

In the United States Court of Federal Claims

No. 11-223C

(Filed: September 22, 2016)¹

AMERICAN INNOTEK, INC.,

Plaintiff,

v.

THE UNITED STATES,

Defendant.

* Patent Infringement; 28 U.S.C. §
* 1498; Prior Art; 35 U.S.C. § 102;
* Priority Date; 35 U.S.C. § 120;
* Invalidity; Obviousness; 35 U.S.C. §
* 103; Graham Factors; Objective
* Indicia of Nonobviousness; Nexus
* Requirement; Commercial Success;
* Long-felt Need; Copying.

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Daniel W. Ernsberger, Behrend & Ernsberger, P.C., 355 Fifth Ave., 12th Floor, Pittsburgh, PA 15222, for Plaintiff.

Benjamin C. Mizer and John Fargo, U.S. Department of Justice, Civil Division, Commercial Litigation Branch, Intellectual Property Staff, Washington D.C., P.O. Box 480, Ben Franklin Station, Washington, D.C. 20044, for Defendant. Corey R. Anthony, U.S. Department of Justice, Of Counsel.

OPINION AND ORDER

WILLIAMS, Judge.

This patent infringement case involves bags for the containment and disposal of bodily fluids. Plaintiff, American Innotek, Inc., claims that the United States infringed its 1992 patent, United States Patent No. 5,116,139 (“the ’139 Patent”) entitled “Fluid Containment Bag,” by purchasing and using the accused product, a containment bag called the “Piddle Pak with Powder.” The accused product was manufactured by the New York City Industries for the Blind

¹ The Court issued this opinion under seal on August 31, 2016, and directed the parties to file any proposed redactions by September 14, 2016. Neither party has proposed redactions. Accordingly, the Court publishes this Opinion correcting errata.

(“NYCIB”), a non-profit entity that provides products to the Government on a noncompetitive basis pursuant to the Javits Wagner O’Day Act (“JWOD”).²

In 2001, a Government entity, the Committee for Purchase from People Who are Blind or Severely Disabled (“AbilityOne Committee”), placed the accused product, NYCIB’s Piddle Pak with Powder, on the JWOD Procurement List as a mandatory source item for Government agencies. Plaintiff alleges that as a result of this listing and the ensuing manifold mandatory purchases and use of the Piddle Pak with Powder by Government agencies, its patent was infringed. Plaintiff contends that it lost Government sales of its competing product, the *Flight Extender*, a urine containment bag using hydrophilic material, and seeks to recoup damages for the period of April 8, 2005 to May 26, 2009.

Findings of Fact³

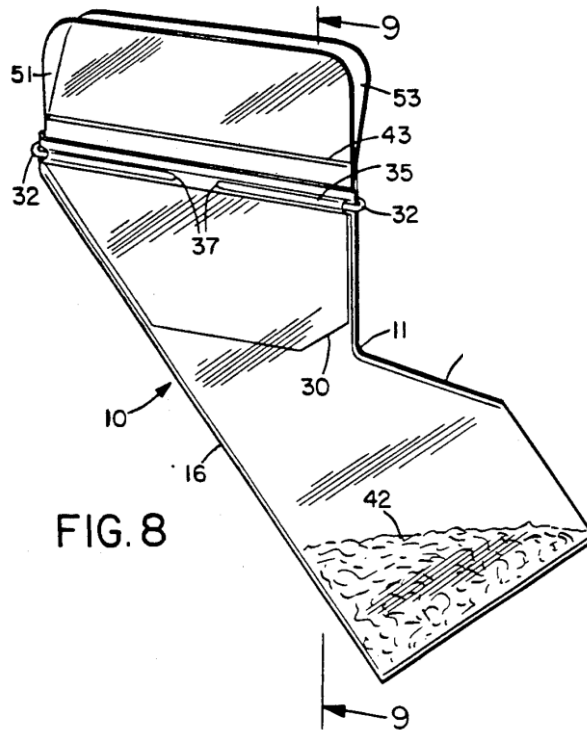
The ’139 Patent

The United States Patent and Trademark Office (“USPTO”) issued the ’139 Patent entitled “Fluid Containment Bag” on May 26, 1992, from U.S. Patent Application No. 657,354 (“the ’354 Application”), filed on February 15, 1991. JX 178 (“’139 Patent”). The ’139 Patent lists four inventors: Ruth E. Young, Daniel L. Young, Richard E. Warrick, and Clarence A. Cassidy, and is assigned to American Innotech, Inc. *Id.* The ’354 Application is a continuation-in-part of Application No. 404,734 (“the ’734 Application”), filed September 8, 1989, which itself is a continuation-in-part of Application No. 3,848 (“the ’848 Application”), filed January 14, 1987. *Id.* Both the ’734 and ’848 Applications were abandoned. *Id.* The ’139 Patent expired on May 26, 2009. DX 154 ¶ 6.

The ’139 Patent teaches a “containment and disposal bag for human bodily fluids.” ’139 Patent Abstract. The specification provides the following drawing as representative of the ’139 Patent:

² Pub. L. No. 92-28, § 1, 85 Stat. 77 (1971) (codified as amended at 41 U.S.C. §§ 46-48c (2006)) (“JWOD”). JWOD was further amended in 2011, and codified at 41 U.S.C. §§ 8501-06, effective January 4, 2011. As this opinion concerns events prior to 2011, the Court references the 2006 version of JWOD.

³ These findings of fact are derived from the record developed at trial. The Court held a trial on liability and damages from September 16 to September 18, 2014, in San Diego, CA, and September 30 through October 3, 2014, in Washington, DC. Unless otherwise noted, “Tr.” references the trial transcript, PX references Plaintiff’s exhibits, DX references Defendant’s exhibits, and JX references the parties’ joint exhibits. The Court has not corrected grammatical errors in quotations from the exhibits and the filings. Additional findings of fact are in the Discussion and the Court’s prior claim construction opinions, *American Innotech, Inc. v. United States*, 113 Fed. Cl. 668, 671-74 (2013), and *American Innotech, Inc. v. United States*, 126 Fed. Cl. 468, 471-73 (2016). Following trial, the parties requested briefing and oral argument on the construction of the term “prevent escape,” which the Court construed to mean “substantially prevent escape” on March 31, 2016. The parties filed supplemental briefs on liability in light of the Court’s post-trial claim construction on May 2, 2016.



'139 Patent Fig. 8.

The '139 Patent contains one independent claim and 16 dependent claims. '139 Patent 8:39 – 10:30. American Innotech asserts that NYCIB's Piddle Pak with Powder infringes independent Claim 1, and dependent Claims 2-4 and 17 of the '139 Patent.

Independent Claim 1 recites:

1. A containment bag for a fluid comprising water or water-based liquid such as bodily fluids which comprises:

a bag having a hollow interior defined by two sides meeting at opposite edges, a bottom and a top, with said edges and bottom sealed and said top at least partially open to receive said fluid;

a gellable hydrophilic material within said bag, said material becoming fully gelled within thirty seconds of said contact with said fluid when said fluid is deposited in said bag, said gellation serving to essentially completely sequester said fluid and prevent said fluid from thereafter being expelled from said bag;

funnel means within said interior and having an open top, said funnel means being secured to said bag at said top of said bag, and extending downwardly within said interior to a narrower open bottom for conduction of fluid entering said open top through said funnel means and into said bag, with the open bottom of said funnel being disposed intermediate between said top and bottom of said bag, said open bottom being free from attachment to said sides of said bag

such that flow of any unsequestered fluid within said bag back toward said funnel means acts to close said funnel means to prevent escape of said unsequestered fluid from said bag; and

closure means for closing the top of said bag after introduction of said fluid into said bag.

'139 Patent 8:39-66.

Dependent Claims 2-4 elaborate on the “hydrophilic material” limitation in Claim 1. They recite:

2. A containment bag as in claim 1, wherein said gellable material is a polymer

3. A containment bag as in claim 1 wherein said hydrophilic material is part of a mixture of materials which also contains at least one material selected from the group consisting of enzymes, deodorants, fragrances, human body abnormality indicators and pregnancy indicators.

4. A containment bag as in claim 1 wherein said hydrophilic material is in a powdered, matted, granular, fibrous, foamed, or woven physical form.

Id. at 8:67 – 9:9.

Claim 17 focuses on the shape of the bag, it recites:

17. A containment bag as in claim 1 wherein said bag has the form of an L shape.

Id. at 10:29-30.

Attorneys James W. McClain and Neil Martin prosecuted the '139 Patent. JX 179 at 000277; Tr. 336. Mr. Martin served as Plaintiff's expert witness during trial, and was qualified as an expert in mechanical engineering with specialty knowledge in one-way valves and absorbent products. Tr. 343-44.⁴

⁴ Mr. Martin has a bachelor's degree in mechanical engineering from Lehigh University. Following graduation, Mr. Martin worked as a quality control engineer for General Dynamics' electric boat division. As a mechanical engineer, Mr. Martin was “required to analyze and design systems, some of which included one-way valves,” over the years and had “a lot of occasion to use, install and replace one-way valves as a low-paid mechanic on—on boats, basically.” Tr. 337. Mr. Martin then became a patent examiner while attending the American University Washington College of Law at night. While still in law school, Mr. Martin moved from the United States Patent and Trademark Office to the United States Department of the Navy, where he served as a patent advisor. After law school, Mr. Martin worked as an attorney at General Dynamics. He later formed his own firm. At the time of trial Mr. Martin was employed at the law firm Gordon & Rees as a senior patent counsel. Mr. Martin's prior experience with waste-collection products, including urine containment devices, is limited to his experience representing American Innotech since its founding in 1988.

The 1968 and 1981 Military Specification For Urine Containment Bags

On April 16, 1968, over 20 years prior to the issuance of the '139 Patent, the United States Air Force issued Military Specification No. MIL-B-83665 ("Mil-Spec A") entitled "Bag, Pilot Relief." DX 70 at 1360. A military specification is a United States Department of Defense ("DoD") required standard used to provide a Government contractor with a product's requirements to satisfy military needs. See 41 C.F.R. §§ 101-29.216-29.217 (defining a military specification for the Department of Defense Index of Specifications and Standards).

The scope of the 1968 Mil-Spec A "cover[ed] the requirements for one type of disposable plastic bag suitable for the collection, retention and temporary storage of urine." DX 70 at G1360. Under Mil-Spec A, the neck of the bag opening had to "incorporate means for preventing spillage when bag is inverted" and "not impede the normal flow input." Id. at G1361. Mil-Spec A further required the bag to contain an absorbent "of either sponge type cellulose (compressed) or granular material not less than 4.75 cubic inches and capable of absorbing 500 [cubic centimeters] of urine." Id. Mil-Spec A also included a series of "performance tests" as "quality assurance provisions" to "assure supplies and services conform[ed] to prescribed requirements." Id. at G1362. These tests included an "inverted leakage test" to be performed prior to closing the bag. Mil-Spec A stated:

4.4.2. Inverted leakage test. The bag shall be filled with a minimum of 550 [cubic centimeters] of water and, without closing, quickly inverted. There shall be no more than 30 [cubic centimeters] of liquid spilled from the opening during a one-minute period.

Id.

On June 2, 1981, the Department of Defense modified the military specification from a 1972 version and issued Military Specification No. MIL-B-83665B ("Mil-Spec B") entitled "Bag, Pilot Relief (Male)." JX 47 at G1378. The scope of Mil-Spec B covered "one type of disposable plastic bag suitable for the collection, retention, and temporary storage of urine" to be "use[d] by all Departments and Agencies of the Department of Defense." Id. The product specifications of Mil-Spec B were nearly identical to Mil-Spec A. Id. at G1379-83. Like Mil-Spec A, Mil-Spec B required a bag made from a flexible plastic film no less than 6 mils, or 0.15 millimeters, thick. Id. at G1379. Mil-Spec B also included the following features that were nearly identical to those required under Mil-Spec A:

3.1.4. Absorbent. Bag shall contain an absorbent of either sponge type compressed cellulose or granular material capable of absorbing 500 [cubic centimeters] of urine.

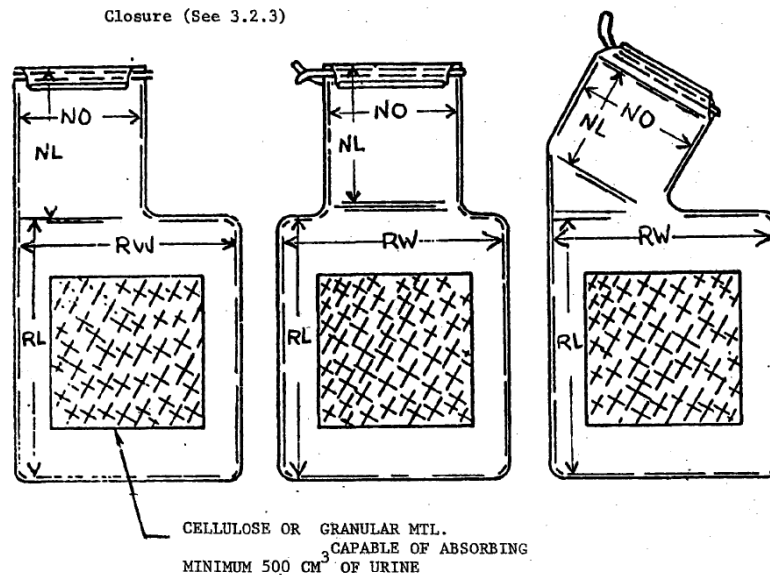
3.2.1. Design. The finished bag shall be of flat rectangular configurations as depicted in figure 1 [below]. Both sides and one end shall be sealed. The opening or neck of the bag shall incorporate means for preventing spillage when bag is inverted and shall not impede flow input.

