UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALBAAD MASSUOT YITZHAK, LTD. AND ALBAAD USA, INC.,

Petitioners

v.

EDGEWELL PERSONAL CARE BRANDS, LLC

Patent Owner

U.S. Patent No. 6,432,075

Filed: Nov. 8, 2000

Issued: Aug. 13, 2002

Title: Applicator for Tampons

Inter Partes Review No. IPR2017-00694

PETITION FOR INTER PARTES REVIEW

OF U.S. PATENT NO. 6,432,075

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1004	U.S. Patent No. D250,663 to Koch et al., issued Dec. 26, 1978 ("Koch")			
1005	U.S. Patent No. 5,807,372 to Balzar, issued Sep. 15, 1998 ("Balzar")			
1006	U.S. Patent No. 3,628,533 to Loyer, issued Dec. 21, 1971 ("Loyer")			
1007	U.S. Patent No. 3,895,634 to Berger et al., issued July 22, 1975 ("Berger")			
1008	U.S. Patent No. 4,428,370 to Keely, issued Jan. 31, 1984 ("Keely")			
1009	PLAINTIFF EDGEWELL PERSONAL CARE BRANDS, LLC'S INITIAL INFRINGEMENT CLAIM CHARTS, in Edgewell Personal Care Brands, LLC v. Albaad Massuot Yitzhak, Ltd. et al., No. 1:15-cv- 01188-RGA (D. Del.).			
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I. INTRODUCTION

Albaad Massuot Yitzhak, Ltd. and Albaad USA, Inc., (collectively "Albaad") petition for *Inter Partes* Review ("IPR") of claims 1-6 of U.S. Patent No. 6,432,075 ("the '075 patent"; Ex. 1001), assigned to Edgewell Personal Care Brands, LLC ("Patent Owner" or "PO").

II. FORMALITIES

A. Real Parties-In-Interest (37 C.F.R. § 42.8(b)(1))

The real parties-in-interest are Albaad Massuot Yitzhak, Ltd. and Albaad USA, Inc.

B. Related Matters (37 C.F.R. § 42.8(b)(2))

The '075 patent (Ex. 1001) issued from U.S. App. No. 09/708,843, filed Nov. 8, 2000, which claims priority from Japanese App. No. 11-329621, published Nov. 19, 1999. (Ex. 1001).

Patent Litigation: On December 21, 2015, Patent Owner filed a complaint alleging infringement of the '075 patent, and U.S. Patent Nos. 9,192,522 and 9,107,775 (the '822 and '775 patents respectively), Case No. 1:2015-cv-01188-RGA (D. Del). On August 8, 2016, the Patent Owner filed an amended complaint alleging infringement of the '075, '522, '775 and added U.S. Patent No. 8,551,034 ("the '034 patent").

On September 6, 2016, Patent Owner filed a Second Amended Complaint

alleging infringement of the '075, '522 and '034 patents. Claims concerning the '775 patent were dropped.

Other IPRs: In addition to this Petition, Petitioner is simultaneously filing a petition for IPR of the '522 patent.

C. Designation of Counsel (37 C.F.R. § 42.8(b)(3)) and Power of Attorney (37 C.F.R. § 42.10(b))

Lead Counsel: David A. Loewenstein (Reg. No. 35,591) tel. 646-878-0806.

Backup Counsel: Guy Yonay (Reg. No. 52,388); tel. 646-878-0808.

Both are at Pearl Cohen Zedek Latzer Baratz LLP, 1500 Broadway, 12th Fl., New York, NY, 10036; fax 646-878-0801.

A Power of Attorney accompanies this Petition under 37 C.F.R. § 42.10(b).

D. Proof of Service (37 C.F.R. §§ 42.6(e) and 42.105(a)), Service Information (37 C.F.R. § 42.8(b)(4)), and Payment of Fees (37 C.F.R. § 42.103)

This Petition is being served simultaneously with its filing on the correspondence address for the counsel of record for the '075 patent and for the related litigation as stated in the attached Certificate of Service. Petitioner consents to service by e-mail only to <u>DLoewenstein@pearlcohen.com</u> and GYonay@pearlcohen.com. The Director is authorized to charge the fee of \$23,000

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under 37 C.F.R. § 42.15(a) and any additional fee required for this Petition to Deposit Account 50-3355.

III. REQUIREMENTS FOR INTER PARTES REVIEW (37 C.F.R. § 42.104)

A. Grounds for Standing (37 C.F.R. § 42.104(a))

Petitioner certifies that the '075 patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR challenging the identified claims on the grounds identified in this Petition.

B. Identification of Claims Being Challenged (37 C.F.R. § 42.104(b)) and Statement of Precise Relief Requested

Petitioner requests that the Board institute IPR of claims 1-6 ("the challenged claims") of the '075 patent and find the claims unpatentable based on **Grounds 1-8**:

Ground	Claim(s)	Reference (s)	Statute (Pre-AIA)
1	Claims 1-5	Koch	35 U.S.C. § 102(b)
2	Claim 6	Koch	35 U.S.C. § 103(a)
3	Claims 1-3, 6	Balzar	35 U.S.C. § 102(b)
4	Claims 4, 5	Balzar in view of Koch	35 U.S.C. § 103(a)
5	Claims 1-3, 6	Loyer	35 U.S.C. § 102(b)
6	Claims 4, 5	Loyer in view of Koch	35 U.S.C. § 103(a)

Ground	Claim(s)	Reference (s)	Statute (Pre-AIA)
7	Claims 1-3, 6	Berger	35 U.S.C. § 102(b)
8	Claims 4, 5	Berger in view of Koch	35 U.S.C. § 103(a)

C. Threshold for *Inter Partes* Review (37 C.F.R. § 42.108(c))

This Petition demonstrates "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." and that claims 1-6 are invalid, as explained below. *See* 35 U.S.C. § 314(a).

IV. THE '075 PATENT

A. Overview of the '075 Patent and Claims

The '075 patent is directed to an "Applicator for Tampons." The applicator comprises: an outer cylinder (element 1 below), and an inner cylinder (or "pushout member") (element 2). A tampon (element 3) is fitted in a forward (or "leading") portion of the outer cylinder (element 1). The inner cylinder (element 2) is movably inserted into a smaller diameter portion (element 8) of the outer cylinder (element 1). A push portion (element 11) of the inner cylinder (element 2) is diverged to push the tampon (element 3) from its rear end and also to prevent the inner cylinder (element 2) from being withdrawn from the rear end (element 9) of the outer cylinder (element 1). A plurality of valves (element 17) is provided an the side of a "leading end" of the outer cylinder (element 1), the valves (element 17) "being converged to have a curved face portion to be diametrically gradually reduced toward the leading end of" the outer cylinder (element 1). (See Ex. 1001, "Summary of the Invention," Ex. 1024, ¶ 31).



Ex. 1001, Fig 1.

The alleged innovation is of the '075 patent is two-fold: (i) a ratio A/B of at most 0.8, when an inflection point for the boundary between the maximum diameter portion of the large diameter portion [element 7] and the curved face portion is designated by Z, a radius of the outer face at the inflection point [element Z] is designated by A, and the axial length from the inflection point [element Z] to the leading end of the curved face portion is designated by B; and (ii) a ratio L/W within a range of 1.0 to 2.0, when the width size of root ends of the valves is designated by W and the length of the valves is designated by L. (*Id.*). (Ex. 1024, ¶ 32). See Ex. 1001, "Summary of the Invention," Figures 2A, 2B, 3:



In independent claim 5, each valve (element 17) has "a root end," "a curved face portion to be diametrically gradually reduced," "a leading end," "a first inflection point at the root end of said valve," "a second inflection point adjacent to the leading end of said valves," and "a curvature radius for said first inflection point" that is "larger than a curvature radius for said second inflection point." (Ex. 1001, claim 5). This limitation is not found in claim 1. (Ex. 1024, ¶ 34).

In independent claim 6, the outer cylinder is made of a thermoplastic resin.

(Ex. 1001, claim 6). This limitation is not found in claim 1. (Ex. 1024, ¶ 35).

Otherwise, claims 5 and 6 recite similar inventions to that of claim 1, which

is representative of the claimed invention (Ex. 1001, col. 7, ll. 24-44):

1. An applicator for a tampon, comprising:

[a] an outer cylinder including forward and rearward ends,

[b] a first portion for fitting the tampon therein formed on a side of the forward end, and

[c] a second portion formed on a side of the rearward end and having a smaller diameter than that of said first portion,

[d] a push-out member movably inserted into said second portion of said outer cylinder, and

[e] a plurality of valves provided with the forward end of said outer cylinder,

[f] each valve being converged to have a curved face portion to be diametrically gradually reduced and define a leading end,

[g] wherein a ratio of a radius of an outer face at an inflection point of a boundary between a maximum diameter portion of said first diameter portion and said curved face portion to an axial length of the outer face from the inflection point to the leading end of said curved face portion is at most 0.8; and

[h] wherein a ratio of a length of said values to a width of root ends of said values is 1.0 to 2.0.

B. Summary of the Prosecution History

The application that issued as the '075 patent was filed on November 8, 2000, and assigned Serial No. 09/708,843 ("the '843 application"). (Ex. 1001).

