

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY
GMBH, BAYER PHARMA AG, and
JANSSEN PHARMACEUTICALS, INC.,

Plaintiffs,

v.

AUROBINDO PHARMA LIMITED,
AUROBINDO PHARMA USA, INC.,
BRECKENRIDGE PHARMACEUTICAL,
INC., INVAGEN PHARMACEUTICALS,
INC., MICRO LABS LTD., MICRO LABS
USA INC., MYLAN
PHARMACEUTICALS INC., PRINSTON
PHARMACEUTICAL INC.,
SIGMAPHARM LABORATORIES, LLC,
TORRENT PHARMACEUTICALS,
LIMITED, and TORRENT PHARMA INC.,

Defendants.

Civil Action No. 1:15-cv-902-RGA

MEMORANDUM OPINION

Jack B. Blumenfeld, Esq., MORRIS NICHOLS ARSHT & TUNNELL LLP, Wilmington, DE;
Rodger D. Smith II, Esq., MORRIS NICHOLS ARSHT & TUNNELL LLP, Wilmington, DE;
Derek J. Fahnestock, Esq., MORRIS NICHOLS ARSHT & TUNNELL LLP, Wilmington, DE.

Attorneys for Plaintiffs

Bruce R. Genderson, Esq., WILLIAMS & CONNOLLY LLP, Washington, DC; Adam L.
Perlman, Esq., WILLIAMS & CONNOLLY LLP, Washington, DC; Dov P. Grossman, Esq.
(argued), WILLIAMS & CONNOLLY LLP, Washington, DC; Alexander S. Zolan, Esq.,
WILLIAMS & CONNOLLY LLP, Washington, DC; Martha C. Kidd, Esq., WILLIAMS &
CONNOLLY LLP, Washington, DC, Kathryn S. Kayali, Esq., WILLIAMS & CONNOLLY
LLP, Washington, DC.

Attorneys for Plaintiffs Bayer Intellectual Property GmbH and Bayer Pharma AG

David T. Pritikin, Esq., SIDLEY AUSTIN LLP, Chicago, IL; Lisa A. Schneider, Esq., SIDLEY AUSTIN LLP, Chicago, IL; Bindu Donovan, Esq., SIDLEY AUSTIN LLP, New York, NY; S. Isaac Olson, Esq., SIDLEY AUSTIN LLP, New York, NY.

Attorneys for Plaintiff Janssen Pharmaceuticals, Inc.

David E. Moore, Esq., POTTER ANDERSON & CORROON LLP, Wilmington, DE; Bindu A. Palapura, Esq., POTTER ANDERSON & CORROON LLP, Wilmington, DE; Stephanie E. O'Byrne, Esq., POTTER ANDERSON & CORROON LLP, Wilmington, DE; Douglas H. Carsten, Esq., WILSON SONSINI GOODRICH & ROSATI P.C., San Diego, CA; Wendy L. Devine, Esq., WILSON SONSINI GOODRICH & ROSATI P.C., San Diego, CA; Christina Dashe, Esq., WILSON SONSINI GOODRICH & ROSATI P.C., San Diego, CA; David M. Hanna, Esq., WILSON SONSINI GOODRICH & ROSATI P.C., San Francisco, CA.

Attorneys for Defendant Mylan Pharmaceuticals Inc.

Kenneth L. Dorsney, Esq., MORRIS JAMES LLP, Wilmington, DE; Stephen R. Auten, Esq., TAFT STETTINIUS & HOLLISTER LLP, Chicago, IL; Andrew M. Alul, Esq., TAFT STETTINIUS & HOLLISTER LLP, Chicago, IL; Roshan P. Shrestha, Ph.D., Esq., TAFT STETTINIUS & HOLLISTER LLP, Chicago, IL.

Attorneys for Defendants Micro Labs, Ltd. and Micro Labs USA, Inc.

John C. Phillips, Jr., Esq., PHILLIPS, GOLDMAN MCLAUGHLIN & HALL, P.A., Wilmington, DE; Megan C. Haney, Esq., PHILLIPS, GOLDMAN MCLAUGHLIN & HALL, P.A., Wilmington, DE; B. Jefferson Boggs, Esq., MERCHANT & GOULD PC, Alexandria, VA; Matthew L. Fedowitz, Esq., MERCHANT & GOULD PC, Alexandria, VA; Christopher J. Sorenson, Esq., MERCHANT & GOULD PC, Minneapolis, MN.