3.2.3. Closure. Closure shall be by means of a 28 gage steel (corrosion resistant), 3/8 inch wide (10 [millimeter]) band or wire of equal strength and flexibility imbedded or laminated in vinyl plastic to enable ease of folding or rolling in

producing a positive closure. The wire or band shall form an integral part of the bag during fabrication.

Id.

Included in Mil-Spec B was Figure 1, providing the “Configurations and dimensions of bags,” that illustrated the requisite structure and design of the urine containment bag:



Id. at G1380.⁵ The 1981 Mil-Spec B also contained identical performance test requirements as those in the 1968 Mil-Spec A, including the inverted leakage test. Compare id. at G1381 with DX 70 at G1362.

A military specification indicates which products satisfy the specification requirements by listing in the specification the product’s National Stocking Number (“NSN”), a number assigned to a product routinely sold to Government agencies. JX 47 at G1383; Tr. 223. The NSN ensures that agencies “know they’re getting the same product every time, or the manufacturer produces the same product every time.” Tr. 528. A given NSN contains 13 digits with the first four designating a commodity category. Id. at 543. For example, the Piddle Pak with Powder has the NSN 4510-01-480-1323; the first four digits - - 4510 - - indicate that it is a “plumbing supply” within the Defense Logistics Agency (“DLA”). Id.; DX 61 at G1277.

Mil-Spec B for “Bag, Pilot Relief (Male)” contained a section called “Ordering Information,” stating “as of the date of this revision, NSN 8105-00-922-9469 was assigned to the commodity described [t]herein.” JX 47 at G1383. The first four digits 8105 indicate that this commodity is a “bag.” Tr. 559. NSN 8105-00-922-9469 is the NSN assigned to NYCIB’s Piddle Pak with Sponge - - the predecessor product to the accused product, the Piddle Pak with

⁵ “NO” in Figure 1 refers to “neck opening”, “NL” refers to “neck length”, “RW” refers to “reservoir width”, and “RL” refers to “reservoir length.” JX 47 at G1380.

Powder. DX 176. Mil-Spec B did not identify any other NSN as being “assigned to the commodity.” JX 47 at G1383.

AbilityOne Procurements from Qualified Nonprofit Agencies

JWOD established the AbilityOne Committee, an independent federal agency, to facilitate the Government’s “purchase of commodities and services from qualified nonprofit agencies.” 41 C.F.R. § 51-1.1(a); see 41 U.S.C. § 46(a) (2006). A “qualified nonprofit agency” is an agency - - such as NYCIB - - that “employs blind or other severely handicapped individuals for not less than 75 per centum of the man-hours of direct labor required for the production or provision of the commodities or services.” 41 U.S.C. § 48b(4)(C). Under JWOD, the Government maintains a procurement list of supplies and services that must be sourced from “any qualified nonprofit agency for the blind” on a noncompetitive basis. Id. at § 47(a); see 48 C.F.R. § 6.302-5(b)(2), 8.702, 8.703.

The AbilityOne Committee’s regulation at 41 C.F.R. § 51-2.8 entitled Procurement List, provides:

(a) The Committee maintains a Procurement List which includes the commodities and services which shall be procured by Government departments and agencies under the JWOD Act from the nonprofit agency(ies) designated by the Committee. Copies of the Procurement List, together with information on procurement requirements and procedures, are available to contracting activities upon request.

(b) For commodities, including military resale commodities, the Procurement List identifies the name and national stock number or item designated for each commodity, and where appropriate, any limitation on the portion of the commodity which must be procured under the JWOD Act.

41 C.F.R. § 51-2.8 (emphasis added).

Once the AbilityOne Committee places a product or service on the JWOD Procurement List, contracting agencies are required to procure the item directly from a qualified nonprofit agency, unless such item is unavailable at the time. 41 U.S.C. § 48. When two products have the same NSN and one is made by a JWOD qualified nonprofit, the Government agency must buy the product from the qualified nonprofit. Id.; 41 C.F.R. § 51-2.8; Tr. 740-41; see, e.g., JX 35 at G4030-33. According to Ms. Patricia Briscoe, Deputy Director of Business Operations, Pricing and Information Management for the AbilityOne Commission, once a product holding a specific NSN is listed on the JWOD Procurement List, that product becomes a mandatory source item for Government agencies “for perpetuity.” Tr. 744, 747.

By 1980, NYCIB Manufactured and Sold the Piddle Pak with Sponge through JWOD

Prior to 1980, the Piddle Pak with Sponge (NSN 8105-00-922-9469) was manufactured by two companies - - Dayton Bag & Burlap Co. and Scott Aviation Co. JX 35 at G4030-31; Tr. 505; DX 187. At the time, Scott Aviation Co. held the trademark to the name PIDDLE-PAK. Tr. 505. The following is a photograph of Scott Aviation’s version of the Piddle Pak with Sponge:



Tr. 513; DX 187.

On April 22, 1980, the New York Association for the Blind (“NYAB”) sought to obtain approval from the AbilityOne Committee to produce a urinary containment bag meeting the requirements of Military Specification No. MIL-B-83665 and cataloged under NSN 8105-00-922-9469, the same NSN number assigned to the Piddle Pak with Sponge. JX 35 at G4028. NYAB titled its product “Bag, Assembly, Crew Relief.” *Id.* The AbilityOne Committee approved this request on May 7, 1980, and the AbilityOne Committee’s approval was published in the Federal Register on May 9, 1980. JX 36 at G4035; JX 37 at G4037. After 1980, NYAB changed its name to Lighthouse. Tr. 459-462. Scott Aviation worked together with New York Lighthouse after it obtained [the Piddle Pak with Sponge] and “won Federal procurements.” Tr. 505.

Mr. Richard Bland, who joined Lighthouse in 1989, and later founded NYCIB in 1995, testified that, in his view, the Scott Aviation Bag and NYCIB’s Piddle Pak with Sponge were “basically identical.” Tr. 459-62, 505. Both the Scott Aviation urine containment bag and NYCIB’s urine containment bag are assigned the same NSN. The Scott Aviation bag is named the Piddle Pak and the NYCIB Bag is named the “Bag, Assembly, Crew Relief,” and later “Pilot Relief Bag, Sponge.”⁶ He further testified that NYCIB used the same manufacturing process to produce the Piddle Pak with Sponge in 1980 until at least 1989. Mr. Bland was the president of

⁶ The parties interchangeably referred to these three products as the “PIDDLE PAK” during trial and in the briefing.

NYCIB from 1995 to 2014, until NYCIB merged with another company, AlphaPoint, in 2014. Tr. 462-63.

Mr. Bland testified that NYCIB or one of its predecessors was the mandatory source for Government agencies to procure a product with NSN 8105-00-922-9469 - - the Piddle Pak with Sponge - - from 1980 to the present. Tr. 464, 503; JX 18 at 84. Ms. Briscoe, Deputy Director of AbilityOne, confirmed that NYCIB's Piddle Pak with Sponge has been listed on the JWOD Procurement List since 1980. Tr. 752. She testified as to the timeline of NYCIB's sales of the Piddle Pak with Sponge, noting "[r]oughly looking at the documents, from our files, [the Piddle Pak with Sponge] went back as far as just 1980 and then one was - another replacement item was produced in 1996. So, it went back a long way." *Id.*⁷

1988: the Founding of American Innotek and Introduction of the *Brief Relief* and the *Flight Extender*

In late 1988, Mr. Clarence A. Cassidy founded American Innotek Corporation, and bought the '848 Application that eventually issued as the '139 Patent from Ruth and Dan Young - - owners of Southland Products. Tr. 60-61, 106. The '848 Application was assigned to American Innotek on January 16, 1990. PX 59.2 at 956-57.

American Innotek developed two types of urine containment bags, both of which contain hydrophilic superabsorbent granules: the *Brief Relief* and the *Flight Extender*. Tr. 73-74;⁸ compare JX 75 (the square-shaped *Brief Relief*) with DX 88 (the L-shaped *Flight Extender*). The *Brief Relief* was American Innotek's commercial product, whereas the *Flight Extender* was for military use. Tr. 73. During trial, Mr. Cassidy testified that the only difference between the two products was the shape, stating that the *Flight Extender* had a cut out so that "it would fit over the edge of the seat for the pilot." Tr. 74. The *Brief Relief*, in contrast, is a "square bag." Tr. 77. The industrial market was and remains the main buyer of American Innotek's products. Tr. 84 ("[O]ur main focus has been and still really is . . . the industrial market. Talking about utilities, Con Edison of New York, Pac Bell, who is AT&T now, is the primary market that we focused on.").

The *Brief Relief* was assigned NSN 4510-01-379-0177, and since 1990, has been and continues to be sold by Plaintiff under that NSN to the military for use by ground troops. Tr. 84; JX 75; JX 179 at 000322. The *Flight Extender* was assigned NSN 4510-01-382-4327, and American Innotek sold it to the military from the early '90s through 2001. Tr. 93; DX 88. Both of these American Innotek bags have NSN numbers in the plumbing category, not in the general

⁷ In 1996, NYCIB needed to be separately qualified from its predecessor company - - Lighthouse International - - to remain listed on the JWOD procurement list to sell the Piddle Pak with Sponge to Government agencies. NYCIB obtained this qualification on April 25, 1996. Tr. 524.

⁸ American Innotek also manufactures a product called the Restop, a urine containment bag for consumers, which it bought from Star Pioneer. Tr. 114, 118. The original version of the Restop contained hydrophilic material in a packet within the urine containment bag. Tr. 118-19; JX 179 at 000377-78.

“bag” category of the Piddle Pak with Sponge. According to Plaintiff, both the *Brief Relief* and *Flight Extender* are covered by Claim 1 of the ’139 Patent. Tr. 199; DX 182 at 111. Mr. David Katz, a contracting officer with DLA, testified that if the Piddle Pak were requested, the agency would have to obtain the Piddle Pak from the mandated source on the JWOD Procurement List. Tr. 740-41. However, if an agency requested the *Flight Extender* specifically, it could obtain that product through other procurement channels - - not from a mandated supplier on the list. Id. This was possible because the *Flight Extender* had a different NSN than the Piddle Pak with Sponge and the Piddle Pak with Powder.

The 1989 Air Force Productivity, Reliability, Availability and Maintainability Study and 1991 Final Report

In 1989, the Productivity, Reliability, Availability and Maintainability (“PRAM”) Program Office of the United States Department of the Air Force undertook a study comparing the efficacy of American Innotek’s *Brief Relief* with NYCIB’s Piddle Pak with Sponge. JX 46 at 000372; JX 52 at 559. The study was led by Mr. James Bealer, at the time a Logistics Management Specialist with the PRAM Program Office, who personally believed that the Piddle Pak with Sponge was ineffective. JX 46 at 000372.⁹ He testified that the sponge was incapable of absorbing the liquid, and that the “sponge would just be floating . . . probably 50 percent was not absorbed.” PX 64.1 at 60. Mr. Bealer drafted a letter to the General Services Administration (“GSA”) informing it that the PRAM Program Office intended to test a new type of relief bag to “replace the old messy and totally unsanitary relief bag (NSN 8105-00-922-9469)” - - the NSN for the Piddle Pak with Sponge. JX 46 at 000372.

Having learned of the PRAM study, Mr. Bland, the former president of NYCIB, wrote to George Mertz, then President of National Industries for the Blind, on November 21, 1989, contesting the initiation of the PRAM study. JX 9 at 334-38.¹⁰ Mr. Bland summarized “concerns and problems we have with the ‘competitive’ relief bag which is currently being tested by the Air Force.” Id. at 334. Mr. Bland stated that, in the 10 years that Lighthouse had sold the Piddle Pak with Sponge via the JWOD Procurement List,

we’ve been made aware of no problems, have had no requests for redesign, and have had no reports of it ever being off spec. Yet we now find that our product has been “accused” - - without proof - - of being a “continual problem for years”, “of posing a health hazard to those using them”, and “not meeting the Mil Spec.”

⁹ Mr. James Bealer served in the Air Force from 1968 through December 1988, where he worked as an Aircraft Maintenance Specialist and retired at the rank of Master Sergeant. PX 64.2 Ex. 1. Mr. Bealer has a high school education with two years of college and significant training in Aircraft and Acquisition Logistics. Id. Since his retirement from the military in 1988, Mr. Bealer has worked as a civilian Logistics Management Specialist for the Air Force from March 1989 through at least the time of his deposition on April 25, 2013. Id.; PX 64.1 at 1. Mr. Bealer testified as a lay witness via deposition. Tr. 445.

¹⁰ Mr. Bland is in the business field and has a Bachelor of Science degree in statistics and an MBA in marketing both from Indiana University. Prior to his work with NYCIB, Mr. Bland was inexperienced in designing and developing urine containment devices. Tr. 459-60.

Id. at 335 (emphasis in original). Mr. Bland further wrote that “[w]e need to see – in writing – the guidelines regarding what price we could charge if we do end up supplying a ‘revised’ design Pilot Relief Bag employing American Innotek’s chemical ‘gelling’ system rather than our sponge absorbent system.” Id. at 337. He also noted:

Lighthouse Industry has no chemists. NIB may be limited also since, we understand, polymer and biochemistry is involved - - perhaps beyond NIB’s capabilities. We can’t afford significant outside labs and consultants. Yet we can’t afford to lose this product [the Piddle Pak with Sponge].

Id. (emphasis in original).

In spite of Mr. Bland’s protests, the PRAM study comparing the Piddle Pak with Sponge to American Innotek’s *Brief Relief* product continued.¹¹ Based on the study, Mr. Bealer wrote a memorandum dated December 12, 1989, requesting a change in Mil-Spec B, finding that the Piddle Pak with Sponge “is not totally leak proof, and has become a problem as well as a health hazard.” JX 48 at G886. Mr. Bealer further testified that the Piddle Pak’s roll and fold closure was “substantially different” than the zipper closure used in American Innotek’s bag, and that the two closure means were not interchangeable because “[t]here was no comparison. The zip lock was the thing to have” PX 64.1 at 42-44. In sum, Mr. Bealer recommended three changes to the military specification: 1) re-titling the specification, “Bag, Pilot Relief (Male/Female),” 2) altering the dimensions of the bag to accommodate female use, and 3) changing the closure to a zip-lock. JX 48 at G886.

