

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MONOSOL RX, LLC,
Petitioner,

v.

ARIUS TWO, INC.,
Patent Owner.

Case IPR2014-00376
Patent No. 7,579,019 B2

Before SHERIDAN K. SNEDDEN, CHRISTOPHER L. CRUMBLEY, and
ZHENYU YANG, *Administrative Patent Judges*.

CRUMBLEY, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318 and 37 C.F.R. § 42.73

I. INTRODUCTION

On January 22, 2014, Monosol RX, LLC (“Monosol”) filed a Petition seeking *inter partes* review of claims 1–7 of U.S. Patent No. 7,579,019 B2 (Ex. 1001, “the ’019 patent”). Paper 1, “Pet.” The owner of the ’019 patent, Arius Two, Inc. (“Arius”), filed a Patent Owner Preliminary Response on May 7, 2014. Paper 10, “Prelim. Resp.” In an August 6, 2014, Decision on Institution of *Inter Partes* Review (Paper 11, “Dec.”), we instituted trial on claims 1–7 based on the following grounds:

1. Whether claims 1–3 and 5–7 are unpatentable under 35 U.S.C. § 102 as anticipated by Flockhart;¹
2. Whether claims 1–5 and 7 are unpatentable under 35 U.S.C. § 102 as anticipated by Babaian;² and
3. Whether claims 1–7 are unpatentable under 35 U.S.C. § 103 as having been obvious over the combined disclosures of Keith³ and Babaian.

Dec. 20–21.

Following institution, Arius filed a Patent Owner Response to the Petition (Paper 22, “PO Resp.”), and Monosol filed a Reply (Paper 25, “Pet. Reply”).

Monosol supported its Petition with the Declaration of Nicholas A. Peppas, Sc.D. (Ex. 1015), and submitted the Declaration of Joseph W. Wyse, Ph.D. (Ex. 1023) with its Reply. Monosol also served a second

¹ Ex. 1008, U.S. Patent No. 5,298,256, issued Mar. 29, 1994 (“Flockhart”).

² Ex. 1007, U.S. Patent No. 4,713,239, issued Dec. 15, 1987 (“Babaian”).

³ Ex. 1011, U.S. Patent No. 4,764,378, issued Aug. 16, 1988 (“Keith”).

Declaration of Dr. Wyse as supplemental evidence under 37 CFR
§ 42.64(b)(2). Ex. 1025.

With its Patent Owner Response, Arius filed two Declarations, from Edith Mathiowitz, Ph.D. (Ex. 2003) and Philip T. Lavin, Ph.D. (Ex. 2014). Monosol took the cross-examination of Dr. Mathiowitz and filed the transcript of the deposition. Ex. 1021.

Arius filed a Motion to Exclude Monosol's Exhibits 1018–1020 and 1023 (Paper 32), Monosol filed an Opposition (Paper 37), and Arius filed a Reply (Paper 38).

Oral hearing was requested by both parties (Papers 31, 34) and was held on April 15, 2015. A transcript of the oral hearing is included in the record. Paper 44, "Tr."

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision, issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73, addresses issues and arguments raised during trial. For the reasons discussed below, we determine that Monosol has not met its burden to prove, by a preponderance of the evidence, that claims 1–7 of the '019 patent are unpatentable. Arius's Motion to Exclude is *dismissed as moot*.

A. The '019 Patent

The '019 patent discloses a water-erodable pharmaceutical carrier device for application to mucosal surfaces, to provide localized delivery of pharmaceuticals to the site of application. Ex. 1001, 3:44–49. The device is

a layered film comprising an adhesive layer and a backing layer; the pharmaceutical may be located in one or more of the layers. *Id.* at 3:50–54.

