NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON (WATERFORD) LTD., AND TEVA PHARMACEUTICALS USA, INC., Plaintiffs, v. AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, AND AMNEAL PHARMACEUTICALS INC. Defendants.	**Civil Action No. 23-20964 (SRC)** **OPINION & ORDER**

CHESLER, U.S.D.J.

This matter comes before the Court on the application for claim construction by Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, "Teva") and Defendants Amneal Pharmaceuticals Of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals Inc. (collectively, "Amneal.") This case arises out of a patent infringement dispute under the Hatch-Waxman Act between Teva and Amneal. Teva holds approved NDA No. 021457 for ProAir® HFA (albuterol sulfate) Inhalation Aerosol ("ProAir® HFA"), and owns certain patents listed in the Orange Book as covering this product: U.S. Patent Nos.

8,132,712 (the "'712 patent"), 9,463,289 (the "'289 patent"), 9,808,587 (the "'587 patent"), 10,561,808 (the "'808 patent"), and 11,395,889 (the "'889 patent") (collectively, the "Patents at issue" or the "Inhaler Patents"). The parties dispute the construction of seven terms in these patents.

ANALYSIS

I. The law of claim construction

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). "[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

> It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

> We have frequently stated that the words of a claim 'are generally given their

> ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .
>
> In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed terms

Teva summarizes the dispute over the construction of the seven terms at issue as follows:

> The claim construction dispute in this case concerns whether the asserted claims – which expressly recite an "inhaler," "medicament canister," or the like – require the presence of an active drug (as Teva argues) or claim only the device with no active drug (as Defendants argue).

(Pls.' Opening Br. at 1.) Teva also summarizes its argument as follows: "Simply put, an 'inhaler' without an active drug is not an 'inhaler.'" (Pls.' Opening Br. at 17.) These quotes concisely give the gist of Teva's position.

In opposition, Amneal urges the Court to "reject Teva's attempt to import 'an active drug' requirement into the "inhaler" preambles." (Defs.' Opening Br. at 1.) As the discussion

that follows will show, the Court finds that this is an apt characterization of Teva's arguments, and, in short, the Court agrees with Amneal that Teva cites no intrinsic evidence to support importing such a requirement into the preambles or into the claim terms at issue. Amneal contends that construction is not needed for any of the terms at issue.

Teva seeks construction of seven terms which fall into two groups. In the first group are five terms which appear in a preamble phrase of various claims; in the second group are two terms which appear in the body of various claims. Teva's summary, just quoted, applies to all seven terms: the core issue is whether the claim term requires the presence of an active drug.

Teva proposes that five preamble phrases should be construed as limiting: 1) in claim 1 of the '289 patent and claims 1 and 12 of the '587 patent: "***An inhaler for metered dose inhalation***, the inhaler comprising:"; 2) in claim 1 of the '808 patent: "***A dose counter for an inhaler***;" and 3) in claim 1 of the '889 patent: "***An incremental dose counter for a metered dose inhaler***."

For each term in the preamble group of disputed terms, Teva proposes an argument with two steps. At the first step, Teva argues that the preamble phrase should be found to be a claim limitation. At the second step, Teva proposes that the Court rewrite the preamble phrase: in each case, Teva contends that the Court should rewrite the phrase to add in the requirement for the presence of an active drug product. For example, as to the preamble phrase "An inhaler for metered dose inhalation," which appears in claim 1 of the '289 patent and claims 1 and 12 of the '587 patent, Teva argues in two steps: 1) the preamble phrase is limiting; and 2) the now-limiting preamble phrase should be rewritten to add "containing an active drug capable of being dispensed via the inhaler to the lungs." Teva proposes that the Court should, first, classify the

preamble phrase as limiting, and then, second, insert new matter into the preamble which should also be viewed as limiting.[1]

This appears to be a roundabout approach to what is essentially – as Amneal argues – an attempt to import a characteristic of specific embodiments from the specification into the claim. It is indisputable that there are a number of places in the specification that disclose use of the invention to contain and dispense medication. Teva proposes constructions that limit the claims to embodiments which contain medication, excluding embodiments empty of medication.

The Court will consider the second step of Teva's argument first: has Teva demonstrated, under Federal Circuit law, that this characteristic of some embodiments (containing medication) should be imported as a claim limitation? The Federal Circuit has — in its own words – "repeatedly warned" against limiting claims to particular embodiments: "although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments." Phillips, 415 F.3d at 1323. The Federal Circuit has explained:

> The written description, however, is not a substitute for, nor can it be used to rewrite, the chosen claim language. Though understanding the claim language may be aided by the explanations contained in the written description, it is important not to import into a claim limitations that are not a part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.

Superguide Corp. v. DirecTV Enters., 358 F.3d 870, 875 (Fed. Cir. 2004); see also Sumitomo Dainippon Pharma Co. v. Emcure Pharms. Ltd., 887 F.3d 1153, 1158 (Fed. Cir. 2018)

[1] Teva cites no cases in which the Federal Circuit used any analogous two-step approach to claim construction of a preamble phrase, first finding a preamble to be limiting, and then entirely rewriting the preamble with new matter that is considered limiting as well.