The '843 application was filed originally with 4 claims. (Ex. 1002, pages 25-26).

A non-final Office Action mailed on July 13, 2001 rejected claims 1-4 under 35 U.S.C. § 102(b), as being anticipated by Keely (U.S. Patent No. 4,428,370, Ex. 1008). According to the Examiner, "Keely discloses an outer cylinder 12, with a large diameter portion and a small diameter portion, as claimed. The valves are 14. The push out member is 38. As the claim is best understood by the Examiner Keely discloses a shape that satisfies the claimed limitations." (Ex. 1002, page 36). The relevant figure from Keely is Fig 1 (Ex. 1008):



The same Office Action also rejected claims 1-4 under the judicially-created doctrine of obviousness-type double-patenting as being unpatentable over claims 1, 2 and 4 of co-pending Application No.09/710,576. (Ex. 1002, page 37).

By Amendment dated October 4, 2001, Applicant amended pending claims

1-4 as follows:

1. (Amended) An applicator for a tampon, comprising:

an outer cylinder including [a large diameter portion for fitting a tampon therein] forward and rearward ends, a first portion for fitting the tampon therein formed on a side of the forward end, and a second portion formed on a side of the rearward end and having a smaller diameter than that of said first portion,

[a small diameter portion provided on the side of a rear end of said cylinder and having a smaller diameter than that of said larger diameter portion and a plurality of valves provided on the side of a leading end of said outer cylinder, said valves being converged to have a curved face portion to be diametrically gradually reduced toward the leading end of said outer cylinder; and],

a push-out member movably inserted into said [small diameter] <u>second</u> portion of said outer cylinder, <u>and</u>

a plurality of valves provided with the forward end of said outer cylinder, each valve being converged to have a curved face portion to be diametrically gradually reduced and define a leading [edge] <u>end</u>,

[wherein a ratio A/B is at most 0.8, when an inflection point for the boundary between the maximum diameter portion of said large diameter portion and said curved face portion is designated by Z, a radius of the outer face at said infection point Z is designated A, and the axial length from said inflection point Z to the leading end of said curved face portion is designated by B, and

wherein a ratio L/W is within a range of 1.0 to 2.0, when the width size of root ends of said valves is designated by W and the length of said valves is designated by L.].

wherein a ratio of a radius of an outer face at an inflection point of a boundary between a maximum diameter portion of said first diameter portion and said curved face portion to an axial length of the outer face from the inflection point to the leading end of said curved face portion is at most 0.8; and

wherein a ratio of a length of said values to a width of root ends of said values is 1.0 to 2.0.

2. (Amended) An applicator for a tampon as set forth in claim 1, wherein [the] <u>said</u> root ends of said valves are located substantially at the [same position of said] inflection point [Z].

3. (Amended) An applicator for a tampon as set forth in claim 1, wherein said curved face portion has two [curvatures] <u>curvature radii</u>, and [a] one curvature <u>radius</u> at the leading [end portions of said valves is larger than at the root ends of said valves] <u>ends of said curved face</u> portions is smaller than the other curvature radius at the <u>root ends of said valves</u>.

4. An applicator for a tampon as set forth in claim 3, wherein an axial length [Y of the valve portions having a larger curvature is one half or less than the axial length B from said inflection point Z to the leading end of said curved face potion] of said valves having a smaller curvature radius is one half or less than the axial length of the outer face from the inflection point to the leading end of said curved face portion.

(Ex. 1002, pages 49- 51). Applicant also added new claims 5-7. New claims 5 and 6 correspond to issued claims 5 and 6; new claim 7 was directed to a method of fabricating an applicator for a tampon. (*Id.*, pages 43-45, compare Ex. 1001).

With respect to Keely, Applicant stated:

[T]his reference fails to disclose that the ratio of a radius of an outer face at an inflection point of a boundary between a maximum diameter portion of a first diameter portion and a curved face portion to an axial length of an outer face from the inflection point to the leading end of the curved face portion is at most 0.8, as well as that a ratio of a length of the valves to a width of root ends is 1.0 to 2.0

(Ex. 1002, pages 47-48).

On January 22, 2002, Applicant filed a Terminal Disclaimer over Application No. 09/710,576. (Ex. 1002, pages 52-54). By Office Action mailed February 27, 2002, the Examiner indicated that claims 1-6 were allowed, and the application was in condition for allowance except for the resolution of claim 7. (*Id.*, pages 55-57). On April 2, 2002, Applicant filed an amendment cancelling claim 7. (*Id.*, pages 59-60). A Notice of Allowability was mailed on April 30, 2002. (*Id.*, pages 60-61).

C. Effective Filing Date of the '075 Patent

The earliest filing date of the '075 patent, the date of Japanese Application No. 11-329621, Nov. 19, 1999, is being used for this Petition. (Ex. 1001; Ex. $1024, \P 70$).

D. Person of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSITA") would have had at least a bachelor's degree in engineering, and would have had at least four years of experience designing and building prototype tampons and tampon applicators. (Ex. 1024, \P 57).

V. CLAIM CONSTRUCTION

A claim is to be given its "broadest reasonable construction in light of the specification" in IPR. *See* 37 C.F.R. § 42.100(b), which is typically broader than the claim interpretation used in the District Court. However, the broadest interpretation cannot be narrower than one used in District Court. *International*

Business Machines Corp. v. Intellectual Ventures I LLC, IPR2014-01385, Paper 64, at *8 (Jan. 15, 2016) ("*Facebook, Inc. v. Pragmatus AV, LLC*, 582 Fed. Appx. 864, 868-869 (Fed. Cir. 2014) (non-precedential) ('The broadest reasonable interpretation of a claim term may be the same as or broader than the construction of a term under the *Phillips* standard. But it cannot be narrower.' [Footnote omitted]).").

A. "Diametrically Gradually Reduced" (claims 1, 5, 6)

The term "diametrically gradually reduced" has no definite meaning. (Ex. 1024, \P 58). The claims with this term do not inform a POSITA about the scope of the claims with reasonable certainty. (*Id.*; see *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120, 2129 (2014). Nor is there any clarifying disclosure in the specification. (Ex. 1024, \P 58).

The ambiguity of the term means that any diametric reduction in the valves is covered by this term. That is, any diametric reduction is "gradual[]." (Ex. 1024, ¶ 59).

B. "inflection point" and "located substantially at the inflection point"; "second inflection point" (claims 1, 2, 5, 6)

The term "inflection point" is indefinite, and the claims with this term do not inform a POSITA about the scope of the claims with reasonable certainty. *Nautilus*, 134 S.Ct. at 2129; Ex. 1024, \P 60.

In particular, to the extent the claim calls for "a curved face portion to be diametrically gradually reduced," it cannot have an inflection point as that term generally is understood. (Ex. 1024, \P 61).

C. "a first portion for fitting [accommodating] the tampon therein" (claims 1, 5, 6)

The term "first portion" is indefinite, and the claims with this term do not inform a POSITA about the scope of the claims' scope with reasonable certainty. *Nautilus*, 134 S.Ct. at 2129. (Ex. 1024, \P 62). Moreover, the term lacks written description in the specification. The specification does not explain where the "first portion" begins and where it ends. (*Id.*).

To the extent that this claim element is susceptible to construction, it should be construed as the entire forward, larger diameter end of the outer cylinder. (Ex. $1024, \P 63$).

D. "a second portion... having a smaller [reduced] diameter than that of [relative to] said first portion" (claims 1, 5, 6)

The term "having a smaller [reduced] diameter than that of [relative to] said first portion" is indefinite, and the claims with this term do not inform a POSITA about the scope of the claims with reasonable certainty. Ex. 1024, \P 64; see *Nautilus*, 134 S.Ct. at 2129.

The first/forward portion of the applicator does not have a single diameter. See Ex. 1001, Fig. 1, where protruding mouth 16 formed at the leading end of forward portion 7 appears to have a smaller diameter than that of/relative to small diameter portion 8. (Ex. 1024, \P 65).



To the extent that this claim element is susceptible to construction, it should be construed as "having a smaller uniform diameter compared to the largest diameter of the first portion." (Ex. 1024, \P 66).

E. "said curved face portion has two curvature radii" (claim 3)

This claim element should be construed as "said curved face portion has exactly two curvature radii." (Ex. 1024, \P 67). Support for this construction may be found in the specification, at Ex. 1001, col. 5, lines 6-19.

To the extent PO asserts this element means more than two radii, the element is indefinite and lacks written description. (Ex. 1024, \P 68).

VI. '075 PATENT CLAIMS 1-6 ARE UNPATENTABLE

A. Introduction

Applicators that inserted material into a human body have been known in the art for decades. For example, U.S. Patent No. 2,178,840 (issued November 7, 1939 from an application filed November 18, 1936; Ex. 1010) described "an appliance for introducing into the vagina, the anus, etc., either liquid, more or less viscous or powdered medicines or capsules, pills, ovules or medicinal agglomerations[,]" (Col. 1 lines-2-5). The disclosed "appliance" included petals that were pushed out of the way when the internal material was ejected. See figures below. (Ex. 1024, ¶ 36).



