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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RAYMOND J. HULL JR., BRUCE C. JOHNSON, PRAMOD MAVINKURVE, and LEONARD ROSENFELD

Appeal 2015-000168
Application 12/974,378
Technology Center 3700

Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

PER CURIAM.

DECISION ON APPEAL

This is an appeal[1] under 35 U.S.C. § 134 involving claims to an intravaginal urinary incontinence device. The Examiner rejected the claims as obvious and obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

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[1] Appellants identify the Real Party in Interest as MCNEIL-PPC, INC., which is a subsidiary of Johnson & Johnson (*see* Br. 2).

Statement of the Case

Background

Appellants' "invention relates to an intravaginal incontinence device comprising a polymeric resilient material" (Spec. 1:8–9). More particularly, the device "has a working portion having a variable equivalent diameter, a length suitable for insertion into a vagina and an anchoring mechanism for retention in the vagina, and is made from high modulus polymers having high tensile modulus properties along with high yield strain properties" (*id.* at 1:10–14).

The Claims

Claims 1–22 are on appeal. Independent claim 1 is representative and reads as follows (emphasis added):

> 1. An intravaginal urinary incontinence device having an insertion end and an opposed withdrawal end, the device comprising a resilient frame comprising:
>
> a working portion disposed proximate the withdrawal end comprising a resilient structure having a plurality of connected elongate elements arranged and configured to define opposed working surfaces for providing support to an associated urinary system;
>
> and an anchoring portion disposed proximate the insertion end and extending beyond the working portion comprising a plurality of connected elongate elements arranged and configured to expand laterally within a user's vagina
>
> *wherein the elongate elements comprise a high modulus polymer having an elastic modulus of at least 2 GPa and an Initial Stress @ 3% Strain of at least about 30 MPa.*

The Issues

A. The Examiner rejected claims 1–22 under 35 U.S.C. § 103(a) as obvious over Bartning[2] and Jackson,[3] as evidenced by Ferguson,[4] ASM,[5] Plastics International,[6] Peters,[7] Engineering Thermoplastics,[8] and Polyethers[9] (Non-Final Act. 3–9; Ans. 2).

B. The Examiner rejected claims 1, 2, 5–7, and 19 under 35 U.S.C. § 103(a) as obvious over Bartning and Stack,[10] as evidenced by Engineering Thermoplastics (Non-Final Act. 9–12; Ans. 3).

C. The Examiner rejected claims 3, 4, 8–18, and 20–22 under 35 U.S.C. § 103(a) as obvious over Bartning and Stack, as evidenced by Engineering Thermoplastics and Guo[11] (Non-Final Act. 13–20; Ans. 3–4).

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[2] Bartning et al., US 2008/0033230 A1, published Feb. 7, 2008.
[3] Jackson et al., US 6,585,755 B2, issued July 1, 2003.
[4] Ferguson et al., US 2007/0282161 A1, published Dec. 6, 2007.
[5] Lee McKague, *Thermoplastic Resin*, ASM Handbooks Online (2003) (http://products.asminternational.org/hbk/do/highlight/content/V21/D02/A17/s0086879.htm (July 18, 2012)) (hereinafter "ASM").
[6] *ULTEM® (Polyetherimide) Flyer*, Plastics International (publication date unknown) (hereinafter "Plastics International").
[7] Peters, *PLASTICS: INFORMATION AND PROPERTIES OF POLYMERIC MATERIALS*, ESHBACH'S HANDBOOK OF ENGINEERING FUNDAMENTALS 392–421 (M. Kutz eds., 5th ed. 2009).
[8] Garbassi et al., *Engineering Thermoplastics*, 10 KIRK-OTHMER ENCYCLOPEDIA OF CHEMICAL TECHNOLOGY 168–228 (2001) (hereinafter "Engineering Thermoplastics").
[9] Dwain, *Polyethers, Aromatic*, KIRK-OTHMER ENCYCLOPEDIA OF CHEMICAL TECHNOLOGY 1–18 (2000) (hereinafter "Polyethers").
[10] Stack et al., US 2005/0021125 A1, published Jan. 27, 2005.
[11] Guo et al., *Isothermal physical aging characterization of Polyether-ether-ketone (PEEK) and Polyphenylene sulfide (PPS) films by creep and stress relaxation*, 11 MECH TIME-DEPEND MATER 61–69 (2007).