In September 1991, the PRAM Office issued its Final Report (“PRAM Report”), finding that American Innotek’s *Brief Relief* product was preferred over NYCIB’s Piddle Pak with Sponge and was less expensive. JX 52 at 559. The PRAM Report recommended design improvements to Mil-Spec B - - zip locks, gel powder, unisex functionality - - present in the *Brief Relief*. Id. at 561. Despite the PRAM Report’s recommendations, Mil-Spec B itself was not changed. Instead, the Air Force PRAM Division Chief, Colonel Ferguson, instructed Mr. Bealer to “cease and desist” his efforts to add design improvements to Mil-Spec B because it was “a Congressional-type thing.” PX 64.1 at 47. The Government has continued to purchase the Piddle Pak with Sponge from the JWOD Procurement List under NSN 8105-00-922-9469 through the present, and Air Force bases continued to buy American Innotek’s *Flight Extender*, under NSN 4510-01-382-4327, until 2001. Tr. 93; DX 88; DX 176.

1992: The PTO Issues the ’139 Patent entitled “Fluid Containment Bag”

The USPTO issued the ’139 Patent on May 26, 1992, to inventors Ruth E. Young, Daniel L. Young, Richard E. Warrick, and Clarence A. Cassidy, who assigned the ’139 Patent to American Innotek. JX 178. During the course of the patent examination, the PTO rejected the ’139 Patent claims as obvious under 35 U.S.C. § 103, six times. JX 179 at G4268-70, G4299-03,

¹¹ The full extent of the PRAM study consisted of the PRAM Program Office distributing 600 American Innotek bags for testing along with a questionnaire. JX 52 at 560. The Office received a total of 30 responses with only 15 being responsive to the questionnaire. PX 64.1 at 44-46; Tr. 522-23.

G4359-64, 000070-73, 000145-49, 000302-06. At no point during prosecution did the Examiner consider Mil-Spec B in relation to the '139 Patent,¹² nor did American Innotek disclose Mil-Spec B as material to the patentability of the '139 Patent. See 37 C.F.R. § 1.56.¹³

1999: The Accused Product - - The Piddle Pak with Powder

Following the PRAM Report, Mr. Bland of NYCIB was under the impression that the military had ceased purchasing the *Flight Extender* because the Piddle Pak with Sponge remained the sole product on the mandatory JWOD Procurement List for NSN 8105-00-922-9469. JX 18 at 84. In late 1998, however, Mr. Bland was notified by a supply store representative that American Innotek was offering “essentially the same product” to the Air

¹² In its March 31, 2016 claim construction opinion, this Court recognized that “references to the military requirements were considered by the Examiner in his review of the '139 Patent.” Am. Innotek, 126 Fed. Cl. at 472-73. These references included a letter from Mr. Bealer to GSA stating the Plaintiff’s *Brief Relief* product exceeded the requirements of Mil-Spec B. Id.; '139 Patent References Cited. Although the Examiner considered Mr. Bealer’s letter, he did not consider Mil-Spec B itself during prosecution of the '139 Patent. JX 179.

¹³ 37 C.F.R. § 1.56 entitled “Duty to disclose information material to patentability” provides:

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.

* * *

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office,
or

(ii) Asserting an argument of patentability.

37 C.F.R. § 1.56.

Force as the Piddle Pak with Sponge except with a “granular hydrophilic material” instead of a compressed sponge. *Id.* By November 1999, NYCIB began the process of obtaining an NSN for a Piddle Pak with a granular gellable hydrophilic material instead of the compressed sponge - - the Piddle Pak with Powder. JX 16. NYCIB considered the replacement of the sponge with a granular hydrophilic material to be a mere line extension of the Piddle Pak with Sponge. Tr. 466.

Mr. Bland testified:

Well, we had a product already on the procurement list, which was the sponge version, and we simply pulled the sponge out and put powder in, so we thought it was a line extension.

* * *

For example, if you’re selling four flavors of ice cream and somebody says, why don’t you have pistachio or why don’t you have chocolate chunk or whatever, every time you have something in the same category, we call it a line extension. Another color, another whatever. So, this [the Piddle Pak with Powder] is just another version of a urine collection bag, just slightly different from the one we had, but we considered it a line extension.

Tr. 466, 527. On November 9, 2000, NYCIB received confirmation from DLA that the Piddle Pak with Powder was assigned NSN 4510-01-480-1323, and on February 1, 2001, the AbilityOne Committee approved NYCIB’s request to add the Piddle Pak with Powder to the JWOD Procurement List. JX 21.

2000: NYCIB Complains to DLA that Plaintiff Is Illegally Selling its *Flight Extender*

On April 6, 2000, at the direction of the AbilityOne Committee, Mr. Bland sent a letter to Ann O’Connor, then Director of Facilities Maintenance Commodity Business Unit at DLA, writing:

In 1990, a California company, American Innotek Corporation, began offering an “essentially the same” product [as the Piddle Pak with Sponge] to Air Force bases. We became aware of it, notified [National Industries for the Blind], and NIB notified the Committee staff. The company was notified by then Chairman of the Committee, Mr. Ira Kemp of the Air Force, and Ms. Beverly Milkman, then Executive Director of the Committee, to “cease and desist” all such efforts. To our knowledge they complied.

However, in late 1998, we were notified by one of the NIB affiliate-run base supply stores that a sales rep from American Innotek was offering this same product to them for resale to flyers thru their store. We obtained a sample and found that they had been assigned NSN 4510-01-382-4327 by DLA, identified as a “field commode”. . . . Thru NIB, we obtained information from DLA indicating purchases of \$520,000 in the four years 1994-1997.

The military spec under which we produce this product (MIL-B-83665B, dated 2 June 1981) allows us to use either compressed sponges or granular material capable of absorbing 500 cubic milliliters of urine. Since day one, we used compressed sponges. The American Innotek product uses granular hydrophilic material.

JX 18 at 84.

In this letter, Mr. Bland indicated that NYCIB would be producing its own “‘granular material’ version of our product [the Piddle Pak],” and sent samples to DLA. Id. at 85. Mr. Bland noted that “there is a definite cost savings if granular material is used . . . and our price for this version reflects the lower material cost.” Id. (ellipsis in original). Mr. Bland also indicated that NYCIB would enlarge the neck opening of the Piddle Pak to accommodate female pilots. Id.¹⁴

Finally, NYCIB complained that American Innotek was able to sell its *Flight Extender* using a different NSN than the Piddle Pak, stating

We believe that American Innotek creatively, but illegally, found a way around the 1990 directive by the Committee by obtaining a separate NSN under the “Plumbing” category of products thru DLA. And they have been selling significant quantities of product since then at the expense of the JWOD product manufactured by NYCIB.

We would like DLA to stop all purchasing of the commercial product and assign their [American Innotek’s *Flight Extender*’s] NSN to NYCIB’s granular version of the pilot relief bag. Our product is significantly stronger, is made to military spec, and undergoes stringent [quality control] testing to assure its integrity during use. We can offer a granular version with either our standard size opening, or a wider opening – if that would make it more attractive to female pilots. And we have comparable prices to the commercial version.

Id. The Piddle Pak with Sponge was in the “bags” category, not plumbing. In November 2000, NYCIB’s Piddle Pak with Powder was assigned a “plumbing” NSN like Plaintiff’s *Flight Extender*. JX 21 at G743; JX 20 at G510.

On July 28, 2000, DLA responded to these concerns in a letter to Mr. Lou Bartalot of the AbilityOne Committee. Tr. 464-65; JX 19 at G848. DLA found the Piddle Pak with Sponge to be dissimilar to American Innotek’s *Flight Extender*, stating:

Upon examination of the two products [Piddle Pak with Sponge and the *Flight Extender*] by this center [DLA] it was discovered that there were some obvious differences between the two products and that we could not find the NYCIB

¹⁴ In NYCIB’s view, Plaintiff was violating the JWOD list by going directly to Air Force bases, making an end-run around the JWOD list by having an NSN assigned to its product under the “plumbing” category, NSN 4510, instead of the “bags” category, NSN 8105. See JX 18 at 2.

product identical to the [American Innotek] product. Some of the obvious differences were pointed out to the NYCIB representative. Those were the use of powder vs. a sponge for the absorbent, the shape of the bag, and the method used to seal the bag. We did not intend to give the impression that these particular differences were the only differences. Nor did we intend to convey that they were the only reason(s) our customers preferred the AI product. We only pointed these differences out to make the point that the two products were indeed different and that we could not simply substitute the NYCIB product as it was currently configured.

JX 19 at G848.

DLA further clarified that any alterations made to NYCIB's products were NYCIB's own choice and not requested by the Agency. *Id.* ("We did not request that NYCIB modify their product to make it more similar to the [American Innotek] product. This was something that NYCIB decided to do of its own accord.").

2001: The Piddle Pak With Powder Is Listed On the Mandatory Procurement List With A "Plumbing" NSN

On February 1, 2001, the AbilityOne Committee placed on the JWOD procurement list NYCIB's "Piddle Pak Relief Bag" containing "non-toxic hydrophilic granules [that] absorb liquid and retains in gel form" - - the Piddle Pak with Powder. JX 21 at G743. Along with the listing, the AbilityOne Committee assigned NSN 4510-01-480-1323 to the Piddle Pak with Powder - - the NSN for "plumbing," not the NSN for "bags" assigned to the Piddle Pak with Sponge - - to be mandatorily sourced from NYCIB. *Id.*; Tr. 543-44. The Piddle Pak with Sponge remains on the JWOD Procurement List and continues to be sold by NYCIB. Tr. 160.

According to Mr. Bland of NYCIB, the Piddle Pak with Powder is exactly the same as the Piddle Pak with Sponge except for the substitution of the sponge with the hydrophilic absorbent. Tr. 466. The following image depicts the two containment bags¹⁵ side-by-side with the Piddle Pak with Powder on the left, and Piddle Pak with Sponge on the right:

¹⁵ In 2000, NYCIB changed the shape of its bag by making a larger opening for female use. This change did not affect any other feature of the bag including the closure, funnel, and absorbent, and this change in shape and size is not at issue with respect to the '139 Patent.



DX 176; PX 70.

Mr. Bland testified that the Piddle Pak with Sponge and Piddle Pak with Powder have identical structures, stating “we had the same design that we had with the sponge, except we put the sponge out and put the powder in.” Tr. 466, 558; JX 22 at 45. The closure and funnel were the same as that of the Piddle Pak with Sponge - - the roll-and-fold closure, and a detached funnel extending downward with two openings. Tr. 507-12; DX 189 (documenting a series of photographs showing the manufacturing process of the Piddle Pak with Sponge and Piddle Pak with Powder, with the insertion of the sponge in the former and powder in the latter). NYCIB obtained the hydrophilic granules used in the Piddle Pak with Powder from a supplier, Global Environmental Products, which informed NYCIB that the powder would gel in six seconds. Tr. 468, 481.

2000-2001: American Innotek’s Attempts to Remove the Piddle Pak with Powder from the JWOD Procurement List

American Innotek learned about NYCIB’s intention to manufacture the Piddle Pak with Powder through one of its salesmen around 2000. Tr. 79; PX 48 at 1-2. Based on a recommendation from Contracting Officer David Lipschutz of DLA, American Innotek reached out to NYCIB in a letter in December of 2000, to try to establish “a reasonable working relationship” and put together a proposal to work together that “we thought would be a win-win for both of us.” Tr. 80-81; PX 48 at 1-2. Plaintiff had hoped to manufacture and sell the Piddle Pak with Powder or *Flight Extender*, to the Government. PX 48 at 2. Specifically, Plaintiff proposed a joint venture in which it would provide a formed and sealed containment pouch at the cost of \$2.035 each and a proprietary blend of polymers, enzymes, and deodorants at a cost of

\$13.1825 per pound, and NYCIB would complete assembly of the bags and send them to DLA. Id. NYCIB did not accept Plaintiff's proposal.¹⁶

Following NYCIB's 2001 placement of the Piddle Pak with Powder on the JWOD Procurement List, Plaintiff claims that it lost sales, but was still able to sell "some *Flight Extenders* to Air Force bases." Tr. 152. On November 20, 2001, Mr. Cassidy wrote to the AbilityOne Committee, requesting that the Piddle Pak with Powder be delisted from the JWOD Procurement List, stating:

This is a situation whose origin is a decade old. In September of 1991, a PRAM Program Final Report recommended a change in the mil specs of this product class to match the specifications of our patented product. The report further recommended that the [National Industries for the Blind] "implement the recommendation" with no mention of our patent protection.

It would appear however, that the NIB recognized the validity of our patent position since they took no action to alter their product to meet the revised specs. Consequently, [t]he military has been using the American Innotech product for over 10 years.

Throughout this time, the DLA and we have been aware that this product class was included in the JWOD Mandatory Source Program. In fact, just last year, we were contacted by the DLA with a request to try and work something out with the NIB so that our patented design could be made available through them. We responded to this request with an immediate trip to meet with NYC Industries for the Blind and with a formal offer to give them exclusive manufacturing rights for our product.

The New York City NIB declined this offer and responded that it would be in their own best interest to develop product improvements that met the mil specs. The result is a product that clearly infringes our patent!

The question I have is, does the Committee take the position that the Wagner O'Day Act allows participating agencies to violate US Patent Law. Furthermore, is it the purpose of the Wagner O'Day Act to give the NIB the right to copy products and destroy the business of small, entrepreneurial firms?