("Appellants' claim construction arguments conflict with *Pfizer* and other precedent because they seek to import limitations from the specification into the claim.") Moreover, the requirements for importing such a limitation are exacting: "Generally, a claim is not limited to the embodiments described in the specification unless the patentee has demonstrated a clear intention to limit the claim's scope with words or expressions of manifest exclusion or restriction." i4i Ltd. P'ship v. Microsoft Corp., 598 F.3d 831, 843 (Fed. Cir. 2010) (quotation omitted). Teva has not pointed to any expressions of manifest exclusion or restriction in the specification which could justify restricting the claims to medication-containing embodiments. In fact, Teva's briefs completely overlook Federal Circuit law about importing limitations from specific embodiments.

In support of the second step of its preamble argument, Teva offers the intrinsic evidence of specification references to inhalers containing medication.[2] Teva begins with the first sentence of the "Background of the Invention" section: "Metered dose inhalers can comprise a medicament-containing pressurised canister containing a mixture of active drug and propellant." '289 patent, col.1 ll.27-29. This sentence does not support Teva's assertion that an inhaler without an active drug is not an inhaler. Instead, it supports the understanding that an inhaler

[2] Teva also offers a definition from Merriam-Webster's Medical Desk Dictionary, but different dictionaries say different things. Merriam-Webster's regular online dictionary gives the word "inhaler" two different ordinary meanings. One is the device by means of which a user inhales something, and the second is the person who is doing the inhaling. See https://www.merriam-webster.com/dictionary/inhaler (last accessed 10/29/2024.) This other Webster's dictionary does not agree with Teva that a person who inhales air but not drugs does not fit within the ordinary definition of an inhaler. Neither dictionary is intrinsic evidence. "While extrinsic evidence can shed useful light on the relevant art, we have explained that it is less significant than the intrinsic record in determining the legally operative meaning of claim language." Phillips, 415 at 1317.

may or may not comprise an active drug.[3] The Court will not pick through the rest of Teva's references to the specification, because none of them supports the proposition that the patentees believed that an inhaler without an active drug is not an inhaler.[4] The intrinsic evidence Teva cites does not support importing a claim limitation restricting the invention to inhalers containing medication. The Court finds no intrinsic evidence to support the proposition that an empty inhaler is no longer an inhaler.

Nor does Teva offer a theory of meaning to support its proposed construction of "inhaler." The options are limited by Federal Circuit law:

> While we read claims in view of the specification, of which they are a part, we do not read limitations from the embodiments in the specification into the claims. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904 (Fed. Cir. 2004). We depart from the plain and ordinary meaning of claim terms based on the specification in only two instances: lexicography and disavowal. *Thorner*, 669 F.3d at 1365. The standards for finding lexicography and disavowal are exacting. "To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning" and must "clearly express an intent to redefine the term." *Id.* at 1365 (quotations omitted).
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> . . .
>
> Disavowal requires that "the specification [or prosecution history] make[] clear

[3] Similarly, Amneal points out that, in the "Summary of the Invention" section, the specification discloses a series of possible inhaler embodiments, and then states: "Each of the above inhalers in accordance with aspects of the present invention may have a medicament canister mounted thereto." '289 patent, col.9 ll.12-14. Note again the use of "may" to express optional potential rather than requirement of a medicament canister.

[4] In quoting from the specification, Teva does not distinguish between statements about potential specific embodiments, which are generally not limiting, and restrictive statements about the entire invention, which might be limiting. The Federal Circuit often cautions courts about importing claim limitations from particular embodiments. See, e.g., Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) ("Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.") Teva does not at any point argue that the specification contains any disclaimer or disavowal of embodiments lacking active drug product.

> that the invention does not include a particular feature," *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001), or is clearly limited to a particular form of the invention.

Hill-Rom Servs. v. Stryker Corp., 755 F.3d 1367, 1371-72 (Fed. Cir. 2014). Teva has not argued that the intrinsic evidence supports a theory based on lexicography or disavowal, and so, under the law, it is left with a theory of ordinary meaning. As Teva repeatedly notes in its opening brief, the first sentence of the "Background of the Invention" section states: "Metered dose inhalers can comprise a medicament-containing pressurised canister containing a mixture of active drug and propellant." '289 patent, col.1 ll.27-29. This is a very clear statement that the genus of metered dose inhalers includes inhalers with a canister containing active drug and propellant, as well as inhalers that do not do so. That statement from the specification appears to provide a better expression of the patentees' understanding of the relationship between inhalers and drug products than does the claim that an inhaler without a reserve of drug product is not an inhaler.