D. The Examiner provisionally rejected claims 1–22 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 8–10, and 15 of copending US application 12/645,800, filed Dec. 23, 2009 ("Hull") (Non-Final Act. 20–25; Ans. 2).

A. 35 U.S.C. § 103(a) over Bartning and Jackson

The Examiner finds that "Bartning teaches the structural elements of independent claims 1, 8, [and] 16, but does not teach the device is made of a high modulus polymer having the claimed material properties" (Ans. 2; *see also* Non-Final Act. 3–6). The Examiner concludes that it would have been obvious to

> modify the intravaginal incontinence device of Bartning et al. to be made of either polyetherimide or polyetheretherketone, as taught by Jackson et al., which discloses a finite number of identified, predictable potential materials, because it would be a functional substitution to utilize the mechanical properties inherent in these two high modulus polymers to provide for secure anchoring of the intravaginal device (*Ferguson discloses device (10) is an elastically deformable material that allows head (12) to move between the deployed and insertion states, such as polyetheretherketone (PEEK)* (paragraph [0059])).

(Non-Final Act. 6; *see also* Ans. 2.) The Examiner indicates that "[t]he evidence references listed [] are cited to provide additional support that polyetherimides and polyetheretherketones are known to exhibit the claimed material properties" (Ans. 2; *see also* Non-Final Act. 6–9).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Bartning and Jackson render the claims prima facie obvious?

Findings of Fact

1. Bartning teaches that "[a]n intravaginal device has a working portion (e.g., intravaginal urinary incontinence device suppository, tampon) and an anchoring portion comprising at least one member extending beyond at least one end of the working portion to maintain the working portion in place during use" (Bartning Abstract; *see also* Non-Final Act. 3–5).

2. Bartning teaches that "[w]orking portion . . . may be made of any elastic material that compresses and recovers with sufficient force to provide the desired effect" (Bartning ¶ 29; *see also* Non-Final Act. 4–5), that "[e]lements of the devices of the present invention may be made from any elastic or superelastic material" (Bartning ¶ 38; *see also* Non-Final Act. 11), and that "[s]everal physical properties of SMPs other than ability to memorize shape are significantly altered in response to external changes in temperature and stress, particularly at the glass transition of the soft segment," and that "[t]hese properties include elastic modulus, hardness, and flexibility. . . . the modulus is high and thereby providing sufficient stiffness" (Bartning ¶ 41; *see also* Non-Final Act. 11).

3. Jackson teaches that "[s]uitable permanent non-biodegradable plastics for a stent would include engineering polymers such as polyetheretherketone (peek), . . . and polyetherimides" (Jackson 6:28–38; *see also* Non-Final Act. 5–6).

4. Peters' Table 34 is shown below:

Table 34 Typical Properties of PEIs

Property	PEI	10% GF + PEI	20% GF + PEI	30% GF + PEI
Density (g/cm^3)	1.27	1.34	1.42	1.51
Tensile modulus (GPa)	3.59	4.69	6.89	9.31
Tensile strength (MPa)	110	116	131	169
Elongation at break (%)	60	6	4	3
Flexural modulus (GPa)	3.52	5.17	6.89	8.95
Flexural strength (MPa)	165	200	228	228
Notched Izod (kJ/m)	0.053	0.053	0.064	0.085
Unnotched Izod (kJ/m)	1.335	0.481	0.481	0.427
HDT at 1.81 MPa (°C)	201	209	210	210
HDT at 0.42 MPa (°C)	210	210	210	212
Vicat softening temperature (°C)	219	223	220	228
RTI (°C)	170	170	170	180
UL94 VO (mm)	---	0.4	0.4	0.3
Oxygen index (%)	47	47	50	50
Hardness (Rockwell)	M109	M114	M114	M114
CTE (10^{-5}/°C)	5.5	3.24	2.52	1.98
Shrinkage (in./in.)	0.006	0.005	0.004	0.003
Water absorption, 24 hr (%)	0.25	0.21	0.19	0.16
Dissipation factor at 1 kHz	0.0012	0.0014	0.0015	0.0016
Relative permittivity at 1 kHz	3.15	3.5	3.5	3.7

Table 34 shows that PEI (polyetherimide) has a tensile modulus of 3.59 GPa and an elongation at break of 60 % (Peters 414, Table 34; *see also* Non-Final Act. 7).