PX 30 at G705. Mr. Cassidy asserted that a "product that meets this particular mil spec is a patented product." Id. at G706. He then asked that

¹⁶ Patricia Briscoe, Deputy Director of Business Operations, Pricing and Information Management for AbilityOne, testified that the AbilityOne Committee has strict rules on subcontracting work for fear that a nonprofit agency would be used "as a front" for a commercial entity. Tr. 746-47. Ms. Briscoe further testified that were a JWOD nonprofit to enter into a subcontracting agreement, "then they're required to provide a draft copy of that subcontracting agreement to the Commission, and [AbilityOne] would review it prior to it being presented to the Commission for final approval" before the nonprofit can enter into the agreement. Tr. at 749-50.

the [C]ommittee de-list this product class from the list of products that must be procured from JWOD-participating nonprofit agencies. In the alternative, I would ask the [C]ommittee to urge the NYC Industries for the Blind to accept our offer to license our technology so as not to be in violation of US Patent Laws.

Id.

Approximately six months later, on May 15, 2002, Leon A. Wilson, Jr., then Executive Director for the AbilityOne Committee, responded, declining to delist NYCIB's Piddle Pak with Powder. PX 31 at G550. Mr. Wilson stated that he had "carefully examined the issues . . . raised about the crew relief bag, Stock Class 8105-00922-9469, and MIL-B-83665B," and that "[o]f course, the Committee does not take the position that JWOD allows participating agencies to violate U.S. patent law." Id. However, "the Committee's process for making additions to its Procurement List (PL) does not specifically consider the existence or nonexistence of patents." Id. Mr. Wilson also noted that "[a] version of the crew relief bag was added to the PL in 1980, approximately 10 years prior to the introduction of the American Innotek (AI) product. No issues with patents were raised at that time." Id. The referenced 1980 "version of the crew relief bag" was the Piddle Pak with Sponge. See Tr. 752; JX 35.

Regarding the alleged infringement, the AbilityOne Committee stated:

When you raised the issue of patent infringement(s) in your letter, the Committee requested that NYCIB document its assertion that its Washington, DC-based patent attorney had done an extensive check of AI's patents, and that it was not in violation of them. NYCIB provided us an extensive discussion of its contention that its crew relief bag violated none of your company's patents relevant to the crew relief bag. As we have no patent experts on our staff, we cannot dispute NYCIB's contention. Accordingly, it would not be appropriate to remove the NYCIB product from the [Procurement List] at this time.

Id. The AbilityOne Committee's letter concluded, "if you obtain a judicial determination that NYCIB has infringed your patents, we will take action to ensure our program is not involved in further infringement." Id.

NYCIB's invalidity and infringement analysis performed by attorney Randolph A. Smith of the Washington-DC based firm, Smith Patent Office, referenced in the AbilityOne Committee's letter was attached to Plaintiff's complaint and is dated May 8, 2002. PX 61.2 at 6; Tr. 480-81. The analysis concluded:

As a general comment, we note that NYCIB's earlier product [the Piddle Pak with Sponge] appears to be almost identical to expired U.S. Patent No. 3,403,410 to Benzel et. al. (copy enclosed). Also, NYCIB's recent products are almost identical to this patent with the only relevant change being the substitution of a powder for the sponge in the bag. We believe that concept of using a granulated powder instead of a sponge should not be able to be covered by a patent because it was mentioned in the military specification prior to the filing of [American Innotek's] application.

We seriously doubt whether any Patent Examiner would have issued such a broad patent [the '139 Patent] if they were presented with the military specification (which they were not). We also do not think that there is any real difference between a granulated powder that can absorb liquid and hydrophilic material since a granulated powder that can absorb liquid is a hydrophilic material. We also believe that any limitations relating to the size of the powder are also invalid since an engineer would typically seek a commercially available powder that we believe is within these ranges.

PX 61.2 at 6.

November 2001: Plaintiff Files a Bid Protest at GAO Seeking Removal of the Piddle Pak with Powder from the JWOD Procurement List

On November 28, 2001, eight days sending after its letter to the AbilityOne Committee requesting delisting of the Piddle Pak with Powder, American Innotek filed a bid protest with the then General Accounting Office (“GAO”)¹⁷ challenging DLA’s listing of the Piddle Pak with Powder on the JWOD Procurement List. JX 83 at 6. Specifically, American Innotek requested

a ruling that requires the Committee for Purchase from People Who Are Blind or Severely Disabled to de-list this product category from the list of products that must be purchased from JWOD-participating nonprofit agencies and to instruct the NYC Industries for the Blind that the Javits, Wagner, O’Day Act does not authorize them to violate U.S. Patent Law.

Id. at 8. GAO dismissed American Innotek’s protest on January 4, 2002, stating that it “has no authority to decide that an item should be deleted from the list.” JX 84 at 40. Further, GAO noted that “our Office does not consider complaints that a contract awardee will violate another firm’s patent” and that the exclusive remedy for patent infringement by authorization or consent by the Government is “a suit against the Government in United States Court of Federal Claims.” Id. at 41.

Plaintiff did not seek relief in the Court of Federal Claims at the time and took no action for a decade. In 2010, NYCIB requested that products assigned with NSN 4510-01-379-0177 - - the NSN assigned to Plaintiff’s *Brief Relief* Product - - be listed on the JWOD Procurement List. Tr. 103-04, 563-65. Mr. Cassidy testified:

Well, the main reason we filed suit is, you know, we had kind of given up on this government relationship on the Piddle Pak. We were too small, didn’t have enough money to defend ourselves. So we kind of rolled over and said “Okay.”

Well, they decided to come after the Brief Relief, and so [National Industries for the Blind] announced the fact they were going to take over that one, and we said, no, you’re not. And we kind of dug our heels in and got into this whole – this

¹⁷ Congress changed the name of the General Accounting Office to the Government Accountability Office in 2004, in accordance with the Government Accountability Office Human Capital Reform Act of 2004, Pub. L. 108-271, § 8, 118 Stat. 811 (July 7, 2004).

whole suit at this point. So the original objective was to keep [NIB] away, and then also maybe recover some of the costs of this whole thing.

* * *

Oh, the NIB. They were back for a second bite, so – only [the *Brief Relief* is] the biggest product we have - -

Tr. 103-04. Plaintiff's counsel then questioned:

QUESTION: New York City Industries for the Blind . . . was going to take it away - - the *Brief Relief*, in addition to the *Flight Extender* product?

MR. CASSIDY: Exactly.

Tr. 103-04.

Discussion

Plaintiff asserts that the Government infringed independent Claim 1 and dependent Claims 2, 3, 4, and 17 of the '139 Patent through its purchase and use of the Piddle Pak with Powder. Defendant argues that the Piddle Pak with Powder does not infringe either independent Claim 1 or dependent Claim 3, and could thus not infringe the remaining dependent claims. In the alternative, Defendant asserts that Claims 1-4 and 17 are invalid as obvious.

Jurisdiction

This Court has exclusive jurisdiction over patent infringement actions against the Government under 28 U.S.C. § 1498(a). *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1363 (Fed. Cir. 2014); *Uusi, LLC v. United States*, 110 Fed. Cl. 604, 609 (2013), mandamus denied, 549 F. App'x 964 (Fed. Cir. 2013). Section 1498 provides in relevant part:

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.

28 U.S.C. § 1498(a) (2012). The remedy in actions under § 1498 is limited to monetary damages. *Advanced Software Design Co. v. Fed. Reserve Bank of St. Louis*, 583 F.3d 1371, 1375 (Fed. Cir. 2009).

As the General Services Administration and DLA purchased, for military use, 981,250 Piddle Paks with Powder from NYCIB from April 8, 2005 to May 26, 2009, the Court has jurisdiction over the instant action under 28 U.S.C. § 1498 for Defendant's alleged infringement of a patented invention without authority from Patent Owner, American Innotek. PX 36 at A88-89; DX 44.

Claims 1 through 4 and 17 of the '139 Patent are Invalid as Obvious

Although Defendant raises invalidity as an alternative affirmative defense, the Court addresses it first, as an invalid patent cannot be infringed. See Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 100 (1993) (stating that “of the two questions [infringement and validity], validity has the greater public importance” and that a trial court should follow “what will usually be the better practice by inquiring fully into the validity of [the] patent.” (quoting Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 330 (1945))); 3Form, Inc. v. Lumicor, Inc., No. 12-cv-293CW, 2015 WL 9463092, at *2 (D. Utah Dec. 28, 2015) (“Since an invalid patent cannot be infringed, considerations of judicial economy dictate that the court address the question of validity before making any determinations of infringement.”).

Legal Standard for Challenging Validity under 35 U.S.C. § 103

An issued patent is presumed valid - - novel, nonobvious, useful, and containing patentable subject matter - - because the “[US]PTO is presumed to do its job.” 35 U.S.C. § 282; Microsoft Corp. v. i4i Ltd. P'ship., 564 U.S. 91, 97 (2011) (citation omitted). To rebut this presumption, an accused infringer must prove its affirmative defense of invalidity by clear and convincing evidence. Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1355 (Fed. Cir. 2007). To succeed on an invalidity challenge based on obviousness, the accused infringer must prove that “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention” with a reasonable expectation of success. Proctor & Gamble, Co. v. Teva Pharms. USA, Inc., 566 F.3d 989, 994 (Fed. Cir. 2009) (quoting Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1361 (Fed. Cir. 2007)); see KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 424 (2007).

The governing statute, 35 U.S.C. § 103, provides:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title [novelty],¹⁸ if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103(a) (2006).

The ultimate determination of obviousness under § 103 is a question of law - - whether the patented subject matter would have been obvious at the time it was made to a person having ordinary skill in the art. Nike, Inc. v. Adidas AG, 812 F.3d 1326, 1334 (Fed. Cir. 2016) (citing In re Baxter Int'l Inc., 678 F.3d 1357, 1361 (Fed. Cir. 2012)); Oatey Co. v. IPS Corp., 665 F. Supp. 2d 830, 842 (N. D. Ohio 2009). However, this legal determination is dependent upon

¹⁸ The pre-America Invents Act version of 35 U.S.C. § 102 is applicable here, entitled “Conditions for patentability; novelty and loss of right to patent,” and sets forth seven conditions for patentability, including what references can be considered prior art. 35 U.S.C. § 102 (2006).

underlying factual findings. Nike, 812 F.3d at 1334. To make these findings of fact, the Court analyzes the following four factors, commonly referred to as the Graham factors:

- 1) the level of ordinary skill in the pertinent art;
- 2) the scope and content of the prior art;
- 3) the differences between the prior art and the claims at issue; and
- 4) any relevant secondary considerations, or objective indicia of non-obviousness - - such as commercial success, long-felt but unsolved needs, and failure of others to invent the patented invention.

Bell Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc., 555 F.3d 984, 991 (Fed. Cir. 2009) (citing Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18 (1966)); KSR, 550 U.S. at 406; Sparton Corp. v. United States, 89 Fed. Cl. 196, 208 (2009). A hypothetical person of ordinary skill in the art is presumed to have all available prior art references relevant to the pertinent field. In re Roufflet, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

The party challenging the patent's validity has the initial burden of showing that a skilled artisan would have been motivated to combine the teachings of the prior art to predictably achieve the claimed invention or improvement with reasonable success, based upon a showing of the first three Graham factors. Pfizer, Inc., 480 F.3d at 1360 (citing Dystar Textilfarben GmbH v. C.H. Patrick Co., 464 F.3d 1356, 1360 (Fed. Cir. 2006)); Proctor & Gamble Co., 566 F.3d at 994. If the challenger meets this initial burden of showing the first three Graham factors, it has made out a "prima facie" case of the subject patent's obviousness. Pfizer, Inc., 480 F.3d at 1360. After the challenger has shown its prima facie case, the burden shifts to the patent owner to show sufficient evidence of the fourth Graham factor, secondary considerations, that indicate that the asserted patent claims are nonobvious. Id. (citing Mas-Hamilton Grp. v. LaGard, Inc., 156 F.3d 1206, 1216 (Fed. Cir. 1998)). The court then considers all the evidence as a whole before reaching its ultimate conclusion on whether the patent challenger has met its burden to show the subject patent is obvious by clear and convincing evidence. Leo Pharm. Prods., Ltd. v. Rea, 726 F.3d 1346, 1357 (Fed. Cir. 2013).

A court must consider the patent owner's proffered secondary considerations before ultimately concluding whether the asserted patent claims are obvious. Lindemann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co., 730 F.2d 1452, 1461 (Fed. Cir. 1984) (holding that "all evidence" including secondary considerations "must be considered before a conclusion of obviousness is reached" (emphasis in original)). However, if the patent challenger presents a strong prima facie case, secondary considerations only rarely overcome the prima facie case. Wyers v. Master Lock Co., 616 F.3d 1231, 1246 (Fed. Cir. 2010) ("[S]econdary considerations of nonobviousness – considered here by the district court – simply cannot overcome a strong prima facie case of obviousness."); see ABT Sys., LLC v. Emerson Elec. Co., 797 F.3d 1350, 1361 (Fed. Cir. 2015) (reversing a jury verdict of nonobviousness, finding that the patent owner's evidence of secondary considerations could not, as a matter of law, overcome "a convincing case of invalidity"); see, e.g., Dow Chem. Co. v. Halliburton Oil Well Cementing

Co., 324 U.S. 320, 330 (1945) (“[Secondary] considerations are relevant only in a close case where all other proof leaves the question of invention in doubt.”).

In comparing the differences between the prior art and the claims at issue, the Court must take into account the common sense and ordinary creativity of a skilled artisan reviewing the prior art. KSR, 550 U.S. at 420-21 (“Common sense teaches, however, that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle A person of ordinary skill is also a person of ordinary creativity, not an automaton.”). “If a person of ordinary skill can implement a predictable variation [of a prior art reference with other prior art components], § 103 likely bars its patentability.” Id. at 417; ABT, 797 F.3d at 1360.