According to Arius, the film of the '019 patent has a number of characteristics that distinguish it from prior art films, which are said to have “unacceptable residence times, excessive bulkiness, unpleasant feel, and/or painful removal.” Prelim. Resp. 5. The layered nature of the device permits “directional release” of the pharmaceutical such that “release will mainly be toward the mucosa and not, for instance, into the oral or vaginal cavity.” Ex. 1001, 11:49–52. The device is composed of water-erodable components that “slowly dissolve[] or erode[] away” over a “residence time.” *Id.* at 6:2–10. The residence time of the device may be adjusted by altering the erosion kinetics of one or more of the layers. *Id.* at 8:28–9:55. During the residence time, the device absorbs water and softens, diminishing foreign body sensation. *Id.* at 6:25–29.

The '019 patent claims a method of using the disclosed device to achieve transmucosal delivery of a pharmaceutical.

B. Illustrative Claims

Of the challenged claims, only claim 1 is independent, while claims 2–7 depend, directly or indirectly, from claim 1. Claim 1 is illustrative of the claimed subject matter, and is reproduced as follows:

1. A method for the transmucosal delivery of a systemic pharmaceutical for achieving a fast onset of activity in a subject or a desired level of a systemic pharmaceutical in the blood of a subject, comprising:

adhering a bioerodable device to an oral mucosa surface of a subject such that there is minimal foreign body sensation; and directionally delivering an amount of a systemic pharmaceutical from the bioerodable device to mucosal tissue of the subject such that an effective amount of the systemic pharmaceutical is delivered to the subject achieving a fast onset of activity in the subject or a desired level of the systemic pharmaceutical in the blood of the subject within about 30 minutes, wherein the bioerodable device has a residence time of less than 1 hour or about 1 hour, and the device comprises a thin and flexible adherent and bioerodable polymeric film containing a systemic pharmaceutical, and wherein the bioerodable device comprises soluble polymers selected based on dissolution rates to achieve the desired residence time and release profile.

Ex. 1001, 24:46–67.

II. DISCUSSION

A. Claim Construction

For purposes of our Decision to Institute, we analyzed each claim term in light of its broadest reasonable interpretation, as understood by one of ordinary skill in the art and as consistent with the specification of the '019 patent, and construed two claim terms: *onset of activity in the subject* and *within about 30 minutes*. Dec. 5–10 (citing 37 C.F.R. § 42.100(b)); *see also In re Cuozzo Speed Techs., LLC*, No. 2014-1301, 2015 WL 4097949, at *7–8 (Fed. Cir. July 8, 2015) (“Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA,” and “the standard was properly adopted by PTO regulation.”).

Based on the full record of the trial, we now consider it necessary to construe an additional term, *bioerodable device*, which is dispositive of the instituted grounds of unpatentability.

Both Monosol and Arius proffer constructions of *bioerodable device*. Monosol asserts that the term means “device made of components which erode and/or disperse and/or dissolve, over a period of time, in the presence of water and/or saliva and/or other bodily fluids.” Pet. 9. Arius asks that we construe the term as “device that erodes in the presence of bodily fluids.” Prelim. Resp. 8. Both parties, therefore, focus on the “bioerodable” aspect of the term, but do not address what is meant by “device.” In particular, neither party addresses whether the *bioerodable device* of the claims is required to have more than one layer.

When construing claims, our “focus must begin and remain centered on the language of the claims themselves.” *Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001). Here, claim 1 requires that the *bioerodable device* comprise “a thin and flexible adherent and bioerodable polymeric film^[4] containing a systemic pharmaceutical,” but does not state whether other layers are present, or required. We do note,

⁴ At oral hearing, the panel asked the parties whether this phrase requires two components: a “thin and flexible adherent” and a “bioerodable polymeric film,” or whether it merely describes one component (“polymeric film”) modified by four adjectives (“thin,” “flexible,” “adherent,” and “bioerodable”). Tr. 12–13, 27–28. Both parties contended that the latter was the correct interpretation; we need not decide this construction for the purposes of this decision.

however, that the use of the open transitional phrase “comprises” indicates that additional layers may be present.