The "sawteeth," as they were called in the '840 patent, were conical and when folded over the front opening formed a tapered end, just as proposed in the '075 patent. (Ex. 1024, \P 37).

At least by 1965 a "catamenial tampon device" was patented that had tapered forward ends. The image below is from U.S. Patent No. 3,433,225 (issued March 18, 1969 from an application filed December 22, 1965; Ex. 1011). (Ex. 1024, ¶ 38).



The height of the segments is 7/16" (col. 3, line1). The outside diameter of the tube is 0.549" (Col. 2, line70), and the radius = 0.549/2=0.2745". (Ex. 1024, ¶ 39). The ratio of the radius to the length of the segment was: 0.2745"/0.4375" = 0.627, which is covered by the "at most 0.8" limitation of claim 1 of the '075 patent, as well as the ratio of 1:2 between the height and width of each segment, as the calculations below show:

Diameter = 0.549" Circumference = 0.549"*3.14=1.723" Width of each of five segments = 1.723"/5=0.3447" Height of each segment = 7/16"=0.4375" Ratio of height to width = 0.4375/0.3447= 1.2692. (Ex. 1024, ¶ 39).

This reference also disclosed "a tampon having a tapered front end" (Ex. 1011, col. 3, lines 33-34), and asserted that "[t]he hygienic device was found to be simple, very economical to make by the described method and highly effective for its intended purpose." (*Id.*, col. 3, lines 47-49; Ex. 1024, ¶ 40).

In the early 1970s the equipment for making the o.b.*tampons had a device that would round the insertion tip. It was a heated, spinning, dome shaped cup. Ex. 1012; Ex. 1024, \P 41).

Proctor & Gamble had tampon applicator products on the market in the 1980s called Rely and Petal Soft that include petals. (See ALBAAD 2806-08; Ex. 1013; Ex. 1024, ¶ 42).

The net result is that tampons—including tapered tampons using applicators—have long been known, and the '075 patent is simply attempting to "reinvent the wheel" (or "re-patent" it). (Ex. 1024, \P 43).

Figures 7 – 9 of the '225 patent show die that can be used to bend the segments. (Ex. 1011, col. 8:42-73). These die can be used to create frusto-conical shapes in which the segments have overlapping tips. If the tips are overlapping, the radii of curvature of each petal changes. That is, the overlapping portion of the tip has a smaller radius of curvature than the wider sections of the segment. (*Id.*, col. 8 and Figures 7-9, 11-12; Ex. 1024, ¶ 44).

These statements demonstrate that years before the earliest priority date of the '075 patent, workers in the field were acutely aware of the relevant design parameters that influenced the proper function of a tampon applicator. (Ex. 1024, \P 45).

Moreover, the law is that optimizing dimensions or chemical compositions alone is not patentable. As the Federal Circuit held in *In re Geisler*, 116 F.3d 1465, 1469-70 (Fed. Cir. 1997) (citations and internal quotes omitted):

> [I]t is not inventive to discover the optimum or workable ranges by routine experimentation. Only if the results of optimizing a variable are unexpectedly good can a patent be obtained for the claimed critical range. Furthermore, it is well settled that unexpected results must be established by factual evidence. Mere argument or conclusory statements in the specification does not suffice.

Accord, *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990); *Gardner v. TEC Sys.*, 725 F.2d 1338, 1345-49 (Fed. Cir. 1984); *In re Boesch*, 617 F.2d 272, 276 (CCPA 1980); *In re Aller*, 220 F.2d 454 (CCPA 1955); *Ex parte LeMay, Gorham, and Jarmon* 2008 Pat. App. LEXIS 6774 (BPAI 2008).

In the litigation, petitioners served an interrogatory seeking PO's evidence of unexpected results, if any, associated with each limitation of the claims of the '075, '522 and '034 patents, and received the following response (pertinent part): Based on information presently available, and without waiver of its objections, Edgewell states the Asserted Patents are believed to have achieved at least the following unexpected results: (i) ease of insertion of the applicator, (ii) ease of expelling the pledget from the applicator, (iii) improved bypass leakage associated with the pledget, and/or (iv) enhanced absorption rate associated with the pledget.

(Ex. 1023, page 6). But, there is no showing anywhere in the '075 patent that the claimed applicator for tampons, including the specifically claimed ratios, promotes ease of insertion of the applicator, or ease of expelling the pledget, or either of the other supposed unexpected results. (Ex. 1024, \P 48).

Further, there is nothing special about the ratios claimed in the '075 patent. Ex. 1001; Ex. 1024, ¶ 49. For example, the prior art disclosed ratios of radius/petal length and petal length to width that were covered by the claims. See e.g. International Publication No. WO 98/06365 (published February 19, 1998 from an application filed July 9, 1997; Ex.1014, Figures 9 and 10 and pages 13 to 14. (Ex. 1024, ¶ 49).

In that application the petal lengths were described at being 7/16 inch long, the diameter in the range on 10-20 millimeters, and any number of petals "3, 5, 7 etc." (page 14) could be used. (Ex. 1014).

The math for this disclosure is as follows:

Radius = 5-10mm Circumference = 31.4 - 62.8 mm

Assuming there were five (5) petals the width of each petal would be the circumference divided by 5:

31.4mm / 5 petals = 6.28mm 62.8mm / 5 petals = 12.56mm

That in turn means the ratio of radius/petal length was:

Radius = 5-10mm Length 7/16 inch = 11.11mm

<u>Ratio of radius/petal length</u> = $\frac{5}{11.11}$ to $\frac{10}{11.11}$ = 0.45 to 0.90

(Ex. 1024, ¶ 51). Additionally, the ratio of petal length to petal width is as follows:

Length = 11.11 mm Width at petal base = 6.28 to 12.56mm

<u>Ratio of petal Length/width</u> = $\frac{11.11}{6.28}$ to $\frac{11.11}{12.56}$ = $\frac{1.77}{1.77}$ to $\frac{0.88}{1.77}$

(Ex. 1024, ¶ 52).

These ratios fall well within those claimed in the '075 patent. Ex. 1001, claims 1, 5, 6; Ex. 1024, \P 53).

Further, switching materials is not a patentable distinction. *Hotchkiss v. Greenwood*, 52 U.S. 248 (1850); *Richie v. Vast Res, Inc.*, 563 F.3d 1334 (Fed. Cir. 2009) (citing cases). To the extent PO argues making a tampon applicator from thermoplastic resin rather than paper is an innovation, that argument must fail. (Ex. 1024, \P 54). In any event, plastic tampon applicators were well known long before the earliest priority date for the '075 patent. (See U.S. Patent Nos.: 3,674,026 (Ex. 1015), col. 3, lines 43-46; 3,699,962 (Ex. 1016), col. 4, lines 28-39; 3,895,634 (Ex. 1007), col. 6, lines 31-39; 4,543,086 (Ex. 1017), col. 1, lines 34-36; 4,857,044 (Ex. 1018), col. 5, lines 49-51; 5,087,239 (Ex. 1019), col. 3, line 24-29; 5,389,067 (Ex. 1020), col. 1, lines 39-43; 5,681,894 (Ex. 1021), col. 3, lines 39-45, and col. 5, lines 4-50; 5,964,741 (Ex. 1022), col. 20, line 63- col. 21, line 3. (Ex. 1024, \P 55).

B. Ground 1: Claims 1-5 Were Anticipated By U.S. Patent No. D250,663 ("Koch") (Ex. 1004)

Overview of Koch

U.S. Patent No. D250,663 ("Koch") issued on December 26, 1978 and is prior art to the '075 patent under 35 U.S.C. 102(b). (Ex. 1004). Koch disclosed a design for a tampon inserter as shown below in the Figure. The inserter included a plurality of valves/petals, with the ratio of the length of the valves to the width of the root ends thereof, as depicted, being between 1.0 and 2.0. (Ex. 1024, ¶ 71).



(Ex. 1004).

It is understood that drawings in design patents can serve as the basis for rejection of claims in utility patents. See *Ex parte LeMay*, Appeal 2008-0786, 2008 Pat. App. LEXIS 6774 at *7 (BPAI, Sep. 24, 2008); *In re Aslanian*, 590 F.2d 911, 913-14 (CCPA 1979) ("[N]umerous decisions have indicated that design patents can be properly cited as the basis for an anticipation rejection of claims in an application for a utility patent... [W]e can find no reason for excluding design patents from the classes of prior art properly citable in a rejection under 35 U.S.C. § 103.") (citations omitted). Accordingly, Koch, which was made of record by the Examiner but not relied upon during the prosecution of the '075 patent, is prior art to that patent.