Level of Ordinary Skill in the Art

Defendant’s expert, Richard Moran,¹⁹ testified that a person of ordinary skill in the field of disposable urine containment devices, would be either a person with a degree in engineering or the sciences with one to three years of experience in the field, or a person without a degree with three to five years of experience. Tr. 662-63. Plaintiff’s expert, Neil Martin, did not offer a competing definition, and Plaintiff did not present any evidence contrary to Mr. Moran’s testimony. As such, the Court adopts Defendant’s un rebutted definition of a person having ordinary skill in the art. Sparton Corp., 89 Fed. Cl. at 208 (citing Scanner Techs. Corp. v. ICON Vision Sys. Corp. N.V., 528 F.3d 1365, 1380 (Fed. Cir. 2008)).

The Scope and Content of the Prior Art

A person cannot obtain a patent unless the invention is new. Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 780 (Fed. Cir. 1985) (“The patent law imposes certain fundamental conditions for patentability, paramount among them being the condition that what is sought to be patented, as determined by the claims, be new.”). Prior art is the universe of information in any form, including inventions, improvements, presentations, and publications, that is available before a patent’s filing date and relevant to the disputed patent’s claims, circumscribed by 35 U.S.C. § 102. In other words, prior art is what is not “new.” See In re Schoenwald, 964 F.2d 1122, 1123 (Fed. Cir. 1992); Titanium Metals, 778 F.2d at 780. To assess what references are considered prior art for conducting an obviousness analysis under Section 103, a court is guided by 35 U.S.C. § 102. Riverwood Int’l Corp. v. R.A. Jones & Co. Inc., 324 F.3d 1346, 1354 (Fed. Cir. 2003) (“The term ‘prior art’ as used in section 103 refers at least to the statutory material named in 35 U.S.C. § 102.”); Sparton Corp., 89 Fed. Cl. at 210. The scope of the prior art relevant to determine obviousness includes those references within the inventor’s field and those references that are “reasonably pertinent to the particular problem in which the

¹⁹ Mr. Moran was accepted as an expert in the field of disposable absorbent products used for the collection and containment of human bodily fluids, without objection. Mr. Moran received a degree in mechanical engineering from Yale University in 1953. Mr. Moran spent almost 40 years at Procter & Gamble, working with one-way valves in a pulp mill, diaper products, adult incontinence devices, tampons, and superabsorbent polymers. Following his retirement from Procter & Gamble in 1994, Mr. Moran started a consulting business that dealt entirely with the “disposables and nonwovens industry.” DX 101.

inventor is involved.” Wyers, 616 F.3d at 1237 (quoting Comaper Corp. v. Antec, Inc., 596 F.3d 1343, 1351 (Fed. Cir. 2010)).

Section 102(b) provides in relevant part:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States[.]

35 U.S.C. § 102(b) (2006).

A reference constitutes prior art if it is a patent or printed publication publicly available one year before the patent application was filed. 35 U.S.C. § 102(b). To ascertain the filing date, the Court must determine a patent’s priority with respect to earlier patent applications. 35 U.S.C. § 120 (2006). Normally, the effective filing date of a continuation-in-part patent, like the ’139 Patent here, is presumed to be the filing date apparent on the face of the patent unless the Patent Examiner found otherwise during prosecution. PowerOasis, Inc. v. T-Mobile USA, Inc., 522 F.3d 1299, 1305-06 (Fed. Cir. 2008). However, a patent owner can rebut this presumption by “com[ing] forward with evidence to prove entitlement to claim priority to an earlier filing date,” such that the patent-in-suit should be deemed as filed on the filing date of its earlier related patents. Id.²⁰

Here, the Examiner did not consider the ’139 Patent’s priority date during prosecution and Plaintiff has neither argued nor presented evidence to rebut the presumption that the ’139 Patent is entitled to a priority date of February 15, 1991 - - the filing date on the face of the ’139 Patent. As such, the Court considers February 15, 1991, to be the priority date, and February 15, 1990, to be the critical date for assessing what references are prior art to the ’139 Patent under Section 102(b). Id. at 1305; see In re NTP, Inc., 654 F.3d 1268, 1279 (Fed. Cir. 2011). Thus, here, in order to be prior art under Section 102(b), a reference must predate February 15, 1990.

Defendant’s Proposed Prior Art References

Defendant posits that the following five references are prior art that render asserted Claims 1 through 4 and 17 obvious:

²⁰ The priority date of the ’139 Patent is relevant here insofar as Defendant offers one reference - - Sherman, “Polymers, Polymers, Everywhere!” from October 1987 - - that could not be considered prior art if the ’139 Patent established priority based upon the grandparent application date of January 14, 1987.

1. United States Patent No. 3,403,410 (“Benzel”) entitled “Disposable Urine Container.” DX 105.
2. Military Specification B-83665B (“Mil-Spec B”) entitled “Bag, Pilot Relief (Male).” JX 47.
3. Gellable absorbents generally, and the polymers described in an article by Marie Sherman from the Journal of Chemical Education entitled “Polymers, Polymers, Everywhere!: A Workshop for Pre-High School Teachers and Students” (“Sherman”). DX 119.
4. United States Patent No. 4,179,367 (“Barthell”) entitled “Thickening Urinary And Intestinal Tract Excrement.” DX 107.
5. United Kingdom Patent Application No. 2,016,929 (“Fjeldså”) entitled “Incontinence device for males.” DX 108.

Plaintiff does not contest the prior art status of any of Defendant’s references.

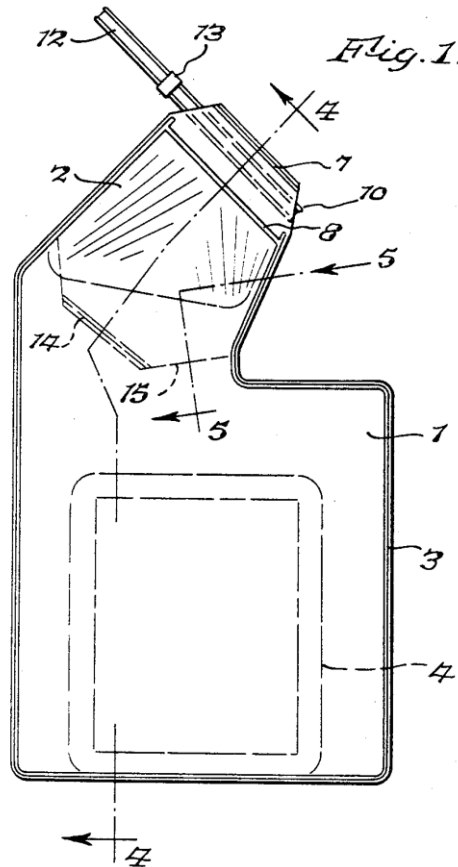
Plaintiff asserts that five claims in total are infringed by NYCIB’s Piddle Pak with Powder - - Claim 1 - - the ’139 Patent’s sole independent claim - - and Claims 2-4, and 17 that are dependent on Claim 1. Defendant challenges each claim as obvious under 35 U.S.C. § 103 based on the following combinations of references:

Asserted Claims of the ’139 Patent	Defendant’s Asserted Invalidity References under 35 U.S.C. § 103
Independent Claim 1	Benzel, Mil-Spec B, and a gellable absorbent, and/or Fjeldså.
Dependent Claim 2	Benzel, Mil-Spec B, a gellable absorbent, and/or Fjeldså, and/or Barthell.
Dependent Claim 3	Benzel, Mil-Spec B, a gellable absorbent, and Barthell.
Dependent Claim 4	Benzel, Mil Spec B, a gellable absorbent, and/or Fjeldså.
Dependent Claim 17	Benzel, Mil Spec B, and a gellable absorbent.

Def.’s Post Trial Br. 47-49.

1. United States Patent No. 3,403,410 (“Benzel”)

Benzel is United States Patent No. 3,403,410, which issued on October 1, 1968, and is entitled “Disposable Urine Container.” DX 105. Figure 1 of Benzel is illustrative of the invention:



Benzel teaches a urine containment bag consisting of an outer body portion and an inner “self-closing valve means” that “clos[es] against the outflow of liquid from said body portion” Benzel 3:8-12; see also Benzel 2:50-54 (“[S]hould the container accidentally be dropped, the slits tend to close . . . against the outflow of liquid from the body portion.”). This “self-closing valve means” is described as “funnel shape[d]” and is free from attachment to the sides of the bag. Benzel, Abstract; Tr. 394-95. Benzel further teaches incorporating a “liquid absorbing sponge material” into the body of the bag “which expands and enlarges as it absorbs liquid, but which is compressed and flat, prior to use.” Benzel 2:7-9. Lastly, the urine containment bag in Benzel has a roll and fold feature to “close the container.” *Id.* at 2:59-68. As a United States Patent issued before February 15, 1990, Benzel is prior art to the ’139 Patent under 35 U.S.C. § 102(b).

2. Military Specification B-83665B (“Mil-Spec B”)

A military specification is a DoD standard used to provide a Government contractor with a product’s requirements to satisfy military needs. See 41 C.F.R. § 101-29.216-29.217. The

1981 Mil-Spec B entitled “Bag, Pilot Relief (Male),” describes “one type of disposable plastic bag suitable for the collection, retention, and temporary storage of urine” to be “use[d] by all Departments and Agencies of the Department of Defense.” JX 47 at G1378. Mil-Spec B expressly provides that the sponge absorbent in a urine containment bag can be substituted with a “granular material.” Id. at G1379. It specifies:

3.1.4. Absorbent. Bag shall contain an absorbent of either sponge type compressed cellulose or granular material capable of absorbing 500 [cubic centimeters] of urine.

Id. Defendant’s expert, Mr. Moran, explained that a superabsorbent polymer, such as that used in the Piddle Pak with Powder, fits the description of Mil-Spec B’s absorbent “granular material,” and would comply with Mil-Spec B’s requirement of absorbing 500 cubic centimeters of urine. Tr. 645-46. Mil-Spec B further describes that the neck of the urine containment bag “incorporate[s] means for preventing spillage when bag is inverted and shall not impede flow output.” JX 47 at G1379. A skilled artisan would have known about these structural features disclosed in Mil-Spec B by February 15, 1990. See Am. Innotek v. United States, 126 Fed. Cl. 468, 486-87 (2016).

Plaintiff and Defendant stipulated during trial that by September 1983, Mil-Spec B “was a printed publication.” Tr. 493. Defendant submitted the declaration of Ms. Barbara S. Selby, Manager of Research and Information Services and Regional Federal Depository Librarian at the University of Virginia, who testified that she was able to obtain a copy of Mil-Spec B from the July 1, 1983 “Department of Defense Index of Specifications and Standards” located in the University of Virginia Library. DX 64 ¶¶ 6, 7. As a Department of Defense public procurement standard, and as Ms. Selby’s testimony confirms, Mil-Spec B was publicly accessible at least by 1983 - - prior to February 15, 1990. See DX 186A. As a printed publication that was publicly accessible prior to February 15, 1990, the Court considers Mil-Spec B to be prior art to the ’139 Patent under 35 U.S.C. § 102(b).

3. United States Patent No. 4,179,367 (“Barthell”)

Barthell is U.S. Patent No. 4,179,367 issued in 1979, entitled “Thickening Urinary and Intestinal Tract Excrement.” DX 107. Barthell teaches a water-swellable polymer that can be combined with perfumes and used to reduce the odor of waste in a urine containment device. Barthell discloses a genus of copolymers that function to “thicken” bodily fluid, including four different sodium acrylates. Barthell 2:17-22. Barthell details how cross-linked homopolymers and copolymers “of salts of acrylic acid or methacrylic acid . . . in particular the corresponding sodium salts or mixtures or polymers from acrylates and methacrylates,” convert liquid excretions into gel. Id. at 1:64-68.

Barthell states:

Surprisingly, the action of the polymer according to the invention is distinctly improved by the incorporation of a hydrophilic adsorption agent; whereas the polymer according to the invention alone converts the liquid excretion products into a soft, flowable gel, a polymer containing an hydrophilic adsorption agent has the effect of converting the liquid excretion products into a stiff, non-flowable,

structured gel. Because of its consistency, the formulation of such a gel is especially desirable and thus represents a considerable improvement over the still soft, flowable gel obtained by thickening with the polymer alone.

Id. at 2:48-59. Barthell further discloses the addition of perfumes to “reduce annoyance caused by smell,” and provides ratios of recipes to add such perfume materials to the polymer combinations. Id. at 3:38-52. As a United States Patent issued before February 15, 1990, Barthell is prior art to the ’139 Patent under 35 U.S.C. § 102(b).

4. Gellable Polymer Absorbents Were Generally Known and Commercially Available Prior to February 15, 1990, and Described in an October 1987 Article: “Polymers, Polymers, Everywhere!” (“Sherman”)

The ’139 Patent specifically claims a “gellable hydrophilic material . . . becoming fully gelled within thirty seconds of contact with [bodily fluid].” ’139 Patent 8:46-48. The parties’ experts agree that superabsorbent polymers capable of gelling within 30 seconds of contact with fluid were widely available in the field prior to 1990. Defendant’s expert, Mr. Moran, testified that in the 1980s, superabsorbent polymers were being used in diapers and similar products, and that such superabsorbent polymers were “much better than any other absorbent material in practice by that time.” Tr. 659-60. Plaintiff’s expert, Mr. Martin, similarly acknowledged that “there are many types of granular material which could be capable of absorbing 500 cubic centimeters of urine” and that superabsorbent polymers “that could gel within 30 seconds were available and [were] on the market prior” to the invention of the ’139 Patent. Tr. 390.

The ’139 Patent itself recognizes the commercial availability of such gellable polymers. It states:

This absorbent material 42 contains a hydrophilic gellable material, usually a polymer, which is water activated and which gels very rapidly (normally within 30 seconds, and often much less than that) upon contact with a water-based liquid (such as urine or blood) and which by gelling completely absorbs and encapsulates all of the fluid. Such polymers are commercially available and are commonly found in a variety of known products, including disposable diapers and cleaning compositions. Typical examples include the acrylonitrile-based polymers described in Elias, Mega Molecules, pp. 157-158 (1987) and the acrylic polymers described in U.S. Patent No. 4,179,367 [Barthell].

