

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

UNITED THERAPEUTICS CORP.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, Inc.,

Defendant.

Civil Action No. 3:14-cv-5498 (PGS)(LHG)

**MEMORANDUM
& ORDER**

SHERIDAN, U.S.D.J.

In this patent infringement case, the parties dispute the construction of the term “a base B” in U.S. Patent No. 8,497,393 (“the ‘393 patent”). After reviewing the parties’ respective submissions and conducting a *Markman* hearing on October 2, 2015¹, the Court finds, for the reasons set forth below, that the disputed claim term does not need construction and should be given its plain and ordinary meaning. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (*en banc*), *aff’d* 517 U.S. 370 (1996).

I. LEGAL STANDARDS FOR CLAIM CONSTRUCTION

There is a two-step analysis for determining patent infringement: “first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the

¹ A tutorial was conducted before the *Markman* hearing. The attorneys for each party who had knowledge in the field of chemistry conducted the tutorial. Since the lawyers acted more like advocates for their respective clients rather than scientists at the tutorial, the tutorial was of little value.

claims as construed to determine infringement.” *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 804 (Fed. Cir. 2007) (citation omitted). When the court engages in claim construction to determine the meaning of disputed claim terms, it is decided as a matter of law. *Markman*, *supra*, 517 U.S. at 372. It is well established that “the construction of a patent, including terms of art within its claim, is exclusively within the province of the court.” *Id.*

When construing claims, the court must focus on the claim language. As explained by the Federal Circuit:

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, 1115-16 (Fed. Cir. 2004) (citations omitted). When looking at the words of a claim, the words “are generally given their ordinary and customary meaning,” which has been defined as “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.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005).

The Federal Circuit has counseled:

It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning usage in the field. The inventor’s words that are used to describe the invention – the inventor’s lexicography – must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decision making process by reviewing the same resources as would that person, viz., the patent specification and prosecution history.

Id. at 1313 (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)). Those resources, called intrinsic evidence, include the claim language, the specification, and the prosecution history. *See id.* at 1314.

However, when intrinsic evidence alone does not resolve the ambiguities in a disputed claim term, extrinsic evidence – evidence that is outside the patent and prosecution history – may also be used to construe a claim. *See id.* at 1317; *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582-83 (Fed. Cir. 1996). “[E]xtrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art” may be consulted; for example, expert testimony, dictionaries, and treatises. *Id.* at 1314. However, when a court relies on extrinsic evidence to construe a claim, the court should be guided by the principle that extrinsic evidence may never conflict with intrinsic evidence, because courts “have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms.” *Id.* at 1319. Thus, a court should take care to “attach the appropriate weight to be assigned to those sources.” *Id.* at 1322-24.

II. ANALYSIS

Set forth below are the parties’ primary arguments advanced in support of the proposed constructions. In determining that the disputed term does not need construction, the Court considered the arguments in the parties’ written submissions, as well as those made at oral argument.

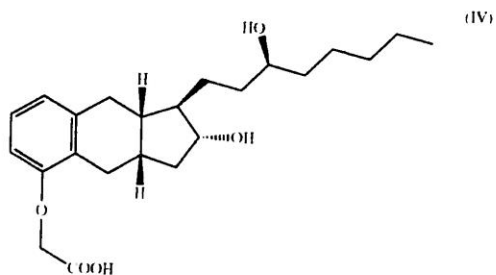
A. “a base B”

The only term at issue in the ‘393 patent is “a base B”. Initially, the term “a” is defined in the patent as “one or more” and does not require construction. Moreover, the parties do not dispute the meaning of “base”, in that it is an elementary and well-understood chemical term. Therefore, the only term at issue is “B.”

By way of background, the ‘393 patent is a product-by-process patent for a more efficient way to develop treprostinil, which UTC markets and sells as REMODULIN®. The ‘393 patent has twenty-two claims, including two independent claims, directed to an improved treprostinil product. Specifically at issue are Claims 1 (C. 19, l. 48 through C. 19, l. 29) and 9 (C. 19, l. 48 through C. 20, l. 47), which consist of four-steps, “(a)” through “(d)”. Although the disputed term, “a base B”, appears only in step (c), each step is cumulative, and builds upon the preceding. The Court focuses on Claim 9, as the parties have in their submissions and presentations. Specifically, representative Claim 9 of the ‘393 patent provides, in pertinent part:

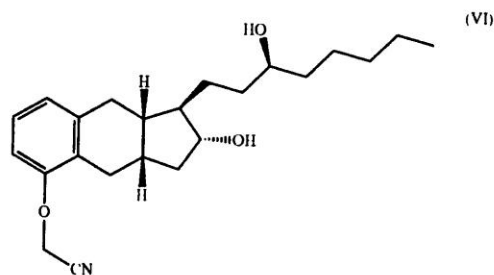
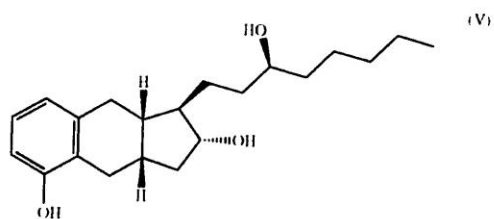
(see next page)

9. A product comprising a compound having formula IV



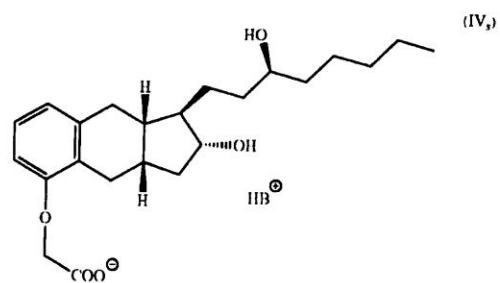
or a pharmaceutically acceptable salt thereof, wherein the product is prepared by the process comprising

(a) alkylating a compound of formula V with an alkylating agent to produce a compound of formula VI.