This alone is sufficient to reject Teva's proposed construction of the preambles, but there are other reasons to reject the proposition that an inhaler should be limited to medication-containing embodiments, and is no longer an inhaler when without medication: the shared specification expressly recognizes the problem of the empty inhaler, expressing serious concern about the possibility of running out of medication, and it is a fair statement that a key benefit of the inventive dose counter is that patients can use it to prevent running out of medicine.[5] Thus, the invention, an inhaler with a more accurate dose counter, has a life cycle which goes from

[5] In the "Background of the Invention" section, the specification explains that a problem with prior art inhalers without accurate dose counters is that a user could run out of medication without knowing it. '289 patent, col.2 ll.25-31. This was an important problem to be solved.

unused to possibly empty, with one goal being to help users avoid the empty state.

The specification goes on to describe how a user can operate the inhaler to receive a dose of the drug. '289 patent, col.1 ll.34-48. It then states:

> A drawback of self-administration from an inhaler is that it is difficult to determine how much active drug and/or propellant are left in the inhaler, if any, especially of the active drug and this is potentially hazardous for the user since dosing becomes unreliable and backup devices not always available.
>
> Inhalers incorporating dose counters have therefore become known.

'289 patent, col.1 ll.49-56.[6] The specification thus explains that the dose counter helps the user determine how much active drug is left in the inhaler, "*if any*." This points out that, at the end of the cycle, there may be no active drug left in the inhaler.[7]

The Federal Circuit has instructed that, in construing claims, courts should consider what the inventor actually invented:

> Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.

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[6] It is worth noting that this quote is directly contrary to Teva's thesis that an inhaler without medication is no longer an inhaler. The reference to "how much . . . are left in the inhaler, if any" is intrinsic evidence that the patentees did *not* believe that an inhaler without medication is no longer an inhaler.

[7] The life cycle of inhalers is further described in detail in the "Detailed Description of the Invention" section. Figure 6B shows details of an embodiment at the beginning of the cycle, "when the inhaler has not been used at all." '289 patent, col.13 ll.10-11. The specification describes how the dose counter may be configured so as to count the number of doses remaining to be dispensed, or to count the number of doses that have already been dispensed. '289 patent, col.17 ll.4-10, col.20 l.62-col.21 l.8. If the counter is inaccurate, "the active drug and/or propellant may run out while the user thinks the device is still suitable for use according to the counter." '289 patent, col.2 ll.29-31. The point of the dose counter is to inform the user about the changing level of the active drug available to be dispensed, with one goal being to help the user prevent running out of medication.

Phillips, 415 F.3d at 1316 (quoting Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed.Cir.1998)). In short, this Court finds that the inventors actually invented a product with a life cycle that may progress from unused (active drug is at original level) to used up (no doses left). Under the construction proposed by Teva, the claims at issue would not encompass the condition in which the inhaler is empty. Teva's proposed construction does not naturally align with the patent's description of the invention.

The Court thus finds that the second step of Teva's preamble argument cannot succeed. The Court need not reach the first step, the question of whether the preamble phrases are limiting, because it is clear that Teva's second step is contrary to Federal Circuit law. Teva has not argued that, even if the Court declines to import the claim limitations as Teva requested, it should still find the preambles to be limiting.

Similarly, Teva proposes that the claim terms, "canister" and "medicament canister," both require the presence of an active drug. For the reasons already stated, the Court finds that the medicament canister also has a potential life cycle ranging from unused to used up, that the claim term does not require that the canister contain a particular amount, and that there is no justification for importing a limitation from the specification into the claims.[8]

[8] In addition, Amneal makes the interesting observation that the same group of inventors received U.S. Patent No. 10,086,156, which descends from a common parent application shared with the '289 patent, which contains this claim:

> 1. A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising . . .

Amneal points out that this shows that the patentees knew how to include such a limitation in a claim for a inhaler/dose counter but, in the four patents at issue, elected not to do so. This is

In its responsive brief, Teva responds to Amneal's arguments as follows:

> Turning to Defendants' arguments against Teva's proposed construction, the parties' dispute centers on what is the "plain and ordinary" meaning of the Inhaler Terms. Def. Br. at 11-12. Despite arguing that Teva's constructions do not capture the plain and ordinary meaning of the Inhaler Terms, Defendants fail to offer any competing evidence regarding the plain and ordinary meaning of those terms.

(Pls.' Resp. Br. at 14.) The Court disagrees with Teva. The central dispute here is not about the ordinary meaning of the claim term "inhaler;" it is about Teva's attempt to import limitations from the specification into the claims. Amneal's position is that no limitations should be imported and the terms need no construction. Because the Court has found that Teva has failed to meet the requirements of Federal Circuit law to import limitations from the specification into the claims, the Court rejects all of Teva's proposed constructions. The Court finds that this resolves the present claim construction disputes and that no further analysis is needed.

In conclusion, the Court determines that the claim terms at issue do not require the presence of an active drug, and that no further construction is necessary.

SO ORDERED.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: November 4, 2024

consistent with the Court's understanding of the terms at issue.