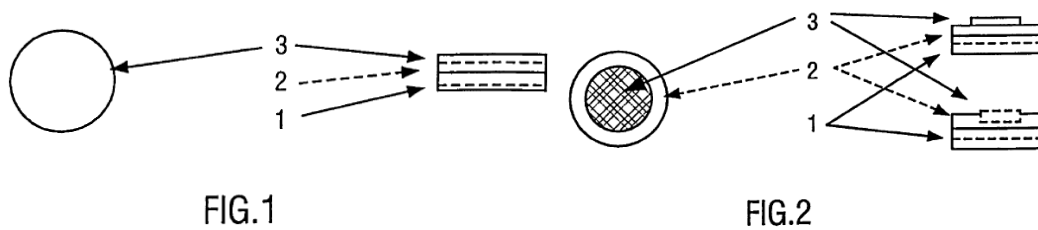
Both parties contend that the broadest reasonable interpretation of claim 1 is that *bioerodable device* requires only one layer. Tr. 12–13, 27–28. The Federal Circuit has cautioned, however, that “[t]he protocol of giving claims their broadest reasonable interpretation . . . does not include giving claims a legally incorrect interpretation.” *In re Skvorecz*, 580 F.3d 1262, 1267 (Fed. Cir. 2009). The broadest reasonable interpretation standard requires, therefore, that we read the claims in light of the specification. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010) (broadest reasonable interpretation must “reasonably reflect the plain language and disclosure” of the patent).

The specification of the ’019 patent consistently describes the invention as a device having multiple layers. The Abstract states that “[t]he device comprises an adhesive layer and a non-adhesive backing layer.” Ex. 1001, Abstract. Similarly, the Summary of the Invention states that the “device includes a layered film disk which is water-erodable,” and that the “device comprises a layered film disk having an adhesive layer and a backing layer.” *Id.* at 1:49–54. While the ’019 patent prefaces this description as “one embodiment,” other disclosed embodiments only *increase* the number of layers; no one-layer device is ever disclosed. *See id.* at 3:55–56 (“[i]n another embodiment, the . . . device comprises a third layer”). Other portions of the Summary of the Invention consistently describe multi-layer embodiments, or describe the composition of the

adhesive layer or backing layer. *Id.* at 5:9–11, 6:41–47, 6:50–53, 7:52–53, 9:35–37, 11:37–40, 11:45–47, 12:19–25, 12:58–59, 13:8–9.

The written description concludes with forty Examples, each of which is directed to describing the preparation or testing of a backing layer (Examples 1–10, 19, 21–25), adhesive layer (Examples 11–17, 26, 27), or a final film product described as having two layers (Examples 17, 18, 20, 31–40) or “multilayer” (Examples 28–30).

Both Figures of the ’019 also depict layered structures, which the specification describes as “layered film disks” (*id.* at 4:36–38):



Figures 1 and 2 of the ’091 patent depict layered film disks having backing layer 1 and bioadhesive layers 2 and 3.

The specification also discloses that a multilayer structure is essential to meet one of the functional limitations of claim 1. A multilayer structure is necessary to permit “localized” or “unidirectional delivery” of the pharmaceutical, for example “toward a mucosal layer.” *Id.* at 11:47–49, 12:17–23. “The pharmaceutical component may be included in either layer, although preferably, it is included in the adhesive layer, which is closest to the treatment site.” *Id.* at 6:44–47. “[I]f pharmaceutical is present in the first adhesive layer then it is prevented from being released through the sides and back of the device.” *Id.* at 12:19–23. The challenged claims each

require this sort of directional delivery, wherein the pharmaceutical is delivered from the device “to the mucosal tissue of the subject.” The specification does not disclose any other manner of providing “directional delivery” other than using a layered structure.

Finally, the ’019 patent explicitly states that:

While the device of the invention only *requires two layers*, i.e., an adhesive layer and a backing layer, it is often preferable to have additional layers. One instance in which this might be advantageous is when specific unidirectional flow of a pharmaceutical is required is toward a mucosal layer.

Id. at 11:45–47 (emphasis added). In all, the specification makes evident that the patentee considered the invention to *require* a multilayer device, at least having one adhesive layer and one backing layer.