* * *

We have successfully used a granular material commercially available under the trade name “Sanwet IM-5600” from Hoechst Celanese, Superabsorbent Material Division, of Portsmouth, Virginia, which is described as containing a starch grafted sodium polyacrylate. This product is a proprietary product and the exact identification of the components and formula is not available to applicants. The product has shown the property in our tests of gelling and sequestering all bodily fluids placed into test bags within no more than twenty seconds.

'139 Patent 6:40 – 7:7 (emphasis added). This specification excerpt explicitly recognizes the broad commercial availability of gellable polymers within the field of urine containment. Id. As such, the Court considers gellable polymers capable of becoming fully gelled within 30 seconds to be prior art under 35 U.S.C. § 102(a).

Defendant further introduced an article by Marie Sherman entitled “Polymers, Polymers, Everywhere!: A Workshop for Pre-High School Teachers and Students.” Tr. 586; DX 119. Sherman was published in October 1987, in the Journal of Chemical Education by the American Chemical Society. DX 119. As Mr. Moran testified, Sherman discloses that superabsorbent polymers existed and that their properties were known by teachers in 1987. Tr. 648-49. The superabsorbent polymer disclosed in Sherman is synthetic sodium polyacrylate.

Sherman states:

One half teaspoon of this superabsorbent powder (synthetic sodium polyacrylate) will almost instantly gel 100 mL of water in a plastic cup. The workshopppers took note of the strange properties of the “gelled” water, and carried it home for further experiments. Practical uses (such as in disposable diapers) for this type of polymer were developed in the discussion.

DX 119 at G4060.

As Sherman was distributed via a known journal, the Court finds that it was sufficiently publicly accessible to be considered a printed publication under Section 102(b), which allows “printed publications” to be considered prior art if the invention is described “in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States.” Moreover, that the Sherman article was publicly disseminated and accessible is demonstrated through its indexing and retrievability via the online service “infotrieve” from the FBI Laboratory Library archives. DX 119 at G4059; see Kyocera Wireless Corp. v. Int’l Trade Comm’n, 545 F.3d 1340, 1350 (Fed. Cir. 2008). Although the document was accessed in 2012, for purposes of the instant litigation, the “infotrieve” order form attached to the first page of the Sherman exhibit notes that Sherman was published in 1987, beginning on page 868 of volume 64 of the Journal of Chemical Education. DX 119 at G4059. As Sherman is a printed publication in the United States published in October 1987, before the critical date of February 15, 1990, it is prior art to the '139 Patent as defined by 35 U.S.C. § 102(b). Id.; Tr. 649.

5. U.K. Patent Application No. 2,016,929 (“Fjeldså”)

United Kingdom Patent Application No. 2,016,929 (“Fjeldså”) entitled “Incontinence device for males,” was published in 1979. DX 108. Fjeldså teaches a urine containment bag for men containing super absorbing polymers that are superior to sponges because pressure to the gelled fluid could not result in the escape of liquid, thus preventing leakage from the urine containment bag more effectively than a cellulose sponge. Id.

Fjeldså states:

It is of importance in this context that the super absorbent material – this material is well known in the art – is used in the container. Super absorbent material, e.g.

of the type to be described in the following, has the quality of retaining the absorbed fluid quantity also when exposed to a certain pressure. In case ordinary fluid absorbing cellulose fibers were used, the fluid would, when the container is exposed to a slight pressure, first be pressed out into the container and then through the meshes of the container. The fluid repellent impregnation would not be able to resist the internal pressure. The conditions will be different when super absorbent material is used because the pressure against the container is unable to press the fluid out of the fluid absorbent material and thus no fluid could be pressed out of the container

Fjeldså 1:37-53. As Fjeldså is a foreign patent application published prior to February 15, 1990, it is prior art to the '139 Patent. 35 U.S.C. § 102(b); see Bruckelmyer v. Ground Heaters, Inc., 453 F.3d 1352, 1353 (Fed. Cir. 2006) (“Foreign knowledge is not prior art [under Section 102(b)] unless it is patented or published.”).

The Differences Between the Prior Art and the Asserted Claims

Independent Claim 1: Combination of Benzel, Mil-Spec B, and Gellable Absorbents

Defendant submits that a person of ordinary skill in the art would be motivated to combine Benzel with Mil-Spec B and gellable absorbents to achieve Claim 1 of the '139 Patent, rendering it obvious under 35 U.S.C. § 103. Plaintiff itself has recognized that each limitation of Claim 1 is a combination of various well known elements available in the prior art and that the primary difference between the prior art and the '139 Patent is the addition of the gellable hydrophilic material. Pl.’s Findings of Fact ¶¶ 51, 52. (“In this case, the primary difference between the prior art and the claims at issue is the use of a powder in place of a sponge.”); see also Pl.’s Post Tr. Br. 9 (“The difference between the old and new Piddle Pak is the powder.”). During prosecution, the Patent Examiner similarly recognized that “Benzel et al. discloses the invention substantially as claimed except Benzel et al. does not show a hydrophilic material.” JX 179 at 000306.

Benzel

Benzel teaches every limitation of Claim 1 of the '139 Patent except the addition of the “gellable hydrophilic material” as the absorbent within the urine containment bag. Benzel teaches an L-shaped urine containment bag, with an absorbent, a funnel shaped “self-closing one-way valve,” and a closure means.²¹ Plaintiff’s expert, Mr. Martin, testified to that effect during cross examination:

²¹ The Court construed the term “closure means” in Claim 1 to be “a clamp 34 or zipper closure 43, and equivalents thereof.” Am. Innotek, 113 Fed. Cl. at 687. Plaintiff’s consistent position throughout this litigation is that the roll-and-fold closure means in the Piddle Pak with Powder is equivalent to “clamp 34 or zipper closure 43” and thus infringes the '139 Patent. Pl.’s Post-Trial Br. 8-9; Tr. 956. However, the Piddle Pak with Powder has an identical roll-and-fold closure means as the Piddle Pak with Sponge that had been sold by NYCIB since 1980, and thus in the public domain well before the February 15, 1990 critical date of the '139 Patent under 35

QUESTION: Okay. Isn't the difference, as a matter of fact, between what's shown in Benzel and the Piddle Pak with powder that you have opined it infringes claim 1 – the difference is there's powder rather than a sponge? Isn't that the difference?

MR. MARTIN: That's certainly the most dramatic difference.

QUESTION: Is there any other difference that's relevant to the claim 1 – to the language of claim 1?

MR. MARTIN: Well, claim 1 calls for the funnel secured and extending into the interior, with a narrower open bottom for conduction of fluid, and where the funnel disposes intermediate between the top and bottom, being free from attachment to the sides of the bag. I – I can't say off – you know, without studying it further, whether the funnel in Benzel qualifies.

QUESTION: Take a look at figure 4 of Benzel, which is, I believe, a side view. Does that show the funnel free from attachment?

MR. MARTIN: Yes, it does.

QUESTION: Okay. So that's there. Any other – basically, the difference between Benzel and what you – and [the Piddle Pak with Powder], that you claim infringes claim 1, is there's hydrophilic powder in the bag rather than a sponge.

U.S.C. § 102(b). This roll-and-fold closure means is also explicitly described in Benzel. Benzel 2:59-68.

Further, Plaintiff's *Brief Relief*, which has a zipper closure means identical to the *Flight Extender*, had been on the market since late 1989, almost 18 months before the February 15, 1991 filing date of the '139 Patent. JX 9 (noting in a November 21, 1989 letter from Mr. Bland to National Industries for the Blind that "American Innotek . . . has a product called 'Brief Relief' which has been on the market for at least a year."); JX 71 at 69 (noting that Plaintiff began selling the *Brief Relief* product to the military in August or September of 1989 for the PRAM study); see also JX 46 (recognizing use of the *Brief Relief* in October 1989); JX 48 (recognizing Government use of the *Brief Relief* on December 12, 1989). As such, zipper closures used in urine containment bags were already being sold in the public domain prior to February 15, 1990, the '139 Patent's critical date.

As the roll-and-fold closure in the Piddle Pak with Sponge and the zipper closure in the *Brief Relief* were already publicly available by February 15, 1990, Defendant has demonstrated that the closure means in Claim 1 was a not novel feature of the '139 Patent.

MR. MARTIN: Hydrophilic powder with the specific characteristics called for in the claim, 30-second gelling and so forth.

Tr. 394-95.

Additionally, Plaintiff's counsel admitted during the claim construction hearing that the difference between Benzel and the '139 Patent is the use of the gellable powder instead of the sponge:

[T]he interesting feature of the funnel though is that the walls or the sides of the funnel are separated from the sides of the bag . . . and that's what gives it sort of what they call a unidirectional valve approach. That means when the product is inverted some of the fluid gets caught between the side of the funnel and the side of the bag, and the concept is that that pressure is supposed to help stop the flow of liquid out of the bag.

If that's all it was, it wouldn't be a patentable invention because this particular design has been used before. What makes this patentable is the use of the powder instead of the sponge. The sponge releases the fluid and it just comes out, and this funnel is incapable of catching it. It just dribbles. But the powder provides two functions.

* * *

The first function is that it gels the fluid, urine or water, within 30 seconds, and so it becomes sort of a gelled mass in 30 seconds. But when you're flying, you don't even want to have 30 seconds of danger, okay. You want to stop it from spilling out in that 30-second interval. And so the second function of the powder is to mix with the urine and change the physical properties of the urine . . . so when you turn the bag over it doesn't spill out.

Claim Construction Tr. 4-5 (emphasis added).

Defendant agrees that the sole difference between Benzel and the '139 Patent is the substitution of gellable hydrophilic material for the sponge. Defendant also points to the '139 prosecution history, in which the Patent Examiner observed, "[Benzel] discloses the invention substantially as claimed except Benzel et al. does not show a hydrophilic material." JX 179 at 000306. As such, Defendant argues that any benefit of using the gellable hydrophilic material - - as opposed to a compressed sponge - - is a benefit inherent to the gellable hydrophilic material itself and not the bag design. Def.'s Post Tr. Br. 49 (citing In re Huai-Hung Kao, 639 F.3d 1057, 1070 (Fed. Cir. 2011) (holding that a claimed benefit is inherent when it is necessarily present in the claimed invention)).

That the substitution of the gellable hydrophilic material for the sponge is the only difference is borne out by NYCIB's nearly identical manufacturing processes for the Piddle Pak with Sponge and the Piddle Pak with Powder. The Piddle Pak with Sponge was listed on the JWOD Procurement List in 1980, over 10 years prior to the '139 Patent's priority date of February 15, 1991. When the Piddle Pak with Powder was introduced into the market in 2001,

Mr. Bland, the former president of NYCIB, testified that the construction of the Piddle Pak with Powder was identical to the Piddle Pak with Sponge except that the sponge was replaced by a commercially available superabsorbent polymer. Tr. 510-13; see Tr. 481 (noting that the powder used in the Piddle Pak with Powder was supplied by a nonparty, Global Environmental Products). Mr. Moran, Defendant's expert, also testified that Benzel is the same as the accused product except for the hydrophilic material:

QUESTION: You said close to the same. What's the difference between Figure 1 of Benzel and Plaintiff's Exhibit 70 [Piddle Pak with Powder]?

MR. MORAN: The difference is in number 4, at the bottom of the figure, the left-hand figure [Piddle Pak with Powder], it is a sponge, whereas this is a powder.

Tr. 644-645.

Therefore, to determine whether Claim 1 is obvious, this Court must assess whether a person of ordinary skill in the art of disposable urine containment devices would, by February 15, 1991, be motivated to and reasonably succeed in combining Benzel with a gellable hydrophilic material capable of "becoming fully gelled" upon contact with fluid within 30 seconds. '139 Patent 8:39-66.

Mil-Spec B

With respect to the "gelalble hydrophilic material" described in Claim 1 of the '139 Patent, the prior art shows that gellable polymers were well known in the art and also increasingly popular in the field of disposable urine containment products prior to the filing of the '139 Patent. Tr. 577-79. The first and foremost suggestion that a skilled artisan would swap a superabsorbent polymer, or a gellable hydrophilic material, for a compressed sponge before February 15, 1991, comes from Mil-Spec B. JX 47. Mil-Spec B explicitly called for a product containing "an absorbent of either sponge type compressed cellulose or granular material capable of absorbing 500 [cubic centimeters] of urine." Id. at G1379. Mil-Spec B thus discloses to a person of ordinary skill to use granular materials in urine containment bags capable of absorbing 500 cubic centimeters of urine. See In re Fulton, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (finding the express teachings of square, triangular, or rectangular stud shapes on shoe soles used to grip artificial turf would motivate a skilled artisan to use hexagonal shaped studs on shoe soles for traction on artificial turf); see also Bayer Healthcare Pharms., Inc. v. Watson Pharms., Inc., 713 F.3d 1369, 1374-76 (Fed. Cir. 2013). A person of ordinary skill wanting to sell a urinary containment bag to the military was required to comply with the military specification to bring a containment bag to the military market. See JX 47 at 1381; see also 41 C.F.R. § 101-29.216-29.217; Am. Elec. Contracting Corp. v. United States, 579 F.2d 602, 613 (Ct. Cl. 1978) (recognizing that to be considered a qualified product per a military specification, a contractor must meet the "particular component[s]" required by the specification itself).