5. Peters' Table 36 is shown below:

Table 36 Typical Properties of Aromatic Polyketones

Property	PEEK	PEEK + 30% GF	PEEK + 30% Carbon Fiber	PEK	PEK + 30% GF
Density (g/cm^3)	1.32	1.49	1.44	1.30	1.53
Tensile modulus (GPa)	3.6	9.7	13.0	4.0	10.5
Tensile strength (MPa)	192	157	208	104	160
Elongation at break (%)	50	2.2	1.3	5	4
Flexural modulus (GPa)	3.7	10.3	13.0	3.7	9.0
Flexural strength (MPa)	170	293	318	---	---
Notched Izod (kJ/m)	0.08	0.1	0.09	0.08	0.1
Unnotched Izod (kJ/m)	---	0.73	0.75	---	---
HDT at 1.81 MPa (°C)	160	315	315	165	340
HDT at 0.42 MPa (°C)	---	---	315	---	---
RTI (°C)	---	---	---	260	260
UL94 VO (mm)	---	---	---	1.6	1.6
Oxygen index (%)	---	---	---	40	46
Hardness (Rockwell)	M126	R124	R124	R125	R125
CTE (10^{-5}/°C)	16	11.5	7.9	5.7	1.7
Shrinkage (in./in.)	0.004	0.005	0.001	0.006	0.004
Water absorption, 24 hr (%)	0.5	0.11	0.06	0.11	0.08
Relative permittivity at 1 MHz	3.2	3.7	---	3.4	3.9

Table 36 shows that PEEK (polyetheretherketone) has a tensile modulus of 3.6 GPa and an elongation at break of 50 % (Peters 414, Table 36; *see also* Final Act. 7).

6. Ferguson teaches "[a]n incontinence management device [that] comprises a head having a first state and a second state" (Ferguson Abstract), in which the device "comprises an elastically deformable material that allows head . . . to move between the deployed state and the insertion state," "the deployed state comprises a natural or non-deformed shape, which is the shape to which the device is biased to return to if elastically deformed," and the device "may comprise a substantially elastic material, such as . . . polyetherketone (PEEK)" (*id.* at ¶ 59; *see also* Non-Final Act. 6).

Principles of Law

"[T]he [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.*, 550 U.S. 398, 418 (2007).

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 416. "If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *Id.* at 417.

Analysis

We adopt the Examiner's findings of fact and reasoning regarding the scope and content of the prior art (Non-Final Act. 2–25; Ans. 2–6; FF 1–7)

and agree that the claims are obvious over Bartning and Jackson. We address Appellants' arguments below.

Appellants contend that "the combination of references fails to establish an 'obvious to try' rationale that meets the test of obviousness under §103" (Br. 10). More particularly, Appellants argue that

> At the same time the Office relies on the Engineering Thermoplastics reference for its teaching of the mechanical properties of engineering thermoplastic materials, this very same reference clearly teaches that the properties of engineering thermoplastics can "change remarkably depending upon . . . the presence of fillers and reinforcing fibers." This combination of references is at best ambiguous, and ambiguous information cannot establish a prima facie case of obviousness of the presently claimed invention.

(*Id.*) Appellants contend that "[t]he rejection is only a hindsight reconstruction of [Appellants'] invention" (*id.*).

We do not find the "obvious to try" argument persuasive. In *O'Farrell*, the court found that

> The admonition that "obvious to try" is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.... In others, what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

In re O'Farrell, 853 F.2d 894, 903 (Fed. Cir. 1988).

This is not a case where the prior art gave no direction or indication of the critical parameters. Bartning teaches an intravaginal device in which the "[w]orking portion . . . may be made of any elastic material that compresses and recovers with sufficient force to provide the desired effect" (FF 1–2). Bartning specifically teaches an "elastic or superelastic material" (FF 2). Bartning teaches that "[s]everal physical properties of SMPs other than ability to memorize shape are significantly altered in response to external changes in temperature and stress, particularly at the glass transition of the soft segment," and that "[t]hese properties include elastic modulus, hardness, and flexibility. . . . the modulus is high and thereby providing sufficient stiffness" (FF 2).