In proceedings such as *inter partes* reviews, in which a patent has been brought back to the Office for a second review, we are also to consult the prosecution history of the patent. *See Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (citing *Tempo Lighting Inc. v. Tivoli LLC*, 742 F.3d 973, 977 (Fed. Cir. 2014)). The prosecution history of the ’019 patent provides additional evidence that the invention requires at least two layers. As originally filed, the application contained 33 claims, of which claims 1, 17, 19, 25, and 31–32 were independent. Ex. 1003, 0878. Application claim 1 was directed to a pharmaceutical carrier device having “a first water-erodable adhesive layer” and “a second, water-erodable non-adhesive backing layer,” while claim 17 was directed to a “layered film

disk” comprising two layers. *Id.* at 0878, 0880. Method claims 19, 25, and 31–32 described the use of an “adherent film” which comprised “a layered pharmaceutical carrier device” or a first and second layer. *Id.* at 0881, 0883. Nor were any originally filed dependent claims directed to a single layer device.

Prior to examination, the Applicant filed several Preliminary Amendments. The first three Preliminary Amendments continued to describe the invention as having multiple layers. *See, e.g., id.* at 0889 (claim 34 has first layer and second layer); *Id.* at 0902 (claim 50 describes adherent film as comprising layered device). Finally, in a Fourth Preliminary Amendment, claims 87–97 were submitted, which were silent regarding the number of layers in the device. *Id.* at 0225–26. Applicant informed the Office, however, that “[n]o new matter is added by this amendment.” *Id.* at 0227. We, therefore, conclude that the applicant did not intend to broaden the claims beyond what was disclosed in the specification and the originally filed claims—namely, a device having at least two layers.

During oral argument, counsel for Arius characterized the portions of the ’019 specification that require at least two layers as “an embodiment,” but could not direct the Board’s attention to any other embodiment that does not require multiple layers. Tr. 29–30. While it is normally “improper to read limitations from a preferred embodiment—even if it is the only embodiment—into the claims,” that rule does not apply where there is a “clear indication in the intrinsic record that the patentee intended the claims to be so limited.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913

(Fed. Cir. 2004); *see Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002) (requiring “words or expressions of manifest exclusion or restriction”). For example, when a patentee refers to a particular embodiment as “the invention,” and the specification does not provide any alternative embodiments, “[t]he public is entitled to take the patentee at his word . . . that the invention is” that embodiment. *Honeywell Int’l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006).

The record convincingly reflects that a multilayer device is more than simply an embodiment of the invention; rather, it *is* the invention. The originally filed claims, all Examples, and every disclosed embodiment in the specification are directed to a multilayer device. The directional delivery of the pharmaceutical, as required by the claims, is enabled only by the use of a backing layer over the adhesive, pharmaceutical-containing layer. That the ’019 patent states that the *invention*—not, importantly, an embodiment—“*requires two layers*” is the final, conclusive piece of the puzzle. The intrinsic record clearly indicates that the inventor did not possess an embodiment encompassing single-layer devices, and intended to claim only multilayer devices.

While the Board applies the broadest reasonable interpretation of a claim during *inter partes* review proceedings, “the Board may [not] construe claims during IPR so broadly that its constructions are *unreasonable* under general claim construction principles.” *See Proxyconn*, 789 F.3d at 1298. Applying general claim construction principles to the ’019 patent paints a

distinct picture: that the inventor intended the invention to cover only multilayer bioerodable devices. As the Federal Circuit has stated:

Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.

SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1341 (Fed. Cir. 2001). We, therefore, conclude that the broadest reasonable interpretation of *bioerodable device* in light of the specification of the '019 patent is “a multilayer bioerodable device.”

B. Patentability of Claims 1–7

Monosol’s Petition does not attempt to set forth evidence that the prior art references upon which we instituted trial disclose multilayer bioerodable devices, presumably because Monosol contends that challenged claims 1–7 do not require more than one layer. We, however, have reviewed the art upon which we instituted trial, and determine that the references do not disclose a multilayer device as claimed.