1. Koch Anticipated Claim 1

Koch disclosed a "[t]ampon [i]nserter." (Ex. 1004). (Ex. 1024, ¶ 73).

a. Claim 1a. "an outer cylinder including forward and rearward ends"

Koch disclosed an outer cylinder having a forward end and a rearward end. (Ex. 1004; Ex. 1024, ¶ 74).



b. Claim 1b. "a first portion for fitting the tampon therein formed on a side of the forward end"

Koch disclosed a first portion for fitting the tampon therein formed on a side

of the forward end. (Ex. 1004; Ex. 1024, ¶ 75).



c. Claim 1c. "a second portion formed on a side of the rearward end and having a smaller diameter than that of said first portion"

Koch disclosed a second portion formed on a side of the rearward end and

having a smaller diameter than that of said first portion. (Ex. 1004; Ex. 1024, ¶ 76).



d. Claim 1d. "a push-out member movably inserted into said second portion of said outer cylinder"

Koch disclosed a push-out member movably inserted into said second portion of said outer cylinder. (Ex. 1004; Ex. 1024, ¶ 77).



e. Claim 1e. "a plurality of valves provided with the forward end of said outer cylinder"

Koch disclosed a plurality of valves provided with the forward end of said outer cylinder. (Ex. 1004; Ex. 1024, ¶ 78).



f. Claim 1f. "each valve being converged to have a curved face portion to be diametrically gradually reduced and define a leading end"
Koch disclosed each valve being converged to have a curved face portion to be diametrically gradually reduced and define a leading end. (Ex. 1004; Ex. 1024, ¶ 79).



g. Claim 1g. "wherein a ratio of a radius of an outer face at an inflection point of a boundary between a maximum diameter portion of said first diameter portion and said curved face portion to an axial length of the outer face from the inflection point to the leading end of said curved face portion is at most 0.8"

In the underlying litigation, PO identified "an axial length of the outer face

from the inflection point to the leading end of said curved face portion" as:



(Ex. 1009, page 8).

Petitioner has used the same definition of "axial length" in its analysis. (Ex. 1024, \P 82). As this definition was sufficient for PO to base its infringement contention, it must also be sufficient to show the claim element was anticipated by Koch. (Ex. 1024, *id.*). "That which infringes if later, would anticipate if earlier. *Peters v. Active Mfg*, 129 U.S. 530, 537 (1889); *Brown, v. 3M*, 265 F.3d 1349, 1352 (Fed. Cir. 2001); *Polaroid Corp. v. Eastman Kodak Co.*, 789 F.2d 1556, 1573, 229 USPQ 561, 574 (Fed. Cir. 1986). See also, e.g., *Upsher-Smith Labs.*,

Inc. v. Pamlab, L.L.C., 412 F.3d 1319, 1322 (Fed. Cir. 2005) (holding that a product "which would literally infringe if later in time anticipates if earlier").

Based on a measurement of the dimensions of the drawings in Koch, using a ruler, the ratio of the radius of the outer face at the recited inflection point, to an axial length of the outer face from the inflection point to the leading end, is approximately 0.3, which falls within the claimed "at most 0.8." (Ex. 1004; Ex. 1024, \P 82).



h. Claim 1h. "wherein a ratio of a length of said valves to a width of root ends of said valves is 1.0 to 2.0"

Based on a measurement of the dimensions of the drawings in Koch, using a ruler, the ratio of the length of the valves to the width of the root end of the valves

is approximately 1.4, which falls within the claimed "1.0 to 2.0." (Ex. 1004; Ex. 1024, \P 83).



 $\frac{L}{W}$ = approx. 1.4

2. Koch Anticipated Claim 2: "An applicator for a tampon as set forth in claim 1, wherein the root ends of said valves are located substantially at the inflection point"

Koch's disclosure of every element of claim 1 has been discussed. (Ex. 1024, ¶¶ 73-83). The '075 patent disclosed an "inflection point":

After the tampon 3 is inserted into the large diameter portion 7 of the outer cylinder 1, a heated press die is applied to the leading portion of the large diameter portion 7 of the outer cylinder 1 to deform the valves 17 thermally. As a result, the valves 17 are deformed to converge toward the leading end so that a curved face portion 7a is formed on the outer cylinder 1 on the side of the leading portion with respect to the large diameter portion 7, as shown in FIG. 3. The curved face portion 7a has a length B, as taken in the axial direction of the outer cylinder 1. The valves 17 having the length L as shown in FIG. 2A, are curved and deformed to form the curved face portion 7a so that the ratio of B to L is B<L. In the shown embodiment, more specifically, the boundary between generally cylindrical large diameter portion 7 and the curved face portion 7a has a <u>inflection point Z</u> (or a first inflection point Z), which is located at a position substantially identical to the root ends of the valves 17 in the axial direction of the outer cylinder 1.

In the curved face portion 7a, a leading end portion 7b within a predetermined length range (i.e., a length range Y in the axial direction of the outer cylinder 1) from the leading end to the root end side of the valves 17 is formed to have a larger curvature than that of the curved face portion 7a closer to the root end side than the leading end portions 7b. Namely, in this outer cylinder 1, there are formed <u>the inflection point Z, at which the large diameter portion 7 leads into the curved face portion 7a</u>, and a second inflection point S which is located in front of the inflection point Z and leads into the leading end portions 7b. Furthermore, the leading end portion 7b in the range Y has a larger curvature than that

of the curved face portion 7a in the range X on the root end side. (Ex. 1001, col. 4, l. 55-col. 5, l.19; emphasis added).

See also '075 patent, Figure 3 (Ex. 1001):



Using the same definition, Koch disclosed that the root ends of said valves are located substantially at the inflection point. (Ex. 1004; Ex. 1024, ¶ 85).



3. Koch Anticipated Claim 3: "An applicator for a tampon as set forth in claim 1, wherein said curved face portion has

two curvature radii, and one curvature radius at the leading ends of said curved face portions is smaller than the other curvature radius at the root ends of said valves."

Koch's disclosure of every element of claim 1 has been discussed. (Ex. 1024, ¶¶ 73-83). The '075 patent disclosed two curvature radii:

"At the tip of the curved face portion 7a, as shown in FIG. 3, <u>the curvature of the leading end portions 7b is</u> <u>made larger than that of the curved face portion 7a in</u> <u>the range X</u>. As a result, the curved deformation of the leading ends of the valves 17 can be enlarged to suppress the leading ends from opening. On the other hand, at the leading end portions 7b, the valves 17 converge at their leading ends with the large curvature so that their leading ends are prevented from abutting against the human body when inserted into the vaginal cavity." (Ex. 1001, col. 5, 1. 64-col. 6, 1. 6, emphasis added)

See also, Figure 3:



Using the same definition of "curvature radius"/ "curvature radii," the drawing in Koch showed two curvature radii, with the curvature radius at the leading end of the curved face portion being smaller than the curvature radius at the root ends of the valves. (Ex. 1004; Ex. 1024, \P 87).



4. Koch Anticipated Claim 4: "An applicator for a tampon as set forth in claim 3, wherein an axial length of said valves having a smaller curvature radius is one half or less than

the axial length of the outer face from the inflection point to

the leading end of said curved face portion."

Koch's anticipation of claim 3 has already been discussed. (Ex. 1024, ¶¶ 73-

83, 87). In the litigation, PO alleged infringement of this claim as follows:



(Ex. 1009, p. 6). Petitioner has used the same ratio in its analysis. (Ex. 1024, ¶ 88).

Based on ruler measurements of the drawing in Koch, Koch disclosed that the axial length Y (or L1 in the below drawing) is less than one half the axial length B (L2):



L1/L2 < 0.5

(Ex. 1004; Ex. 1024, 89).

5. Koch Anticipated Claim 5

Claim 5 of the '075 patent claims an applicator for a tampon comprising:

[a] an outer cylinder including forward and rearward ends,

[b] a first portion for fitting a tampon therein formed on a side of the forward end, and

[c] a second portion formed on a side of the rearward end and having a reduced diameter relative to said first portion,

[d] a push-out member movably inserted into said second portion of said outer cylinder, and

[e] a plurality of valves provided with the forward end of said outer cylinder,

[f] each having a root end, a curved face portion to be diametrically gradually reduced, a leading end, a first inflection point at the root end of said valve and a second inflection point adjacent to the leading end of said valves,
[g] a curvature radius for said first inflection point being larger than a curvature radius for said second inflection point,

[h] wherein a ratio of a radius of an outer radius at said first inflection point to an axial length of said curved face from said first inflection point to the leading end of said curved face portion is at most 0.8; and

[i] wherein a ratio of a length of said valves to a width of said root ends of said valves is 1.0 to 2.0.

(Ex. 1001, col. 8, ll. 6-28).

For claims 5a through 5e, 5h and 5i, see analysis with respect to claims 1a

through 1e, 1g and 1h, respectively. (Ex. 1024, ¶¶ 74-78, 81-83).

For claim 5f, the '075 patent disclosed first and second inflection points:

In the curved face portion 7a, a leading end portion 7b within a predetermined length range (i.e., a length range Y in the axial direction of the outer cylinder 1) from the leading end to the root end side of the valves 17 is formed to have a larger curvature than that of the curved face portion 7a closer to the root end side than the leading end portions 7b. Namely, in this outer cylinder 1, there are formed the *inflection point Z*, at which the large diameter portion 7 leads into the curved face portion 7a, and a second inflection point S which is located in front of the inflection point Z and leads into the leading end portions 7b. Furthermore, the leading end portion 7b in the range Y has a larger curvature than that of the curved face portion 7a in the range X on the root end side. (Ex. 1001, col. 5, ll. 6-19; emphasis added; Ex. 1024, ¶ 92).

