sarangapani teaches that the coating materials should be rendered acidic by including acidic chelating components" (Appeal Br. 14). Appellant later contends

> Sarangapani is merely additive to Hunter. In no case, does Sarangapani suggest that organic acid should be added to the acidic cross-linked polymer once it has been formed. Sarangapani provides no motivation to add organic acid to an already acidic polymer, in particular to a linear polymer that exhibits a pH dependent water solubility.

(Appeal Br. 19).

We are not persuaded. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850 (CCPA 1980). Here, having found Hunter reasonably renders obvious a urinary catheter with silicone and HPMC-AS as obvious selections from within Hunter's disclosure above (FF 5–10), we also find it obvious to incorporate Sarangapani's compounds such as citric acid that inhibit bacterial growth in urinary catheters (FF 11, 14).

Moreover, "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *KSR*, 550 U.S. at 421. Here, Sarangapani demonstrates that incorporation of citric acid results in reduced growth of *E. coli* in the urinary catheter context (FF 11–14), a result that would have

reasonably motivated an ordinary artisan to include such components into Hunter's urinary catheter (FF 5) in order to further reduce bacterial growth.

Appellant contends that

> Sarangapani merely extends the application of Wood's carboxylic acid group-containing HYPOL™-based crosslinked water absorbing (but non-water-soluble and non-water-erodible) polymers by using them in coatings for urinary catheters. Sarangapani's HYPOL ™-based polymers are still crosslinked, such as with an organic acid, and still cannot erode or dissolve in water, specifically, because they are crosslinked.

(Appeal Br. 17).

We find this argument unpersuasive because it argues the references separately, rather than addressing the combination of Hunter's polymers such as HPMC-AS and silicone on a urinary stent combined with Sarangapani's disclosure of citric acid. Prior art "must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole." *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

Appellant contends "the claimed invention is different than either of Sarangapani's solutions in at least two keys aspects . . . Neither of Sarangapani's polymers is water soluble or erodible . . . Neither of Sarangapani's coating compositions contains both a pH sensitive polymer . . . AND additional organic acid" (Appeal Br. 18).

We find Appellant's argument unpersuasive because it fails to recognize that the rejection is based on the combination of Hunter and Sarangapani, not on Sarangapani alone. "The test for obviousness . . . is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642, F.2d 413, 424 (CCPA

1977). If Sarangapani had taught all of the elements of the claim, it would anticipate, not be part of an obviousness rejection.

Appellant contends "even if Sarangapani were deemed to suggest addition of organic acid to an already acidic water swellable crosslinked polymer (which it does not), Sarangapani does not suggest how much organic acid should be added to a water soluble linear polymer in order to provide the claimed functionality" (Appeal Br. 19).

We are not persuaded. Sarangapani suggests the use of 1% and 2% citric acid is effective by experimenting with both concentrations (FF 14), demonstrating that the amount of organic acid is a results-effective variable. To the extent that an ordinary artisan would need to determine how much acid to add to Hunter's polymers, "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." *In re Boesch*, 617 F.2d 272, 276 (CCPA 1980).

Appellant contends "the organic acid helps reduce the rate of erosion or dissolution of the pH sensitive polymer and thereby of the pH dependent layer, ultimately slowing down its erosion and extending the useful lifetime of the instant device and providing improve antibacterial and anti-encrustation performance as compared to a layer only including the pH sensitive polymer" (Appeal Br. 21).

To the extent that Appellant is arguing a secondary consideration such as unexpected results here, we find the argument unpersuasive because no evidence is presented. "It is well settled that unexpected results must be established by factual evidence. Mere argument or conclusory statements . . . [do] not suffice." *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995). In the instant case, Appellant relies solely on attorney argument. However,

"attorney argument [is] not the kind of factual evidence that is required to rebut a prima facie case of obviousness." *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997).

Appellant addresses claims 79, 91, and 97 separately as not disclosed by Sarangapani (*see* Appeal Br. 26), but does not address Hunter, and are therefore not persuasive because the rejection is based on the combination of these two references.

In their Reply Brief, Appellant reiterates many of the points addressed above (Reply Br. 2), which we find unpersuasive for the reasons given. We have considered the prior art, including Appellant's additional references, as a whole, but find that the evidence of record (FF 1–16) supports the Examiner's conclusion of obviousness. While we are aware that hindsight bias may plague determinations of obviousness, *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966), we are also mindful that the Supreme Court has clearly stated that the "combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 550 U.S. at 416. Here, the evidence supports the position that Hunter teaches a urinary tract stent/catheter where polymers may be selected that include both silicone and HPMC-AS and Sarangapani teaches that to improve urinary catheters, it is beneficial to include citric acid (FF 1–16). Appellant provides no evidence that the combination would be unpredictable or that the elected combination resulted in any unexpected results.

Conclusion of Law

A preponderance of the evidence of record support the Examiner's conclusion that Hunter and Sarangapani render claims 1, 79, 91, and 97

obvious. Claims 28, 63, 78, 81, 82, 84, 87, 90, 92–95, 98–100, and 102–109 are not separately argued and fall with claim 1.

B. 35 U.S.C. § 103(a) over Hunter, Sarangapani, and Hanselle

Appellant substantially relies upon the arguments addressed above, which we find unpersuasive. Appellant makes one new argument specific to the combination with Hanselle, "that Hanselle is in a field of non-analogous art as regards Hunter and Sarangapani" (Appeal Br. 22). Appellant asserts "an artisan working in the field of catheters would not look to art in the field of biological sample storage for materials requiring particular functionality as required by Hunter. Hunter and Hanselle are therefore in non-analogous fields of art" (*id.* at 23).

The Examiner responds that "Hunter and Hanselle are in the same field of Appellant's endeavor as well as reasonably pertinent to Appellant's problem because both references use pH dependent polymers in matrices that release active agents" (Ans. 8).

We find that Appellant has the better position. Under the analogous arts test, "a reference is either in the field of the applicant's endeavor or is reasonably pertinent to the problem with which the inventor was concerned in order to rely on [that] reference as a basis for rejection." *In re Kahn*, 441 F.3d 977, 986–87 (Fed. Cir. 2006). While Hunter and Sarangapani are both in the polymer coated stent field of endeavor, Hanselle is drawn to matrices for obtaining biological samples (*see* Hanselle 7:5–17). We are not persuaded by the Examiner's reasoning because Hunter is designed to "reduce the foreign body response to implantation (FF 5) while Hanselle's matrix must be "suitable for the collection of a biological sample" (Hanselle 12:15). Hanselle is also not pertinent to the problem with which either the

Specification or Hunter and Sarangapani are concerned, which is the use of catheters and stents in the urinary tract.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 28, 63, 78, 79, 81, 82, 84, 87, 90–95, 97–100, 102–109	103	Hunter, Sarangapani	1, 28, 63, 78, 79, 81, 82, 84, 87, 90–95, 97–100, 102–109	
85, 86	103	Hunter, Sarangapani, Hanselle		85, 86
Overall Outcome			1, 28, 63, 78, 79, 81, 82, 84, 87, 90–95, 97–100, 102–109	85, 86

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-IN-PART