(b) hydrolyzing the product of formula VI of step (a) with a base,

(c) contacting the product of step (b) with a base B to form a salt of formula IV_s, and



(d) optionally reacting the salt formed in step (c) with an acid to form the compound of formula IV.

Teva argues that the use of the word “base” in step (b) and the use of the term “a base B” in step (c) above is confusing to the POSITA, and construction of the term “a base B” is necessary to distinguish the word “base” from the term “a base B.” As such, Teva recommends the construction of “a base B” to be “an organic or inorganic base that is a different base than the base used in step (b).”

UTC contends that the term “a base B” does not require construction because a POSITA would understand that “B” is a “placeholder” for any base. When one reads the claims as a specification of the ‘393 patent, there is no reference to the “placeholder” theory but UTC claims that use of “B” is an elementary chemistry concept which all chemistry novices learn early on from textbooks. See, Brown, et al. *Chemistry: The Central Science* (9th ed. 2003); March, et al. *March’s Advanced Organic Chemistry* (5th Ed. 2001). Although UTC claims it is basic chemistry, the Court is leery of relying upon extrinsic evidence. See, *Philips v. AWH Corp.*, 415 F. 3d 1303, 1319 (Fed. Cir. 2005).

Acknowledging the problem with relying upon extrinsic evidence, Teva argues that the Court should adopt the language of the inventors in the related ‘305 patent. In the prosecutorial history of the ‘305 Patent, the inventors described the word “base” in step (b) was “different” from “a based B” in step (c). In seeking reconsideration of a denial by the examiner, the inventors distinguished their application from the Moriarty patent by noting:

Applicants respectfully submit that one of the ordinary skill in the art would not have interpreted Moriarty’s additions of HCl disclosed in the second and/or third sentences of Moriarty’s paragraph 0079 as step d of instant independent claim 1 or 10, which recite reacting the salt formed in step (c) with an acid. The salt formed in step (c) is a salt of the base B, which is different from the base recited in step b of the instant claims, see step c) “contacting the product of step (b) with a base B.” One of the ordinary skill in the art would interpret the additions of HCl

disclosed in the second and/or third sentences of Moriarty's paragraph 0079 only as reacting with an acid of the base recited in step b, which is different from the salt of the base B (the salt formed in step (c)). Applicants respectfully submit that claims 6, 15, 16, 24, 25, 29 and 30 further emphasize the differences between the claimed invention and Moriarty by providing particular examples of the base B. [need cite]

Although the word "different" does appear in the prosecutorial history, the use of the word "different" does not materially improve the construction of "a base B" materially because it does not describe how the word "base" and the term "a base B" are not the same.

Rather than injecting the word "different" into the construction of "a base B", the Court reviewed the claims of the '393 patent to determine whether any clarification was necessary.

Looking at the '393 patent, claim 1, sets forth step (b) and step (c) as enumerated above. Immediately thereafter, Dependent claims 4 and 5 state the substances that are utilized in step (b) and step (c). Those dependent claims read:

4. The product of claim 1, wherein the base in step (b) is KOH or NaOH.
5. The product of claim 1, wherein the base B in step (c) is selected from the group consisting of ammonia, N-methyl-glucamine, procaine, tromethamine, magnesium, L-lysine, L-arginine, triethanolamine, and diethanolamine.

The POSITA would use the Defendants claims 4 and 5 as an instruction on how to develop the product. The instruction is clear, and inserting "different" to construct "a base B" is of minimal value, if any.

The same analysis applies to claim 9, which has the same steps as claim 1; and like claim 1, there are dependent claims setting forth the substance used in the preparation of the product.

Dependent claims 12 and 13 reads:

12. The product of claim 9, wherein the base in step (b) is a KOH.
13. The product of claim 9, wherein the base B in step (c) is selected from a group consisting of ammonia, N-methyl-glucamine, procaine, tromethamine, magnesium, L-lysine, L-arginine, triethanolamine, and diethanolamine.

The instruction within claim 9 and the dependent claim are quite clear. Use of the word “different” in the instruction of “a base B” is of little help.

In conclusion, the POSITA can easily follow the instructions in the claims 1 – 9 to prepare the product. I do not see any reason to construct the term “a base B” with the word “different” when the two dependent claims state the procedure. As such, the Court denies Teva’s request to construct the term “a base B.”

ORDER

The Court, in having reviewed the parties’ submissions and having heard oral argument on the disputed terms; and

IT IS on this 2nd day of December, 2015

ORDERED that the disputed term “a base B” be given its plain and ordinary meaning and need not be construed.

s/Peter G. Sheridan

PETER G. SHERIDAN, U.S.D.J.