See also, Figure 3:



Using the same definitions, the drawing in Koch disclosed a first inflection point and a second inflection point at locations corresponding to those in the '075 patent. (Ex. 1004; see Ex. 1001; Ex. 1024, ¶ 93).



For claim 5g, using the same definition for "first inflection point" and "second inflection point" as with claim 5f, the drawing in Koch disclosed a larger

curvature radius at the first inflection point than the curvature radius at the second inflection point. (Ex. 1004; Ex. 1024, ¶ 94).



C. Ground 2: Claim 6 Would Have Been Obvious Over Koch (Ex. 1004)

Claim 6 of the '075 patent recites an applicator for a tampon comprising:

[a] an outer cylinder made of a thermoplastic resin and including forward and rearward ends,

[b] a first portion for accommodating the tampon therein formed on a side of the forward end, and

[c] a second portion formed on a side of the rearward end and having a reduced diameter relative to said first portion;

[d] a push-out member movably inserted into said second portion of said outer cylinder;

[e] a plurality of valves provided with the forward end of said outer cylinder,

[f] each value being converged to have a curved face portion to be diametrically gradually reduced and define a leading end;

[g] wherein a ratio of an outer radius at an inflection point of a boundary between a maximum diameter portion of said first portion and said curved face portion to an axial length of said curved face portion from the inflection point to the leading end of said curved face portion is at most 0.8; and

[h] wherein a ratio of a length of said valves to a width of root ends of said valves is 1.0 to 2.0.

(Ex. 1001, col. 8, ll. 29-50).

For claims 6b through 6h, see analysis with respect to claims 1b through 1h, respectively. (Ex. 1024, ¶¶ 75-83).

For claim 6a, the choice of material—thermoplastic resin—would have been obvious to a POSITA. (Ex. 1024, \P 97). This is especially true in light of the state of the art at the time. See, e.g., Berger, Ex. 1007, col. 1, lines 41-45 and col. 6, lines 31-49: "... thermoplastics, have been widely used in the past... [T]hermoplastics, and particularly polyolefin are preferred materials..." In any case, that this choice is not a patentable endeavor. (*Id.*).

D. Ground 3: Claims 1-3 and 6 Were Anticipated By U.S. Patent No.

5,807,372 ("Balzar") (Ex. 1005)

Overview of Balzar

U.S. Patent No. 5,807,372 ("Balzar") issued on September 15, 1998 and is prior art to the '075 patent under 35 U.S.C. §102(b). (Ex. 1005). Balzar was not considered during the prosecution of the '075 patent. (Ex. 1002).

Balzar disclosed a tampon along with a tampon applicator. The applicator has an outer tube and an inner tube, as well as an insertion tip formed on one end of the outer tube and containing a plurality of petals. (Ex. 1005, col. 8, line 50 – col. 9, line 47, describing Figures 9, 10; Ex. 1024, ¶ 100).



1. Balzar Anticipated Claim 1

Balzar disclosed a tampon along with a tampon applicator. See, e.g., Ex, 1005, col. 8, 1. 50-col. 10, 1. 33, Figures 9, 10; Ex. 1024, ¶ 101:



a. Claim 1a

Balzar disclosed a tampon applicator as follows:

Referring now to FIGS. 9 and 10, a tampon applicator 66 is shown having an arcuate or curved profile. The tampon applicator 66 includes an <u>outer tube 68</u> and an inner tube 70. Preferably, both the outer tube 68 and the inner tube 70 are arcuate members formed on a radius and therefore each has an arcuate shape. It should be noted that the outer tube 68 has a radius 'r' and the inner tube 70 has a radius 'r1', and the radius 'r' can be equal to or different from the radius 'r1.'

The tampon applicator 66 also contains an insertion tip 72 which is formed on one end of the outer tube 68 and contains a plurality of soft and flexible petals 74. The petals 74 can be arranged to form a dome-shaped nose. The petals 74 are separated by narrow slots 76. The slots 76 allow each petal 74 to radially flex or bend outward so as to provide an enlarged opening through which the tampon 64 can exit when it is pushed forward by the inner tube 70. Either an even or an odd number of petals 74 can be used, but preferably, there are an odd number of petals 74, such as 3, 5, 7, etc. By using an odd number of petals 74, one can prevent the outer tube 68 from collapsing or flattening after the tampon 64 has been expelled. Most preferably, the tampon applicator 66 will contain five petals 74. By preventing the outer tube 68 from collapsing, one can be assured that the vaginal tissue will not be pinched when the tampon applicator 66 is inserted or removed from the user's vagina. For optimum performance, all of the petals 74 should have approximately the same shape and dimension. Each of the petals 74 can have an elongated, approximately truncated shape, with a rounded end and each can have a length of about 7/16 of an inch (about 11.1 mm).

The tampon applicator 66 can also contain a fingergrip 78 formed on the opposite end of the outer tube 68. The fingergrip 78 can contain one or more ridges 80 which will prevent the user's fingers from slipping as she holds the tampon applicator 66." (Ex. 1005, col. 8, 11. 50-58, col. 9, 11. 26-52, emphasis added; see Figures 9-10; emphasis added; Ex. 1024, ¶ 103)

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"Insertion tip 72" and "fingergrip 78" correspond to the forward and rearward ends, respectively, of outer tube 68. (Ex. 1024, \P 103).

b. Claim 1b

Figure 10 of Balzar showed a first portion of outer tube 68 for fitting tampon 64 therein, formed on a side of the forward end of outer tube 68. (Ex. 1005; Ex. 1024, ¶ 104).



c. Claim 1c

Figure 10 of Balzar (above) showed a second portion of outer tube 68 namely, fingergrip 78—formed on a side of the rearward end of outer tube 68. (Ex. 1024, ¶ 105). Fingergrip 78 is shown having a smaller diameter than the first potion of outer tube 68 having tampon 64 contained therein. (*Id.*).

d. Claim 1d

Balzar disclosed a push-out member—namely, inner tube 70. "The inner tube 70 is slightly smaller in diameter than the outer tube 68 and is designed to telescopically slide within the inner diameter of the outer tube 68." (Ex. 1005, col. 9, 11. 17-19, see Figures 9-10; Ex. 1024, ¶ 106).

e. Claim 1e

Balzar disclosed "an insertion tip 72 which is formed on one end of the outer tube 68 and contains a plurality of soft and flexible petals 74." (Ex. 1005, col. 9, ll. 26-28, see Figures 9-10; Ex. 1024, ¶ 107).

f. Claim 1f

Balzar disclosed (emphasis added; Ex. 1024, ¶ 108):

The petals 74 can be arranged to form a dome-shaped

nose. The petals 74 are separated by narrow slots 76. The slots 76 allow each petal 74 to radially flex or bend outward so as to provide an enlarged opening through which the tampon 64 can exit when it is pushed forward by the inner tube 70. Either an even or an odd number of petals 74 can be used, but preferably, there are an odd number of petals 74, such as 3, 5, 7, etc. By using an odd number of petals 74, one can prevent the outer tube 68 from collapsing or flattening after the tampon 64 has been expelled. Most preferably, the tampon applicator 66 will contain five petals 74. By preventing the outer tube 68 from collapsing, one can be assured that the vaginal tissue will not be pinched when the tampon applicator 66 is inserted or removed from the user's vagina. For optimum performance, all of the petals 74 should have approximately the same shape and dimension. Each of the petals 74 can have an elongated, approximately truncated shape, with a rounded end and each can have a length of about 7/16 of an inch

(about 11.1 mm). (Ex. 1005, col. 9, ll. 28-47, emphasis added)

A POSITA would understand that Balzar's petals arranged to form a domed end, and having an elongated, truncated shape, corresponds to the claimed each valve being converged to have a curved face portion to be diametrically gradually reduced and define a leading end. (Ex. 1024, \P 109).

g. Claim 1g

Balzar disclosed "The outer tube 68 has a relatively small diameter of from between about 10 mm to about 20 mm." (Ex. 1005, col. 9, ll. 10-12; Ex. 1024, ¶ 110).

Given that the length of the petals in Balzar is about 11.1 mm (see claim element 1f), the ratio of the radius of outer tube 68 ("an outer face at an inflection point of a boundary between a maximum diameter portion of said first diameter portion and said curved face portion") to the length of petal 74 ("an axial length of the outer face from the inflection point to the leading end of said curved face portion") is $\frac{5}{11.1}$ to $\frac{10}{11.1}$, or 0.45 to 0.9. (Ex. 1024, ¶ 111).

h. Claim 1h

Balzar disclosed that "[e]ither an even or an odd number of petals 74 can be used, but preferably, there are an odd number of petals 74, such as 3, 5, 7, etc." (Ex. 1005, col. 9, 11. 33-36; Ex. 1024, ¶ 112). Given the diameter of outer tube 68 is about 10mm to 20mm (see claim element 1g), the circumference of outer tube 68 (π * d) varies from about 31.4 to 62.8 mm. (Ex. 1024, ¶ 113).