Monosol contends that claims 1–3 and 5–7 are anticipated by Flockhart. Flockhart discloses a buccal patch “in the form of a thin wafer or disk” that is placed against the mouth mucosa. Ex. 1008, 5:22–23. No layered structure is mentioned. Rather, the method of preparing the buccal patch is through melting and stirring to “form a homogeneous mass.” *Id.* at 5:8–19, 10:12–39. Flockhart, therefore, discloses a single-layer,

homogeneous structure that does not anticipate the multilayered device of claims 1–3 or 5–7.

Monosol contends that Babaian anticipates claims 1–5 and 7. Babaian discloses an antianginal film that is a “plate,” comprising an active substance and a biologically soluble carrier. Ex. 1007, Abstract. As with Flockhart, no disclosure of a multilayered structure is given. Example 1 of Babaian discloses a process of preparing the antianginal film, in which a solution of mixed carrier and pharmaceutical is cast onto a polished metal plate in a single, 4–5 mm thick layer. *Id.* at 15:45–61. Disks are stamped out of this layer to create the antianginal film. *Id.* at 15:65–67. Babaian, therefore, discloses a single-layer device, and we conclude that it does not anticipate claims 1–5 and 7.

Finally, Monosol contends that the combination of Keith and Babaian renders claims 1–7 obvious. Babaian’s single-layer device is described above; Keith does not remedy this deficiency. Keith discloses “buccal dosage forms” in which a pharmaceutical is mixed with a matrix material. Ex. 1011, 1:5–10. The matrix material mixture is chosen to achieve a form that “rapidly disintegrates and dissolves” to leave a coating of the matrix ingredients on a relatively large area of the mucosa. *Id.* at 4:16–21. The devices are prepared by mixing the ingredients in molten form, followed by casting the composition in a thin layer on a flat surface, followed by cutting into dosage forms. *Id.* at 4:34–51. Again, we conclude that this preparation method results in a single-layer, homogenous product.

Indeed, Keith distinguishes its product from those in the prior art which have multiple layers. For example, Keith describes Zaffroni⁵ as teaching an adhesive buccal device having an impermeable backing layer and a drug-containing adhesive layer, similar to the layered structure of the '019 patent. *Id.* at 1:39–45. Keith criticizes Zaffroni's multilayer device, however, stating that it has “the drawback that it must be removed from the mouth after the drug has been dispensed.” *Id.*

Based on the disclosures of Keith and Babaian, we cannot conclude that the references teach or suggest the multilayered bioerodable device of claims 1–7. Neither reference discloses a layered structure, and Keith's discussion of the drawbacks of the layered devices of the prior art calls into question whether a skilled artisan would modify its single-layer device to incorporate multiple layers. Monosol has not met its burden to establish that claims 1–7 would have been obvious over the combined disclosures of Keith and Babaian.

For the foregoing reasons, Monosol has not proven by a preponderance of the evidence that the prior art teaches all elements of challenged claims 1–7. We, therefore, cannot conclude that claims 1–7 are anticipated by, or would have been obvious over, the instituted prior art of record.

⁵ U.S. Patent No. 3,598,122, issued Aug. 10, 1971.

III. CONCLUSION

We conclude that Monosol has not demonstrated, by a preponderance of the evidence, that claims 1–7 of the '019 patent are unpatentable under 35 U.S.C. §§ 102 or 103, as anticipated by Flockhart or Babaian, or having been obvious over the combined disclosures of Keith and Babaian.

Our determination that none the prior art references cited by Monosol teach or suggest a layered bioerodable device is the same whether or not we consider Monosol's Exhibits 1018–1020 and 1023. We therefore *dismiss as moot* Arius's Motion to Exclude these Exhibits.

IV. ORDER

Accordingly, it is

ORDERED that claims 1–7 of U.S. Patent No. 7,579,019 B2 are *not unpatentable*;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 318(b), upon expiration of the time for appeal of this decision, or the termination of any such appeal, a certificate shall issue confirming claims 1–7; and

FURTHER ORDERED that, because this is a final decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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