It is uncontroverted that Mil-Spec B is prior art with respect to the '139 Patent. Plaintiff's expert Mr. Martin admitted that the superabsorbent polymer called for in the '139 Patent fit within the Mil-Spec B's "granular material" capable of absorbing 500 cubic

centimeters of urine.” Tr. 390 (testifying that “I recall that there are many types of granular material which could be capable of absorbing 500 cubic centimeters of urine” and affirming that “polymers that could gel within 30 seconds were available on the market prior to the invention of the ’139 [Patent]”). So too, Inventor Cassidy himself linked compliance with Mil-Spec B with infringement of the ’139 Patent. He stated in his letter to the AbilityOne Committee that the alleged infringer, NYCIB, developed “product improvements that met the mil specs,” and the result was a “product that clearly infringes our patent!” PX 30 at G0705. Further, Mr. Cassidy touted the fact that the product that meets Mil-Spec B is his “patented product.” *Id.* Moreover, it is telling that the 1981 Mil-Spec B - - a critical prior art reference for this obviousness inquiry - - was never considered by the Patent Examiner during prosecution.

Mil-Spec B describes a urine containment bag with the “opening or neck of the bag” that “incorporate[s] means for preventing spillage when bag is inverted and shall not impede flow input.” JX 47 at G1379. This Court construed the term “prevent escape” to mean “substantially prevent escape” such that no more than 30 cubic centimeters of fluid per 550 cubic centimeters of water poured into the urine containment bag would be able to escape the bag in a one-minute period. *Am. Innotek*, 126 Fed. Cl. at 486-87. Mil-Spec B discloses this exact limitation in its inverted leakage test:

4.4.2 Inverted leakage test. The bag shall be filled with a minimum of 550 cm³ of water and, without closing, quickly inverted. There shall be no more than 30 cm³ of liquid spilled from the opening during a one-minute period.

JX 47 at G1381. As such, the “substantially prevent escape” limitation in Claim 1 of the ’139 Patent is also disclosed by Mil-Spec B.

Gellable Polymers

While Mil-Spec B describes a urine containment bag using a granular material absorbent capable of absorbing 500 cubic centimeters of liquid with no more than 30 cubic centimeters of leakage within one minute, Claim 1 requires a gellable hydrophilic material capable of becoming “fully gelled” and thus “completely sequestering” fluid in 30 seconds. ’139 Patent 8:46-51. Sherman and gellable polymers generally known before 1990 meet that 30-second limitation of Claim 1 missing from Mil-Spec B. Sherman teaches a person of ordinary skill in the art to use the exact superabsorbent gellable polymer described in the ’139 specification - - sodium polyacrylate. *Compare* DX 119 at G4060 with ’139 Patent 7:1-2. The ’139 specification itself notes that sodium polyacrylate was a “commercially available” polymer at the time of the ’139 Patent and that it “has shown the property in our tests of gelling and sequestering all bodily fluids placed into test bags within no more than twenty seconds.” ’139 Patent 6:65 – 7:7. In so stating, the ’139 specification recognizes that by February 15, 1991, sodium polyacrylate was known to perform the function of the “gellable hydrophilic material” recited in Claim 1 of the ’139 Patent. Sherman recognizes sodium polyacrylate as a polymer in which a teaspoon would “almost instantaneously gel 100 [milliliters] of water.”²² DX 119 at G4060. In describing the

²² Fluid milliliters have a 1 to 1 conversion rate to cubic centimeters; as such, 100 mL converts to 100 cubic centimeters.

time frame for completion of gelling as “almost instantaneously,” Sherman teaches that sodium polyacrylate would fully gel fluid within 30 seconds upon contact. See id.

With respect to “gellable hydrophilic material” in Claim 1 of the ’139 Patent, Defendant’s expert, Mr. Moran, testified to the increasing effectiveness and popularity of superabsorbent polymers in the field of disposable urine containment that “really blossomed in the ’80s.” Tr. 579. He further testified that a skilled artisan would have considered replacing a sponge with a super absorbent polymer by as early as 1990, based on other products available in the market:

QUESTION: And you had mentioned a hot new thing, what hot new thing are you talking about?

MR. MORAN: The superabsorbent materials that had such a high capability of absorbing liquid.

QUESTION: And any type of liquids in particular?

MR. MORAN: Well, they all wouldn’t be the same, water would be the easiest thing, but that’s not useful in anything I could think of, offhand, but in the case of urine, it would still be very much better than any other absorbent material in practice by that time, earlier actually in the ’80s than that.

* * *

QUESTION: And what about the sponge in Benzel, would a superabsorbent be better than that?

MR. MORAN: Yes, it would. I don’t know of any sponge that comes anywhere close to that, so it would be a huge advantage to substitute that.

Tr. 659-63.

Some two years before the ’139 Patent was filed on February 15, 1991, it was not only known to a person of ordinary skill that superabsorbent gellable polymers were effective in urinary containment products, but also that superabsorbent polymers were cheaper than the cellulose sponge or fluff. Tr. 576; see Tr. 788, 826 (noting that from 2001 through 2011, the average price per Piddle Pak with Powder was \$4.13, which was \$2.32 cheaper than the Piddle Pak with Sponge). Mr. Moran testified that by 1989, the price of superabsorbent polymers had decreased due to their widespread use in the disposable diaper industry. Tr. 575-79. A person of ordinary skill in the art would have been aware of these lower costs and would have been motivated to redesign his urine containment product to use the cheaper, more effective, superabsorbent polymer capable of gelling fluid, as expressly sanctioned by Mil-Spec B, instead of the more expensive, less absorbent sponge. This skilled artisan would further select a well known superabsorbent polymer capable of fully gelling fluid within 30 seconds, such as sodium polyacrylate - - expressly disclosed in Sherman, when making this urine containment product.

Based on these three prior art references, Benzel, Mil-Spec B, and the gellable polymers capable of sequestering fluid within 30 seconds, the Court finds that Defendant has shown a prima facie case of Claim 1's obviousness with respect to the first three Graham factors - - level of skill in the art, scope and content of the prior art, and the differences between the prior art the claimed invention.

Objective Indicia of Nonobviousness

The final Graham factor requires the Court to consider whether a patent owner's proffered objective indicia of nonobviousness, referred to as secondary considerations, provide sufficient evidence to overcome Defendant's prima facie showing that prior art teaches the claimed invention - - here, the '139 Patent Claim 1. Graham, 383 U.S. at 18; Prometheus Labs., Inc. v. Roxane Labs., Inc., 805 F.3d 1092, 1101-02 (Fed. Cir. 2015) (“[O]nce a challenger has presented a prima facie case of invalidity, the patentee has the burden of going forward with rebuttal evidence. But, all that means is that . . . once a challenger introduces evidence that might lead to a conclusion of invalidity . . . the patentee would be well advised to introduce evidence sufficient to rebut that of the challenger.” (quoting Pfizer, 480 F.3d at 1360)). A court must consider a patent owner's objective indicia to assure that the accused infringer has met his burden to show invalidity by clear and convincing evidence. Transocean Offshore Drilling, Inc. v. Maersk Contractors USA, Inc., 617 F.3d 1296, 1305 (Fed. Cir. 2010).

Objective indicia of nonobviousness assist a court in assessing whether the asserted patent claims meaningfully added a new invention into the field even though the invention appears to be a clear-cut combination of teachings in the prior art. Leo Pharm. Prods., 726 F.3d at 1358. Objective indicia of nonobviousness, however, cannot overcome a strong showing of obviousness based on combinations of prior art applied according to the prior art's expected function. Apple Inc. v. Samsung Elecs. Co., Ltd., 816 F.3d 788, 804 (Fed. Cir. 2016) (recognizing the long line of case law finding that weaker secondary considerations cannot overcome a strong prima facie showing of obviousness); Allergan, Inc. v. Sandoz Inc., 726 F.3d 1286, 1293 (Fed. Cir. 2013).

Objective indicia of nonobviousness include, but are not limited to, commercial success of embodiments of the patented invention, long-felt but unsatisfied need solved by the claimed invention, unexpected results of the claimed invention, copying the claimed invention, and failure of others to invent the claimed invention. See e.g., Graham, 383 U.S. at 17-18. Plaintiff must establish that an objective indicium actually relates to the patented invention by showing a nexus between the '139 Patent claims and the indicium invoked. Ethicon Endo-Surgery, Inc. v. Covidien LP, 812 F.3d 1023, 1034 (Fed. Cir. 2016); Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1311-12 (Fed. Cir. 2006). To show a nexus between objective indicia and the patented invention, the patent owner must show “a legally sufficient relationship between that which is patented and that which is sold.” ABT, 797 F.3d at 1361 (quoting Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392 (Fed. Cir. 1988)). The stronger the nexus between the objective indicium and the patented invention, the greater weight a court affords the evidence of the objective indicium. In re GPAC Inc., 57 F.3d 1573, 1580 (Fed. Cir. 1995) (“To the extent that the patentee demonstrates the required nexus, his objective evidence of nonobviousness will be accorded more or less weight.”). Accordingly, this nexus requirement acts to tie objective indicia “to the merits of the claimed invention beyond what was readily

available in the prior art.” ABT, 797 F.3d at 1361 (quoting J.T. Eaton & Co. v. Atl. Paste & Glue Co., 106 F.3d 1563, 1571 (Fed. Cir. 1997)).

Plaintiff has repeatedly characterized the patentable feature of the '139 Patent as the replacement of the sponge in the prior art with a hydrophilic powder capable of gelling within 30 seconds and capable of changing the physical properties of the urine so that the urine is completely sequestered. See e.g., Claim Constr. Tr. 4-5 (“What makes [the '139 Patent] patentable is the use of the powder instead of the sponge.”). Thus, to establish a nexus, Plaintiff must show sufficient evidence that this patentable feature - - the inclusion of the gellable hydrophilic material - - led to its claimed objective indicia of nonobviousness supporting the validity of the '139 Patent. Plaintiff asserts that three objective indicia of nonobviousness - - commercial success, long-felt but unsolved need, and copying - - rebut Defendant’s prima facie case of obviousness based on the combined teachings of the prior art.

Commercial Success

Plaintiff argues that the commercial success of American Innotek’s *Flight Extender* and *Brief Relief* is demonstrated by the increase in sales of its *Brief Relief* from 3,600 at its introduction in the first quarter of 1990, to 13,000 products after 18 months on the market, and that this success indicates that Claim 1 of the '139 Patent was not obvious. Pl.’s Suppl. Commercial Success Br. at 5-6; JX 179 at 000322. Plaintiff relies solely on the September 6, 1991 affidavit of Inventor Cassidy relating this sales data that was presented to the Examiner during prosecution as evidence of commercial success. Pl.’s Post Tr. Br. 12; JX 179 at 000321-325.

In his September 6, 1991 affidavit, Mr. Cassidy testified:

During 1989 the “BRIEF RELIEF” product was actively field tested by a number of potential utility customers. In these field tests the customers made their own comparisons of the “BRIEF RELIEF” product with a number of different prior art urination relief alternatives, including (to the best of my knowledge) the “RESTOP” product.

By the end of 1989, much of the comparative field testing had been done “in house” by prospective customers to be superior in function, convenience and ease of use by the customers. Thereafter, orders from the customers began to increase rapidly It will be seen that the average monthly sales increased from approximately 3,600 units in the first quarter of 1990 to 13,000 units in the second quarter of 1991

The sales data presented . . . show[s] that the “BRIEF RELIEF” product has been a marked success over the closest prior art device, the “RESTOP” product, since the customers have found that the “BRIEF RELIEF” product structure is such that the product is significantly more effective and easier to use than the “RESTOP” product.

Id. at 000322-23.

While these sales data might indicate commercial success of the *Brief Relief*, nothing in Mr. Cassidy's affidavit demonstrates that the addition of the hydrophilic polymer - - the allegedly patentable feature of the '139 Patent - - actually drove the commercial success of the *Brief Relief*. Indeed, the deposition testimony of Mr. James Bealer, the former Air Force Logistics Management Specialist with the PRAM Program Office, and the trial testimony of Ms. Niki Kopenhaver, the Chief Operations Officer of American Innotek, provide probative evidence that the commercial success of the *Brief Relief* was unrelated to the use of the gellable polymer. Mr. Bealer testified that the closure means, i.e., the "sealing method," of the '139 Patent made the *Flight Extender* a desirable item for purchase for the military, stating:

QUESTION: You call for the zip lock to be - zip lock closure?

MR. BEALER: Yes.

QUESTION: Is that something you considered an important feature?

MR. BEALER: Very important.

QUESTION: Why?

MR. BEALER: Well, because it was the second way of not allowing anything to spill out of it. Again, with that - - well, if you had taken just the zip lock with the old sponge, chances are, unless you put pressure on it, which you could explode those things, but the zip lock back then, if you have one way to keep it from doing it, two ways was better. And that's what the Air Force train of thought was.

QUESTION: Okay.

MR. BEALER: But the zip lock - - to me - - was the most positive way of keeping it fresh - - or fresh - - from coming out.

PX 64.1 at 35-36.

Ms. Kopenhaver similarly testified that the commercial success of the *Brief Relief* and *Flight Extender* was the result of the leak-proof nature of the zip-lock closure means, not the addition of the gellable absorbent:

QUESTION: Okay. And do you have a feeling as to what they [military customers] like about your product over the Piddle Pak?

KOPENHAVER: They like the wide opening. They like the fact that it is more secure once it's used.

QUESTION: What do you mean by "more secure once it's used"?

KOPENAHVER: It's more secure once it's used.

QUESTION: Are you referring to the sealing?

KOPENHAVER: To the sealing method.

QUESTION: And by “the sealing,” we’re talking about the snap-in-groove?

KOPENHAVER: Correct.

PX 59.1 at 84-85. As such, Plaintiff has not shown that the commercial success of the *Flight Extender* was primarily due to the inclusion of the gellable hydrophilic material to the bag. Moreover, Plaintiff’s evidence of commercial success is exclusively based upon the rectangular shaped *Brief Relief*, not the L-Shaped *Flight Extender*. As such, Plaintiff has not demonstrated a nexus between the commercial success of the *Brief Relief* and dependent Claim 17, which discloses an L-shaped bag.