Assuming that cumulative widths of the root ends of petals 74 is approximately equal to the circumference of outer tube 68, the width of the root ends of individual petals 74 can be estimated by dividing the circumference of outer tube 68 by the number of petals 74, thus (Ex. 1024, ¶ 114:

	3 petals	5 petals	7 petals
31.4 mm	10.46	6.28	4.48
circumference	mm	mm	mm
62.8 mm	20.93	12.56	8.97
circumference	mm	mm	mm

This yields a ratio of length of petal (11.1 mm) to width of petal of between

1.0 and 2.0, as follows (Ex. 1024, ¶ 115):

	3 petals	5 petals	7 petals
31.4 mm circumference	1.06	1.77	2.48
62.8 mm circumference	0.53	0.88	1.24

2. Balzar Anticipated Claim 2

Balzar's disclosure of every element of claim 1 has been discussed. (Ex. 1024, ¶¶ 101-115). The '075 patent's disclosure of "inflection point" has been discussed with respect to the analysis of claim 2 over Koch.

Figure 9 of Balzar showed that the root ends of petals 74 are located substantially at the inflection point, i.e., the point at which the large diameter potion of outer tube 68 leads to the curved face potion of insertion tip 72 (Ex. 1005; Ex. 1024, ¶¶ 117):



See also Figures 10-12.

3. Balzar Anticipated Claim **3**

Balzar's disclosure of every element of claim 1 has been discussed. (Ex. 1024, ¶¶ 101-115). Likewise, the '075 patent's disclosure of two curvature radii

has been discussed in connection with the analysis of claim 3 over Koch. (*Id.*, \P 87).

Figure 9 of Balzar showed petals 74 where the curvature of the leading portion (nearest insertion point 72) is larger than the curvature at the root ends of petals 74; that is, the curvature radius of the leading potion of petal 74 is smaller than the curvature radius of the root end of said petal (Ex. 1005; Ex. 1024, \P 119):



See also, Figure 11 (petals 90):



4. Balzar Anticipated Claim 6

For claims 6b through 6h, see analysis of claims 1b through 1h, respectively, over Balzar. (Ex. 1024, ¶¶ 104-115).

For claim 6a, see analysis of claim 1a over Balzar. (Ex. 1024, ¶¶ 102, 103). In addition, Balzar disclosed the use of thermoplastic resins (Ex. 1005, col. 9, lines 5-6: "Suitable plastic materials include polyolefins such as low density polyethylene and polypropylene"). (Ex. 1024, ¶121).

E. Ground 4: Claims 4 and 5 Would Have Been Obvious Over Balzar (Ex. 1005) in View of Koch (Ex. 1004)

The disclosure of Balzar has been discussed. (Ex. 1024, ¶¶ 99-127).

Likewise, the disclosure of Koch has been discussed. (Ex. 1024, ¶¶ 71-97).

1. Claim 4 Would Have Been Obvious Over Balzar in View of Koch

See analysis of Balzar with respect to claim 3, Koch with respect to claim 4. (Ex. 1024, \P 119; 88-89). The claimed axial length ratio is arbitrary. There is nothing in the specification of the '075 patent suggesting that an axial length ratio of less than one have is any more desirable than an axial length ratio of one half or slightly higher. There is no identified "unexpected result." The choice of axial length ratio "is no more than a matter of obvious design choice for a person of ordinary skill in this art." *Ex parte LeMay*, 2008 Pat. App. LEXIS 6774 at *14. In any case, a POSITA would have found it obvious to try the claimed ratio. See *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007).

2. Claim 5 Would Have Been Obvious Over Balzar in View of Koch

For claims 5a through 5e, 5g through 5i, see analysis of Balzar with respect to claims 1a through 1e, claim 3, and claims 1g and 1h, respectively. (Ex. 1024, ¶¶ 102-107, 119, 111-115).

For claim 5f, the '075 patent's disclosure of the "second inflection point" has been discussed with respect to the patentability of claims 2 and 5f over Koch. (Ex. 1024, ¶¶ 88, 92-93). See also '075 patent Fig. 3 (Ex. 1001):



Figure 9 of Balzar showed petals 74 having two inflection points, a first infection point at the root of said petals 74, where the curvature of the petals begins; and a second inflection point at the leading end of said petals 74 (nearest insertion point 72), where the curvature of said petals 74 is larger than the curvature at the root ends of petals 74 (Ex. 1005; Ex. 1024, \P 128):



See also, *id.*, Figure 11 (petals 90):



See also the analysis of claim 3 over Balzar, claim 4 over Koch. (Ex. 1024, ¶¶ 119, 88-89).

F. Ground 5: Claims 1-3 and 6 Were Anticipated By U.S. Patent No.

3,628,533 ("Loyer") (Ex. 1006)

Overview of Loyer

U.S. Patent No. 3,628,533 ("Loyer") issued on December 21, 1971 and is prior art to the '075 patent under 35 U.S.C. 102(b). (Ex. 1006; Ex. 1024, 1131). Loyer was not considered during the prosecution of the '075 patent. (Ex. 1002). Loyer disclosed a tampon applicator consisting of an outer tubular member and an inner tubular member positioned telescopically for slideable movement within the outer tube. At the forward end of the outer tubular member and formed integrally therewith are a plurality of circumferentially spaced, substantially triangularly shaped segments (petals, valves) having their apices converging forwardly to be radially spaced from one another to define an opening having a diameter smaller than the diameter of the outer tube. A tampon is contained within the outer tubular member, positioned forward of the inner tubular member. (Ex. 1006, col. 2, lines 23-47, describing Figures 1, 3; Ex. 1024, ¶ 132).





1. Loyer Anticipated Claim 1

Loyer disclosed an applicator for a tampon. Ex. 1006, col. 2, lines 23-47. See Figures 1-5. Ex. 1024, ¶ 133.

a. Claim 1a

Loyer disclosed an outer cylinder (outer tubular member 12) including forward and rearward ends. Ex. 1006. See Figures 1-3; Ex. 1024, ¶ 134.

b. Claim 1b

Loyer disclosed a first portion for fitting the tampon therein:

Positioned forwardly of the inner tubular member 14 and contained within the outer tubular member 12, is a catamenial tampon 24 which, upon forward movement of the inner tubular member 14 within the outer tubular member 12, is adapted to be expelled from the forward, domed end of the applicator 10 in a manner more fully explained hereinafter. (Ex. 1006, col. 2, lines 42-47; emphasis added; Ex. 1024, ¶ 135)

See Figure 3.

c. Claim 1c

Loyer disclosed a second, rearward portion having a smaller diameter:

The rearward end of the outer tube 12 consists of a **finger-gripping section 16 of reduced diameter**, the internal diameter of the inner tube 14 thereby providing a bearing surface for slideably engaging the inner tube 14. (*Id.*, col. 2, lines 27-30; emphasis added; Ex. 1024, ¶ 136).

See also Figures 1 and 3, element 16.

d. Claim 1d

Loyer disclosed inner tubular member 14 positioned for slidable movement within the outer tube:

Referring now particularly to FIGS. 1 through 3, a tampon applicator, designated generally by the numeral 10, consists of an outer tubular member 12 and an inner tubular member 14 positioned telescopically for slideable

movement within the outer tube. (Id., col. 2, lines 23-27;

Ex. 1024, ¶ 137).

See also Figures 1 and 3, element 14.

e. Claim 1e

Loyer disclosed a plurality of valves at the forward end of the outer cylinder:

At the forward end of the outer tubular member 12 and formed integrally therewith are a plurality of circumferentially spaced, substantially triangularly shaped segments 20 having their apices converging forwardly to be radially spaced from one another to define an opening 22 having a diameter smaller than the diameter of the outer tube 12. While four such segments are shown, a greater or lesser number can be used. (*Id.*, Col. 2, lines 34-41; Ex. 1024, ¶ 138).

See Figures 1-3, element 20.

f. Claim 1f

See claim 1e. (Ex. 1024, ¶ 138). See also Loyer, Ex. 1006, Figures 1-4, disclosing each of the plurality of valves being converged to have a curved face portion diametrically gradually reduced to define a leading end (id.):



g. Claim 1g

Figure 5 of Loyer showed the diameter is about 13 mm and the length of the triangular segments is about 8.5mm (and they are not fully extended as in Figure 2A of the '075 patent). (See Ex. 1006; Ex. 1024, \P 140). The ratio of the radius to the length (6.5/8.5) is about: 0.76, and would be less if the length were measured when the triangular segments were flat. (Ex. 1024, \P 140).

h. Claim 1h

Based on Figures 2, 3 and 5 in Loyer (Ex. 1006), the following dimensions are disclosed: the diameter is 13mm and there are 4 valves; there are gaps between the valves of about 1.5mm each. (Ex. 1024, \P 141). The Figures showed four valves, but the text says any number of value could be used (*Id.*, col. 2, lines 40-41).

Assuming only 4 valves, this means each valve is about (13 mm (diameter)*3.14) - 4 (gaps @1.5 mm each) \div 4 (valves) = 8.7 mm. (Ex. 1024, ¶ 142).

The length is 8.5mm (or more). Therefore the ratio of length/width (8.5/8.7) is slightly less than 1.0. (Ex. 1024, \P 143) However, if 5 valves were used to for this calculation the ratio would be about 1.28. (*Id.*). Similarly if the length of the valves were measured before they are curved, as in Figure 2a of the '075 patent, they might be 10mm, in which case the ratio for 4 valves would be 1.15. (*Id.*).