Thus, Bartning does not give only general guidance, but rather Bartning directs the ordinary artisan to specific materials with specific properties and further gives direction as to which parameters were critical and likely to be successful (FF 2).

Moreover, Jackson provides guidance on polymers that are desirable for use in patients, teaching that "[s]uitable permanent non-biodegradable plastics for a stent would include engineering polymers such as polyetheretherketone (peek), . . . and polyetherimides" (FF 3). Ferguson evidences that "an elastically deformable material that allows head . . . to move between the deployed state and the insertion state," "may comprise a substantially elastic material, such as . . . polyetherketone (PEEK)" (FF 6).

Using the guidance of Bartning, Jackson, and Ferguson, the Examiner relies upon Peters to evidence the particular elastic polymers taught as useful by Jackson in patients have properties that meet the requirements of Bartning. Specifically, Peters teaches that PEI (polyetherimide) has a tensile

modulus of 3.59 GPa and an elongation at break of 60 %, and that PEEK (polyetheretherketone) has a tensile modulus of 3.6 GPa and an elongation at break of 50 % (FF 4–5).

We thus agree with the Examiner that one skilled in the art would have had reason to choose polyetherimide or polyetheretherketone from the list polymers in Ferguson because "Ferguson provides a teaching, suggestion, or motivation to use polyethereterketone (PEEK) . . . , because it is a material that is substantially elastic to allow a device to move between a deployed and insertion state (paragraph [0059] of Ferguson)" (Ans. 4).

As the Examiner explains,

> The properties of the polymer itself would not change with the presence of fillers or fibers, just the property of the resulting material. The claims recite "wherein the elongate elements comprise a high modulus polymer" so the properties of the elongate elements that are made from the polymer and the additional elements [might possibly] change, but not the properties of the polymer itself. Nothing in the claim language limits the elongate elements to being made from only a high modulus polymer (i.e. the claim language uses "comprise" rather than "consist").

(*Id.* at 4–5.)

The Examiner also explains that

> Since claim 5, which specifies the high modulus polymer as polyetherimides, polyetheretherketones, or combinations thereof, depends from claim 1, polyetherimides and polyetheretherketones thereof must therefore possess the material properties recited in claim 1. The evidence references are cited to provide additional support that polyetherimides and polyetheretherketones are known to exhibit material properties of the claimed values, which are open-ended numerical ranges,

> claiming, for example, "at least 2 GPa" or "an Aged Stress @ 3% strain that is greater than about 35 MPa."

(*Id.* at 5.)

We also agree with the Examiner that given Bartning's specific requirements for elastic materials and the known elastic materials disclosed by Jackson,

> The experimentation disclosed in the specification involves testing material properties of sample materials including expansion force test, elastic modulus and yield strain, and stress relaxation testing (see pages 9–14 of the Specification), which describes optimizing a result effective variable, something that has been determined to involve only routine skill in the art.

(*Id.* at 5.) *See In re Aller,* 220 F.2d 454, 456 (CCPA 1955) ("where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation"). "[T]he discovery of an optimum value of a variable in a known process is usually obvious." *Pfizer, Inc. v. Apotex, Inc.,* 480 F.3d 1348, 1368 (Fed. Cir. 2007). Appellants do not identify any secondary consideration, such as unexpected results, that would overcome the prima facie case of obviousness based on routine optimization of selecting the appropriate polymers for an intravaginal device as disclosed by Bartning and Jackson.

We recognize, but find unpersuasive, Appellants' contention that

> the properties of the NITINOL material used in the example of Bartning in paragraph [0058] and those of the high modulus polymers of the presently claimed invention can vary widely. Indeed, it can be critical to the performance of the invention of claim 15 to balance the material properties with the cross-section of the elongate elements to provide the desired

> mechanical properties of the finished intravaginal urinary incontinence device.

(Br. 9–10.) Appellants' argument fails to address the combination of teachings of Bartning and Jackson, with the evidentiary references, as discussed above. "Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references []. [The reference] 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). *See also In re Geisler,* 116 F.3d 1465, 1470 (Fed. Cir. 1997) ("[A]ttorney argument [is] not the kind of factual evidence that is required to rebut a prima facie case of obviousness").