Lastly, as Defendant argues, the addition of the gellable hydrophilic material was present in prior art urine containment devices, and therefore is less indicative of commercial success. See *Ormco Corp.*, 463 F.3d at 1312 (recognizing that “if the feature that creates the commercial success was known in the prior art, the success is not pertinent”). Here, the addition of the gellable hydrophilic material within a urine containment bag was known for decades in the prior art references Mil-Spec B, Barthell, and Fjeldså. These references all include a urine containment bag containing a gellable polymer absorbent. As such, the Court rejects Plaintiff’s commercial success argument based on the inclusion of the gellable polymer in the urine containment bag, because “that feature was not new.” *Id.* at 1312.

Long-Felt But Unsolved Need

Plaintiff also submitted affidavits during prosecution from Ms. Jane Muir, a marketing consultant for American Inntoek, Mr. John M. Chalmers, a private pilot, and Mr. James Sniffen, a former Marine Corps logistics Commanding General, to testify to the long-felt but unsolved needs fulfilled by the *Brief Relief* product. JX 179 at 000238-252. During the course of prosecution, the Patent Examiner considered these declarations but still rejected the application claims as obvious based on the prior art, albeit without explanation. Compare *id.* with JX 179 at 000263.

Each of these individuals discussed the ability to serve both men and women with a unisex product. But unisex use is not a feature claimed in the ’139 Patent, and Plaintiff has not shown that the long-felt but unsolved need for a urine containment device usable by women was solved by inclusion of the hydrophilic material.

Mr. Chalmers, the private pilot, did testify to the qualities of the hydrophilic material as part of the long-felt need. He stated:

Because of my interest in urinary relief products as both a pilot and a urological medical patient, I have done extensive research in the field of available devices and proposals for such devices

Based on this background . . . , I can state without hesitation that for at least twenty (20) years the military and civilian aircraft markets, as well as, the urological medical market, have experienced a need for a urinary relief device

which would provide for rapid and complete sequestration of urine; eliminate leakage, spillage and handling problems, be usable with equal facility by both males and females; which could be handled and stored in the close confines of locations such as aircraft cockpits

JX 179 at 000249.

The Court recognizes that Plaintiff has shown that there was a need for a urine containment device with the capability of sequestering fluid. However, this need does not overcome Defendant's convincing prima facie case of obviousness. See ABT, 797 F.3d at 1361 (finding that a patent owner's demonstrated evidence of commercial success and long-felt but unsolved need could not, as a matter of law, overcome "a convincing case of invalidity" based on the combination of prior art references); Leapfrog Enters., Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1162 (Fed. Cir. 2007) (holding that when a showing of obviousness based on the combination of prior art references is strong, the court should hold a patent invalid as obvious even if the patentee presents "substantial evidence of commercial success, praise, and long-felt need").

Copying

Copying can be evidence of nonobviousness because it shows that an accused infringer would prefer to copy a patented product rather than use other prior art products in the public domain, indicating that there is something "essential" about the patented product. Diamond Rubber Co. of N.Y. v. Consol. Rubber Tire Co., 220 U.S. 428, 441 (1911). Plaintiff argues that NYCIB's Piddle Pak with Powder evidences copying of the '139 Patent. Defendant counters that despite some showing of copying tied to the patentable feature - - the gellable hydrophilic material - - of the '139 Patent, the strong showing of a motivation to combine Benzel with a well known gellable hydrophilic polymer outweighs the limited secondary considerations shown by Plaintiff. See Leapfrog, 485 F.3d at 1162.

To establish evidence of copying, Plaintiff relies on the cross-examination testimony of Defendant's expert Mr. Moran:

QUESTION: [L]et me ask you read to paragraph 116 [of your expert report] into the record

MR. MORAN: [reading from expert report] "Whether others copied the claimed invention, weighs in favor of nonobviousness. Although the military specification permitted the use of granular hydrophilic material . . . it appears that NYCIB only began making the Piddle Pak with powder after learning of Innotek's patented product."

* * *

QUESTION: Now, I think what you're saying here is two things. One is that copying is a tool to determine whether a product is obvious or unobvious, and the other thing is - that you're saying here is that NYCIB began making the Piddle Pak

only after learning of the patented invention. Basically you're saying they copied it. This objective evidence weighs in favor of a finding of unobviousness. Is that what you said in your report?

MR. MORAN: Yes.

Tr. 713-14.

Mr. Moran testified on redirect examination, however, to the overwhelming evidence of obviousness, even in view of objective indicia, noting that the copying was not necessarily tied to American Innotek's product, but to the way the industry was moving at the time. He testified:

QUESTION: Now, you considered copying in your obviousness analysis, correct?

MR. MORAN: Yes.

QUESTION: And yet you still - - what was your conclusion in terms of obviousness of the invention?

* * *

MR. MORAN: That the key elements of this change were generally used by other companies, other products, and therefore that would weigh heavily in the case of a decision somebody would make about what they tried producing the same product, in my opinion.

QUESTION: And the key element was - - could you explain what?

MR. MORAN: The use of the superabsorbent.

QUESTION: And what was your ultimate conclusion as to obviousness of the invention?

MR. MORAN: That that was being used by many different people for different products, and therefore was reasonable to do so.

Tr. 715-16.

As Mr. Moran testified, the fact that NYCIB copied the '139 Patent does not itself demonstrate Claim 1's nonobviousness. PX 30 at G0705; Sparton Corp., 89 Fed. Cl. at 241-42 ("To be meaningful toward establishing non-obviousness, 'more than the mere fact of copying by an accused infringer is needed to make that action significant to a determination of the obviousness issue.'" (quoting Cable Elec. Prods., Inc. v. Genmark, Inc., 770 F.2d 1015, 1028 (Fed Cir. 1985))). Copying by an accused infringer may occur for various reasons unrelated to the patent claims, for example here, where the industry was changing and moving toward the use of superabsorbent polymers and Mil-Spec B had previously expressly sanctioned the use of hydrophilic granular material in disposable urine containment devices. "[A] showing of

copying is only equivocal evidence of non-obviousness in the absence of more compelling objective indicia of other secondary considerations.” Geo. M. Martin Co. v. All. Mach. Sys. Int’l, LLC, 618 F.3d 1294, 1305 (Fed. Cir. 2010) (finding a patent owner’s reliance on an accused infringer’s internal memos suggesting copying to be “hardly compelling” because evidence of other secondary considerations, while present, was minimal) (quoting Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1380 (Fed. Cir. 2000)). Here, Plaintiff has not introduced “compelling objective indicia of other secondary considerations” in addition to copying in arguing commercial success or long-felt but unsolved need to show the ’139 Patent is not obvious.

Although Plaintiff raises some objective indicia of long-felt but unsolved needs, and copying, they are, on the whole, insufficient to overcome the substantial and strong showing of obviousness from combining well known prior art references according to their anticipated functions. Leapfrog, 485 F.3d at 1162; see ABT, 797 F.3d at 1361; Wyers, 616 F.3d at 1246 (finding that secondary considerations could not overcome the convincing prima facie case because the patented invention “represented no more than ‘the predictable use of prior art elements according to their established functions.’” (quoting KSR, 550 U.S. at 417)). Indeed, all of the claimed features of the ’139 Patent were recognized in the prior art, preventing Plaintiff’s cited objective indicia from rebutting Defendant’s strong showing of obviousness. See Ormco, 463 F.3d at 1312.

The Combination of Benzel with Mil-Spec B and Superabsorbent Gellable Polymers Render Independent Claim 1 Obvious

In conclusion, the Court finds that three prior art references render Claim 1 obvious under 35 U.S.C. § 103. Benzel teaches every limitation of Claim 1 except the “gellable hydrophilic material,” Mil-Spec B both discloses the use of a gellable hydrophilic material in a urine containment bag and requires the bag to “substantially prevent” fluid leakage from the urine containment bag, and Sherman teaches that gellable polymers capable of fully gelling fluid within 30 seconds, including sodium polyacrylate, were well known prior to February 15, 1991. See KSR, 550 U.S. at 417; Wyers, 616 F.3d at 1246. Mr. Moran’s testimony adds that gellable polymers were cheaper than the absorbent sponge, and were a feature the industry was moving toward by 1990. Tr. 659-63. The Court further finds that Plaintiff’s evidence of secondary considerations is insufficient to show that Claim 1 of the ’139 Patent is nonobvious. Rather, Defendant has shown by clear and convincing evidence that a person of ordinary skill in the art would be motivated to combine Benzel, Mil-Spec B, and 30-second fluid-gelling superabsorbent polymers, and would reasonably succeed in “implement[ing] a predictable variation” of the urine containment bag described in Claim 1 ’139 Patent. KSR, 550 U.S. at 417 (“If a person of ordinary skill can implement a predictable variation [of a patented invention with a combination of elements of prior art], § 103 likely bars its patentability.”); ABT, 797 F.3d at 1360. As such, Section 103 bars Claim 1 from patentability.

Dependent Claims 2, 3, 4, and 17 Are Invalid as Obvious

The Court further finds dependent Claims 2, 3, 4, and 17 to be obvious. Claims 2-4 and 17 are all dependent on Claim 1, and thus incorporate the obviousness analysis with respect to Claim 1.

Claim 2 teaches that the “gellable material” in Claim 1 is a “polymer.” ’139 Patent 8:67-68. Barthell expressly discloses polymers, including sodium acrylates that are gellable upon contact with liquid. Sherman discloses the same. As such, the combination of Benzel with Barthell or Sherman would render Claim 2 obvious to a person of ordinary skill in the art.

Claim 3 teaches a “hydrophilic material” that is “part of a mixture of materials which also contains at least one material selected from a group consisting of enzymes, deodorants, fragrances, human body abnormality indicators and pregnancy indicators.” ’139 Patent 9:1-6. Barthell teaches combining a gellable polymer with fragrances, binders and enzyme inhibitors, to reduce the smell of urine. Barthell Abstract. Moreover, a skilled artisan would have the common sense and be motivated to manufacture urinary containment products that block odors. See KSR, 550 U.S. at 417. Although Barthell does not disclose every additive expressed in Claim 3, prior art does not have to literally disclose every claim limitation because a person of ordinary skill in the art has the common sense and creativity to derive knowledge beyond the literal limitations of a claim. Id.; see In re Sovish, 769 F.2d 738, 743 (Fed. Cir. 1985). Here, a person of ordinary skill in the art of disposable urine containment devices would appreciate that the perfume fragrances described in Barthell would also suggest similar additives to control the odor of urine. Moreover, a person of ordinary skill in the art, as a person of ordinary creativity, would take the creative steps to control the odor of urine through a variety of means, as it is basic knowledge that urine smells. Randall Mfg. v. Rea, 733 F.3d 1355, 1362-63 (Fed. Cir. 2013) (rejecting a USPTO finding of nonobviousness because the agency failed to account for the “prior art in context” and the “inferences and creative steps that a person of ordinary skill in the art would employ.” (quoting KSR, 550 U.S. at 418)).

Claim 4 teaches that the hydrophilic material “is in powdered, matted, granular, fibrous, foamed, or woven physical form.” ’139 Patent 9:7-9. Mil-Spec B explicitly authorizes the use of a “granular material.” JX 47 at G1379. Fjeldså further teaches the use of various superabsorbent materials, including “fibres, powders or granules.” Fjeldså 1:102-03. As such, a person of ordinary skill would have been aware of the varieties of absorbent materials available on the market listed in Claim 4 before February 15, 1990, and it would have been obvious to a skilled artisan to implement any of these absorbents in a urine containment bag by February 15, 1991.

Claim 17 teaches the use of an L-shaped bag. ’139 Patent 10:29-30. Both Benzel and Mil-Spec B explicitly disclose L-shaped bags for the purposes of serving pilots as early as 1983. DX 105 at G1474, Fig. 1; JX 47 at 1380, Fig. 1. As such, a person of ordinary skill would have been aware of using an L-shaped bag when designing a urinary containment bag for a pilot as shown in Benzel and would have known that it was the shape required per Mil-Spec B. Based on the express teaching of Mil-Spec B, it would have been obvious to a skilled artisan to make L-shaped urine containment bags for sitting pilots.

In sum, Defendant has shown by clear and convincing evidence that dependent Claims 2, 3, 4, and 17 are invalid as obvious.

An Invalid Patent Cannot be Infringed

An invalid patent cannot be infringed. Commil USA LLC v. Cisco Sys., Inc., 135 S. Ct. 1920, 1931 (2015) (Scalia J., dissenting on other grounds) (recognizing the cardinal maxim that

“[i]t follows, as night the day, that only valid patents can be infringed. To talk of infringing an invalid patent is to talk nonsense”); Dow Chem. Co. v. Nova Chems. Corp. (Canada), 803 F.3d 620, 626 (Fed. Cir. 2015). As such, the Court need not reach the issue of infringement here as it has found Claims 1-4 and 17 of the ’139 Patent invalid as obvious under 35 U.S.C. § 103 based upon clear and convincing evidence. See Del Mar Eng’g Labs. v. United States, 524 F.2d 1178, 1186 (Ct. Cl. 1975) (“In view of the conclusion on validity, it is unnecessary to reach the question of infringement, for an invalid patent cannot be infringed.”) (internal citation omitted); Sparton Corp., 89 Fed. Cl. at 242 (declining to decide infringement after finding two patents invalid for obviousness, and thus holding that the plaintiff “no longer has a claim under 28 U.S.C. § 1498”).

Conclusion

As the Court determined that Claims 1, 2, 3, 4, and 17 of the ’139 Patent are invalid, Plaintiff’s claim of patent infringement is **DENIED**.

The Clerk is directed to enter judgment in favor of Defendant consistent with this Opinion.

s/Mary Ellen Coster Williams

MARY ELLEN COSTER WILLIAMS

Judge