IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
Clarksburg

ASTRAZENECA AB and **ASTRAZENECA PHARMACEUTICALS LP,**

Plaintiffs,

v.

CIVIL ACTION NO. 1:22-CV-35
Judge Bailey

MYLAN PHARMACEUTICALS, INC. and **KINDEVA DRUG DELIVERY L.P.,**

Defendants.

MEMORANDUM OPINION AND ORDER

This patent infringement case involves one (1) United States Patent issued to AstraZeneca AB and sold and distributed by AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca"). Specifically, the patent at issue is U.S. Patent No. 11,311,558 ("the patent-in-suit"). AstraZeneca uses the pharmaceutical compositions and methods described in the patent to produce Symbicort®, a prescription drug approved for the treatment of inflammatory conditions/disorders, especially respiratory diseases such as asthma, chronic obstructive pulmonary disease ("COPD"), and rhinitis. The patent-in-suit shares a specification with U.S. Patent Nos. 7,759,328, 8,143,239, 8,575,137, and 10,166,247 that were the subject of two prior trials before Judge Keeley, but their claims have different scopes.

Pending before this Court is the parties' proposed competing claim construction of four (4) terms:

Claim Term	AstraZeneca's Proposed Construction	Mylan's Proposed Construction
"pharmaceutical composition"	"suspension for therapeutic administration"	Indefinite. Alternatively, "a formulation intended for therapeutic administration"
"formoterol"	"formoterol"	"Formoterol, including its enantiomers, mixtures of its enantiomers, the free base, salt or solvate, or a solvate of a salt"
"budesonide or an epimer thereof"	"budesonide or an epimer thereof"	"Budesonide, including epimers, esters, salts, and solvates thereof"
"about 0.001% w/w"	"approximately 0.001% w/w"	"0.001% ± 0.0002% w/w, i.e. within 0.0008%–0.0012% w/w"

I. Background

According to AstraZeneca, 3M Company, through its 3M Drug Delivery Systems division, submitted Abbreviated New Drug Application ("ANDA") No. 211699 to the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale of budesonide and formoterol fumarate dihydrate inhalation aerosol, 80 mcg/4.5 mcg and 160 mcg/4.5 mcg ("Mylan's ANDA Products"). *See* [Doc. 1 at 4]. On August 17, 2018, 3M transferred certain interests in ANDA No. 211699 to Mylan Pharmaceuticals Inc. [Id.]. Thereafter, on May 1, 2020, 3M closed on a transaction whereby 3M sold substantially all of its drug delivery systems business to an affiliate of Altaris Capital Partners, LLC ("Altaris"). [Id.]. Following this transaction, Altaris launched Kindeva as an independent company, and all of 3M's

activities relating to ANDA No. 21169 were transferred to Kindeva. [Id.]. Kindeva will manufacture Mylan's ANDA Products. [Id. At 4–5]. ANDA No. 21169 was approved on March 16, 2022.

In a letter dated August 30, 2018, Mylan notified AstraZeneca that it had filed ANDA No. 211699 seeking approval to market Mylan's ANDA Products prior to the expiration of the patents listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations for Symbicort. [Id. at 5]. In its letter, Mylan asserted that the '328, '239, and '137 patents are invalid, unenforceable, and not infringed by the commercial manufacture, use, or sale of Mylan's ANDA Products. [Id. at 6].

In a second letter dated October 11, 2019, Mylan notified AstraZeneca that it had submitted a certification to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of the product described in ANDA No. 211699 prior to the expiration of the '247 patent. [Id. at 5]. In its second letter, Mylan also asserted that the '247 patent was invalid, unenforceable, and not infringed by the commercial manufacture, use, or sale of Mylan's ANDA Products. [Id. at 6].

The parties proceeded to trial on the '328, '239, and '137 patents (the "Trial Patents") in October 2020. [Id.]. Prior to trial, Mylan stipulated to infringement of the asserted claims of the Trial Patents. [Id.]. After a five-day trial, Judge Keeley entered judgment of nonobviousness as to each asserted claim. *See* ***AstraZeneca AB v. Mylan Pharms. Inc.***, 522 F.Supp.3d 200 (N.D. W.Va. Mar. 2, 2021) (Keeley, J.). The Court held that a person of ordinary skill in the art ("POSA") "would not have been motivated to select the specific formulation claimed by the patents-in-suit." ***Id***. at 219. The Court further found

that the prior art "teaches away and does not render the claims obvious" because it "cut against the very goal a POSA would have been trying to achieve–a stable product with a consistent dose." ***Id***. at 220. Judge Keeley likewise found that "a POSA would not have had a reasonable expectation of success in creating a stable budesonide pMDI using HFA 227, PVP K25, and PEG-1000, much less when these ingredients were combined with formoterol." ***Id***.

Mylan appealed, and the Federal Circuit affirmed the Court's judgment of nonobviousness. ***AstraZeneca AB v. Mylan Pharms. Inc.***, 19 F.4th 1325, 1337–38 (Fed. Cir. 2021).[1]

In a letter dated March 8, 2022, AstraZeneca notified Mylan that the United States Patent and Trademark Office ("USPTO") allowed the pending claims of U.S. Patent Application No. 16/832,590 ("the '590 application"), which issued as the '558 patent on April 26, 2022. [Doc. 1 at 7]. In its letter, AstraZeneca notified Mylan of two items: (1) that its proposed generic Symbicort products infringe every limitation of the allowed claims and (2) that the allowed claims were substantially identical to the invention claimed in the U.S. Patent Application Publication No. 2021/0069215 ("the '215 publication"). [Id.].

II. Legal Standards

The construction of patent claims is a matter of law governed by federal statutes and the decisions of the Supreme Court of the United States and the United States Court

[1] The Federal Circuit disagreed with the Court's construction of a term not at issue in most claims of the patent-in-suit (0.001%). The Federal Circuit vacated for further proceedings. Judge Keeley issued a Memorandum Opinion and Order Following Bench Trial on November 9, 2022, holding Mylan carried its burden of proving that the asserted claims are invalid pursuant to 35 U.S.C. § 112 for lack of enablement and lack of written description. *See* Civ. Act. No. 1:18-CV-193 [Doc. 606].

of Appeals for the Federal Circuit. *See* ***Markman v. Westview Instruments, Inc.***, 52 F.3d 967, 979 (Fed. Cir. 1995). When interpreting the meaning of a claim, a court may consider the context, the specification, and the prosecution histories as intrinsic evidence. ***Id.*** (quoting ***Unique Concepts, Inc. v. Brown***, 939 F.2d 1558, 1561 (Fed. Cir. 1991)). "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." ***Phillips v. AWH Corp.***, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). The description of an invention in the claims, therefore, limits the scope of the invention. ***Id.*** "[T]here is no magic formula or catechism for conducting claim construction." ***Id.*** at 1324. Instead, the Court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." ***Id.***

"[T]he words of a claim are generally given their ordinary and customary meaning [which 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." ***Id.*** at 1312–13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." ***Id.*** at 1321 (internal quotation marks omitted).

When construing patent claims, then, a court must consider the context of the entire patent, including both asserted and unasserted claims. ***Id.*** Because a patent will ordinarily use patent terms consistently, "the usage of a term in one claim can often illuminate the meaning of the same term in other claims." ***Id.*** Accordingly, "[d]ifferences among claims" can provide insight into "understanding the meaning of particular claim terms," and "the

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.