Attorneys for Defendant Breckenridge Pharmaceutical Inc.

Richard L. Renck, Esq., DUANE MORRIS, LLP, Wilmington, DE; Anthony J. Fitzpatrick, Esq. (argued), DUANE MORRIS, LLP, Boston, MA; Vincent L. Capuano, Ph.D., Esq., DUANE MORRIS, LLP, Boston, MA; Emily N. Winfield, Esq., DUANE MORRIS, LLP, Chicago, IL.

Attorneys for Defendant Princeton Pharmaceutical Inc.

John W. Shaw, Esq., SHAW KELLER LLP, Wilmington, DE; Jeffrey T. Castellano, Esq., SHAW KELLER LLP, Wilmington, DE; Nathan R. Hoeschen, Esq., SHAW KELLER LLP, Wilmington, DE.

Attorneys for Defendants Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc.

March 3, 2017



ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of claim construction of a single term in U.S. Patent No. 7,157,456 (“the ‘456 patent”). The Court has considered the Parties’ Claim Construction Briefs. (D.I. 144, 156, 162, 168). The Court heard oral argument on March 3, 2017.

I. BACKGROUND

This suit arises from Defendants’ filing Abbreviated New Drug Applications (“ANDA”) for generic versions of Plaintiffs’ anticoagulant, sold under the brand name XARELTO. (D.I. 144 at 6). Plaintiffs filed suit, alleging that the generic products that are the subjects of the ANDA filings would infringe a number of Plaintiffs’ patents. (D.I. 1). The patents-in-suit claim compounds for use in treating thromboembolic disorders and methods of treatment using these compounds.

II. LEGAL STANDARD

“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) (en banc) (internal quotation marks omitted). “[T]here is no magic formula or catechism for conducting claim construction.’ Instead, the court is free to attach the appropriate weight to appropriate sources ‘in light of the statutes and policies that inform patent law.’” *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996). Of these sources, “the specification is always highly relevant to the claim construction

analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted).

“[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 (citations and internal quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). “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.” *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court’s construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Phillips*, 415 F.3d at 1317–19 (internal quotation marks omitted). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

“A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent.” *Renishaw PLC v. Marposs Societa’ per*

Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GMBH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation and internal quotation marks omitted).

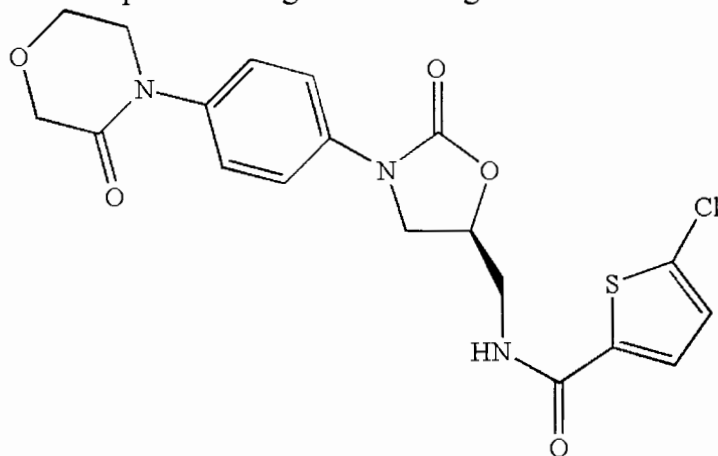
III. CONSTRUCTION OF DISPUTED TERMS

The ’456 patent is directed to compounds and methods for treatment of thromboembolic disorders. The only disputed term appears in dependent claim 14, which reads as follows:

14. *The compound of claim 6 that is purified and isolated.*

(’456 patent, claim 14) (disputed terms italicized). Independent claim 6, from which claim 14 depends, reads as follows:

6. The compound having the following formula



or a pharmaceutically acceptable salt or hydrate thereof.

(’456 patent, claim 6).

1. “The compound of claim 6 that is purified and isolated.”
 - a. *Plaintiffs’ proposed construction*: “The compound of claim 6 that is sufficiently free of impurities and any synthesis-related compounds to permit its use in a pharmaceutical composition. The claim does not exclude a pharmaceutical composition that contains the compound of claim 14 and one or more pharmacologically acceptable auxiliaries or excipients.”
 - b. *Defendants’ proposed construction*: “The compound of claim 6 that is sufficiently free of impurities and any synthesis-related compounds to permit its use in a

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