2. Loyer Anticipated Claim 2

Loyer's disclosure of every element of claim 1 has been discussed. (Ex. 1024, ¶¶ 133-143). Likewise, the '075 patent's disclosure of an "inflection point" has been discussed (see analysis of claim 2 re Balzar; Ex. 1024, ¶¶ 117).

Loyer disclosed that the root ends of the valves (Ex. 1006, shown in Figures 1, 3 and 5) are "substantially at the inflection point" (Ex. 1024, ¶ 145):



3. Loyer Anticipated Claim 3

The '075 patent's disclosure of two curvature radii has been discussed. See analysis of claim 3 re Balzar. (Ex. 1024, ¶ 119).

Loyer (Ex. 1006) disclosed a curvature radius at the leading end of the curved face portions of the valves that is smaller than the curvature radius at the root end of said valves. (Ex. 1024, ¶ 147). See Claim 1 above, including Figures 1, 3.





4. Loyer Anticipated Claim 6

For claims 6b through 6h, see Loyer analysis for claims 1b through 1h, respectively. (Ex. 1024, ¶¶ 135-144).

For claim 6a, see Loyer analysis for claim 1a. (Ex. 1024, \P 134). In addition, see Ex. 1006 at col. 1, lines 23-25, disclosing the use of plastic to make cardboard applicators. A POSITA would have understood plastic to include thermoplastic resins. (Ex. 1024, \P 149).

G. Ground 6: Claims 4 and 5 Would Have Been Obvious Over Loyer (Ex. 1006) in View of Koch (Ex. 1004)

The disclosure of Loyer has been discussed. (Ex. 1024, ¶¶ 131-156). Likewise, the disclosure of Koch has been discussed. (Ex. 1024, ¶¶ 71-97).

1. Claim 4 Would Have Been Obvious Over Loyer in View of Koch

See Loyer analysis, claim 3 (Ex. 1024, ¶ 147), and Ex. 1006 Figures 1-5. See also Koch analysis, claim 4. (*Id.*, ¶¶ 88-89). Further, see argument with respect to claim 4 over Balzar in view of Koch, citing *Ex parte LeMay*, 2008 Pat. App. LEXIS 6774 at *14; *KSR*, 127 S. Ct. at 1742.

2. Claim 5 Would Have Been Obvious Over Loyer in View of Koch

For claims 5a through 5e, 5g through 5i, see Loyer analysis for claims 1a through 1e, 3, 1g, 1h, respectively. (Ex. 1024, ¶¶ 134-138, 147, 140, 141-144).

For claim 5f ("each having a root end, a curved face portion to be diametrically gradually reduced, a leading end, a first inflection point at the root end of said valve and a second inflection point adjacent to the leading end of said valves"), the '075 patent disclosure of first and second inflection points has been discussed (see Balzar analysis re claim 5f; Ex. 1024, ¶¶ 127-128).

Loyer, in view of Koch, disclosed the same first and second inflection points. See Loyer, Ex. 1006, Figures 1-5; see also, Koch analysis, claim 4. (Ex. 1024, ¶ 154). It would have been obvious to a POSITA that the curved face portion of the valves would have two inflection points, one at the root end and another at the leading end.

H. Ground 7: Claims 1-3 and 6 Were Anticipated By U.S. Patent No. 3,895,634 ("Berger") (Ex. 1007)

Overview of Berger

U.S. Patent No. 3,895,634 ("Berger") issued on July 22, 1975 and is prior art to the '075 patent under 35 U.S.C. §102(b). (Ex. 1007). Berger was not considered by the Examiner during prosecution of the '075 patent. (Ex. 1002).

Berger disclosed a tampon inserter comprising an elongated, generally cylindrical, front barrel member which tapers at its rear end to a cylindrical finger grip of lesser diameter than the front barrel member. An ejection means, such as a cylindrical plunger, is provided at the rear of the front barrel member extending through the cylindrical finger grip into the interior of the front barrel member. The forward end of the front barrel member is fabricated into an insertion tip comprising a generally hemispherical dome formed from converged triangular segments (petals, valves). The valves are converged to minimize the space between the individual valves and form the desired shape without valves overlapping. (Ex. 1007, col. 5, lines 4-41, Figures 1-4). (Ex. 1024, ¶ 159).






1. Berger Anticipated Claim 1

Berger disclosed a tampon inserter. See Ex. 1007, col. 5, lines 4-8; Figures 1-5. (Ex. 1024, ¶ 160).

a. Claim 1a

Berger disclosed that the tampon inserter:

comprises an <u>elongated</u>, <u>generally cylindrical</u>, <u>front</u> <u>barrel member 14 which tapers at its rear end to a</u> <u>cylindrical finger grip 16 of lesser diameter than the</u> **front barrel member** and including a plurality of spaced external circumferential ribs 18 which provide finger grips to facilitate use of the inserter. An ejection means, such as a cylindrical plunger 20 is provided at the rear of the front barrel member 14 extending through the cylindrical finger grip 16 into the interior of the front barrel member. (Ex. 1007, col. 5, lines 6-18; emphasis added)

See Figures 1-3. (Ex. 1024, ¶ 161).

b. Claim 1b

Berger disclosed a tampon 12 fitted in a first portion of the front barrel member 14. See Ex. 1007, Figure 3. (Ex. 1024, ¶ 162).

c. Claim 1c

Berger disclosed a cylindrical finger grip portion having a smaller diameter than front barrel member 14. See claim element 1a, Ex. 1007 Figures 1 - 3, element 16. (Ex. 1024, ¶ 163).

d. Claim 1d

Berger disclosed a cylindrical plunger 20. See claim 1a, Ex. 1007 Figures 1 -

3, element 20. (Ex. 1024, ¶ 165).

e. Claim 1e

Berger disclosed a plurality of valves:

The forward end of the front barrel member 14 is fabricated into an insertion tip 28 comprising a generally

hemispherical dome formed from converged triangular segments 30 which are integrally formed from the same material of construction as the front barrel member 14 and are extentions of the forward terminus of the front barrel member. (Ex. 1007, col. 5, lines 25-31).

The converged triangular segments 30 correspond to a plurality of valves. See also, *id.*, Figures 1-3, element 30. (Ex. 1024, \P 166).

f. Claim 1f

See Berger, Figures 1-4. (Ex. 1007; Ex. 1024, ¶ 167).

g. Claim 1g

Berger Figure 5 showed the diameter is about 22 mm and the length of the triangular segments is about 11 mm. The ratio of the radius to the length $(\frac{11}{11})$ is about: 1.0. (Ex. 1007; Ex. 1024, ¶ 168). However, Berger also disclosed that "[t]he shape of the insertion tip also is not critical to the present invention and, while a substantially blunt hemispherical tip is preferred, other shapes will also be useful. For example, more pointed, steeple-shaped, frusto-conical or parabolic tips may also be used." (Ex. 1007, col. 9, lines 9-13; emphasis added). A POSITA would have understood that the ratio of radius to axial length for an insertion tip with a pointed, steeple-shaped, frusto-conical or parabolic tip would be less than 1.0, and in all likelihood less than 0.8. (Ex. 1024, ¶ 168).

h. Claim 1h

Based on Berger Figure 5 the following dimensions were disclosed: the diameter is 22 mm and there are 6 valves in the preferred embodiment (although the text states any number can be used (Ex. 1007, col. 9; 13-16). (Ex. 1024, ¶ 170).

Assuming 6 valves, this means each valve was about (22 mm (diameter)*3.14) ÷ 6 (valves) = 11.5 mm. The length was 14mm (see Figure 5). Therefore the ratio of length/width (14/11.5) was 1.2. (Ex. 1024, ¶ 171).

2. Berger Anticipated Claim 2

Berger's disclosure of every element of claim 1 has been discussed. (Ex. 1024, ¶¶ 160-170). Similarly, the '075 patent's disclosure of "inflection point" has been discussed. See analysis of claim 2 re Balzar. (Ex. 1024, ¶ 117).

Figures 1 - 3 and 5 of Berger showed the root ends of valves "substantially at the inflection point." (Ex. 1007; Ex. 1024, ¶ 172).

3. Berger Anticipated Claim **3**

Berger's disclosure of every element of claim 1 has been discussed. (Ex. 1024, ¶¶ 160-170). Similarly, the '075 patent's disclosure of "two curvature radii" has been discussed. See, e.g., analysis of claim 3 re Balzar. (Ex. 1024, ¶¶ 119).

See Claim 1 above and Berger, Ex. 1007, col. 9, lines 9-13 ("The shape of the insertion tip is also not critical to the present invention and, while a substantially blunt hemispherical tip is preferred, other shapes will also be useful. For example, more pointed, steeple-shaped, frusto-conical or parabolic tips may also be used."). (Ex. 1024, ¶¶ 174).

4. Berger Anticipated Claim 6

For claims 6b through 6h, see Berger analysis for claims 1b through 1h, respectively. (Ex. 1024, ¶¶ 162-170).

For claim 6a, see Berger analysis for claim 1a. See also Berger, Ex. 1007, col. 1, lines 41-45 and col. 6, lines 31-49: "... thermoplastics, have been widely used in the past... [T]hermoplastics, and particularly polyolefin are preferred materials..." (Ex. 1024, ¶¶ 161, 176).