B–C. 35 U.S.C. § 103(a) over Bartning and Stack

The Examiner finds that "Bartning teaches the structural elements of claim 1, but does not teach the device is made of a high modulus polymer having the claimed material properties" (Ans. 3; *see also* Non-Final Act. 9–11). The Examiner concludes that it would have been obvious to "substitute the resilient plastic, such as PEEK, taught by Stack for the shape memory polymer taught by Bartning as a simple substitution in order to achieve the predictable result of a radially outward, expandable support element (Stack, paragraph [0045])" (Non-Final Act. 11). The Examiner indicates that "[t]he additional evidence reference listed [] is cited to provide additional support that polyetheretherketone is known to exhibit the claimed material properties" (Ans. 3; *see also* Non-Final Act. 11–12).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Bartning and Stack render the claims prima facie obvious?

Findings of Fact

7. Stack teaches an "expandable support element . . . may comprise materials exhibiting shape memory properties, such as spring steel, Nitinol, superelastic or shape memory nickel-titanium alloys, and resilient engineering plastics such as polysulfones, PEEK, . . ." (Stack ¶ 45; *see also* Ans. 3, Non-Final Act. 11).

Analysis

We agree with the Examiner that the claims are obvious over Bartning and Stack. We address Appellants' arguments below.

Appellants contend that "[a]gain, this is a classic 'Obvious to try' rationale, described in MPEP §2143 (E). As in the rejection based upon Bartning/Jackson, above, it must fail" (Br. 17, 21). Appellants also contend that "[t]he resort to Engineering Thermoplastics and Guo for additional hindsight selection of physical properties that are not disclosed or suggested in either Bartning or Stack is further evidence of the improper hindsight rejection" (*id.* at 18, 21–22).

We are not persuaded. These arguments are similar to Appellants' previous contentions based on the combination of Bartning and Jackson (*see also* Ans. 5–6). Accordingly, we are not persuaded for the reasons discussed above.

Appellants contend that "Stack merely lists 'spring steel, Nitinol, Superelastic or shape memory nickel-titanium alloys, and resilient

engineered plastics such as polysulfones, PEEK, polysulfides, LCPs, etc.' (Stack, pages 4–5, paragraph [0045])" (Br. 17, 21). Appellants also contend that "the disclosure of Stack is primarily directed to a sheath for delivery of a vascular stent. The particular physical properties of this stent do not appear to be critical to the invention of Stack" (*id.* at 17–18, 21).

This argument is unpersuasive. The Examiner combines the teachings of Stack only for the polymeric material, PEEK, with Bartning ("substitute the resilient plastic, such as PEEK, taught by Stack for the shape memory polymer taught by Bartning as a simple substitution in order to achieve the predictable result of a radially outward, expandable support element" (Non-Final Act. 11). *See In re Merck & Co.,* 800 F.2d at 1097.

D. Obviousness-type double patenting over claims 1, 4, 5, 8–10, and 15 of Hull

Appellants "request that [this] rejection be held in abeyance until claims are determined to be allowable in either application" (Br. 25). We therefore summarily affirm the obviousness-type double patenting rejection based upon the Examiner's explanation and reasoning (Non-Final 20–25). *See In re Berger*, 279 F.3d 975, 984 (Fed. Cir. 2002).

SUMMARY

In summary, we affirm the rejection of claims 1, 8, 14, and 16 under 35 U.S.C. § 103(a) as obvious over Bartning and Jackson, as evidenced by Ferguson, ASM, Plastics International, Peters, Engineering Thermoplastics, and Polyethers. Claims 2–7 and 19 fall with claim 1, claims 9–13 and 20

fall with claim 8, claims 15 and 21 fall with claim 14, and claims 17, 18, and 22 fall with claim 16.

We affirm the rejection of claims 1, 2, 5–7, and 19 under 35 U.S.C. § 103(a) as obvious over Bartning and Stack, as evidenced by Engineering Thermoplastics. Claims 2, 5–7, and 19 fall with claim 1.

We affirm the rejection of claims 3, 4, 8–18, and 20–22 under 35 U.S.C. § 103(a) as obvious over Bartning and Stack, as evidenced by Engineering Thermoplastics and Guo.

We affirm the rejection of claims 1–22 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 8–10, and 15 of Hull.

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