I. Ground 8: Claims 4 and 5 Would Have Been Obvious Over Berger (Ex. 1007) in View of Koch (Ex. 1004)

The disclosure of Berger has been discussed. (Ex. 1024, ¶¶ 158-170). Likewise, the disclosure of Koch has been discussed. (Ex. 1024, ¶¶ 71-97).

1. Claim 4 Would Have Been Obvious Over Berger in View of Koch

See Berger, Ex. 1007, Figures 1-5 and analysis for Claim 3. (Ex. 1024, ¶ 174). See also Koch analysis for Claim 4. (*Id.*, ¶¶ 88, 89). Further, see argument under claim 4 over Balzar in view of Koch, citing *Ex parte LeMay*, 2008 Pat. App. LEXIS 6774 at *14; *KSR*, 127 S. Ct. at 1742.

2. Claim 5 Would Have Been Obvious Over Berger in View of Koch

For claims 5a through 5e, 5g through 5i, see Berger analysis for claims 1a through 1e, claim 3 and claims 1g and 1h, respectively. (Ex. 1024, ¶¶ 161-166, 174, 168, 169-70).

For claim 5f, the '075 patent disclosure of first and second inflection points has been discussed (see Balzar analysis for claim 5f, Ex. 1024, ¶¶ 127-128).

Berger Figures 1-4 disclosed first and second inflection points at, respectively, the root end of the valves and adjacent to the leading end of the valves. (Ex. 1007). See also Koch analysis re claim 4. (Ex. 1024, ¶ 182). It would have been obvious to a POSITA that the curved face portion of the valves would have two inflection points, one at the root end and another at the leading end.

VII. STATEMENT OF NON-REDUNDANCY

The grounds raised in this Petition are not redundant to each other.

Ground I uses Koch to anticipate claims 1-5, while Ground II, uses Koch to render claim 6 obvious. Ground III uses Balzar to anticipate claims 1-3 and 6, while Ground IV uses Balzar in combination with Koch to render claims 4 and 5 obvious. Ground V uses Loyer to anticipate claims 1-3 and 6, while Ground VI uses Loyer in combination with Koch to render claims 4 and 5 obvious. Ground VII uses Berger to anticipate claims 1-3 and 6, while Ground VIII uses Berger in combination with Koch to render claims 4 and 5 obvious. The PTAB has instituted IPR including an anticipation ground and an obviousness ground using the same reference. *Monsorol RX, Inc. v. Aruis Two, Inc.*, IPR2014-00376 (Paper no. 11), at *20-21 (August 6, 2014). The success of Grounds IV, VI and VIII require accepting Petitioner's respective principal references' reasons for combination, which are different for each, and which are not required in Ground I. In addition, the non-redundancy of the secondary reference—Koch—is discussed below.

For example, claim 4 includes recites "[a]n applicator for a tampon as set forth in claim 3, wherein an axial length of said valves having a smaller curvature radius is one half or less than the axial length of the outer face from the inflection point to the leading end of said curved face portion." And, claim 5f recites "each having a root end, a curved face portion to be diametrically gradually reduced, a leading end, a first inflection point at the root end of said valve and a second inflection point adjacent to the leading end of said valves." Neither of these elements is disclosed in any of Balzar, Loyer or Berger.

The Ground I rejections of claims 1-3 as anticipated by Koch are not redundant with the use of any of Balzar, Loyer or Berger to anticipate these claims.

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For example, depending on the claim construction, Patent Owner may argue that Koch, and possibly Balzar, does not teach the larger and smaller radii of curvature of claim 3, and Patent Owner may argue that Koch alone lacks limitations that are found in the references used in Grounds III-VIII. Finally, Grounds III-VIII are not redundant over each other. The primary references in each may be argued by the Patent Owner to lack limitations provided by the others, and Patent Owner is expected to make non-redundant arguments against each reference. Indeed, The primary references in Grounds I/II, III/IV, V/VI and VII/VIII each have different relative strengths and weaknesses as follows:

Limitation	Koch	Balzar	Loyer	Berger
applicator for a tampon	~	~	~	~
outer cylinder including	~	~	~	~
forward, rearward ends				
first portion for fitting	v	~	~	~
tampon therein formed on				
side of forward end				
second portion formed on	~	~	~	~
side of rearward end with				
smaller diameter than				
first portion				
push-out member	~	 	~	~
movably inserted into				

second portion				
plurality of valves	 	 	~	~
provided with forward				
end of outer cylinder				
each valve converged to	v	v	~	~
have a curved face				
portion diametrically				
gradually reduced				
defining leading end				
ratio of radius of an outer	•	~	~	~
face at inflection point of				
boundary between				
maximum diameter				
portion of first diameter				
portion and curved face				
portion to axial length of				
outer face from inflection				
point to leading end of				
curved face portion is at				
most 0.8				
ratio of length of valves	•	~	~	~
to width of root ends of				
valves is 1.0 to 2.0				
root ends of valves are	~	•	~	~
substantially at inflection				
point				

curved face portion with	•	♦	~	•
two curvature radii, and				
one at leading ends of				
said curved face portions				
being smaller than other				
at root ends of valves				
axial length of valves	 	×	*	*
with smaller curvature				
radius is one half or less				
axial length of outer				
face from inflection point				
to leading end of curved				
face portion				
face portion each valve having a root	•	×	×	*
face portion each valve having a root end, a curved face portion	•	*	*	*
face portion each valve having a root end, a curved face portion to be diametrically	*	*	×	*
face portion each valve having a root end, a curved face portion to be diametrically gradually reduced, a	•	*	*	*
face portion each valve having a root end, a curved face portion to be diametrically gradually reduced, a leading end, a first	•	*	*	*
face portion each valve having a root end, a curved face portion to be diametrically gradually reduced, a leading end, a first inflection point at the root	•	*	*	*
face portion each valve having a root end, a curved face portion to be diametrically gradually reduced, a leading end, a first inflection point at the root end and a second	•	*	*	*
face portion each valve having a root end, a curved face portion to be diametrically gradually reduced, a leading end, a first inflection point at the root end and a second inflection point adjacent	•	*	*	*
face portion each valve having a root end, a curved face portion to be diametrically gradually reduced, a leading end, a first inflection point at the root end and a second inflection point adjacent to the leading end	•	*	*	*
face portion each valve having a root end, a curved face portion to be diametrically gradually reduced, a leading end, a first inflection point at the root end and a second inflection point adjacent to the leading end outer cylinder made of a	 ★ ★ 	*	*	*

(" \checkmark " indicates the limitation is present in the reference, " \bigstar " indicates the limitation is not present, and " \blacklozenge " indicates that although present, under a differing interpretation, Patent Owner may challenge disclosure of this limitation.)

Should the Board be inclined to adopt only one ground among Grounds III/IV, V/VI and VII/VIII, Petitioner requests that the Board adopt Grounds V/VI (Loyer), because Loyer does not include the disclosure of any limitation that may be challenged by the Patent Owner under a different interpretation. Specifically, Loyer teaches or suggests these limitations—root ends of valves substantially at inflection point; curved face portion with two curvature radii, radius at leading ends of curved face portions being smaller than radius at root ends of valves—regardless of Patent Owner's interpretation of the claims.

VIII. CONCLUSION

This Petition identifies non-cumulative grounds of rejection not previously considered during the examination of the '075 patent, and establishes a reasonable likelihood that Petitioner will prevail in challenging the patentability of claims 1-6 of the '075 patent. Petitioner respectfully requests institution of a Trial for IPR of the '075 patent claims 1-6 and that these claims be rejected and cancelled.

The undersigned certifies that the word count for this document, excluding a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing, is 11,531 words.

DATED: January 19, 2017

Respectfully submitted, Pearl Cohen Zedek Latzer Baratz LLP

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CERTIFICATE OF SERVICE

I hereby certify, pursuant to 37 C.F.R. Sections 42.6 and 42.105, that a complete copy of the attached **PETITION FOR** *INTER PARTES* **REVIEW OF U.S. PATENT NO. 6,432,075**, including all exhibits (**Ex. Nos. 1001-1024**), are being served by FedEx on the 19th day of January, 2017, the same day as the filing of the above-identified document in the United States Patent and Trademark Office with the Patent Trial and Appeal Board, upon the patent counsel of record for U.S. Patent No. 6,432,075:

Darby & Darby P C 805 Third Avenue New York NY 10022

and upon the attorneys of record in the related litigation:

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By: / David A. Loewenstein / David A. Loewenstein Reg. No. 35,591 Lead Counsel for Petitioner

CERTIFICATE OF SERVICE

I hereby certify, pursuant to 37 C.F.R. Sections 42.6 and 42.105, that a complete copy of the attached **POWER OF ATTORNEY** for Petition for *Inter Partes* Review of U.S. Patent No. 6,432,075 is being served by FedEx on the 19th day of January, 2017, the same day as the filing of the above-identified document in the United States Patent and Trademark Office with the Patent Trial and Appeal Board, upon the patent counsel of record for U.S. Patent No. 6,432,075:

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and upon the attorneys of record in the related litigation:

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