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DOC #:
DATE FILED: OCT 17 2014

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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REGENERON PHARMACEUTICALS,
INC.,

Plaintiff,

-v-

MERUS B.V.,

Defendant.
-----X

REGENERON PHARMACEUTICALS,
INC.,

Plaintiff,

-v-

ABLEXIS LLC,

Defendant.
-----X

KATHERINE B. FORREST, District Judge:

On March 11, 2014, Regeneron Pharmaceuticals, Inc. (“Regeneron”) sued both Merus B.V. (“Merus”) and Ablexis LLC. (“Ablexis”) for patent infringement. Regeneron asserts that both companies have infringed its U.S. Patent No. 8,502,018. Before this Court is Regeneron’s motion to amend its infringement contentions. (Case No. 14-cv-1650, ECF No. 127.) For the reasons set forth below, that motion is granted in part and denied in part.

14 Civ. 1650 (KBF)

MEMORANDUM DECISION
AND ORDER

14 Civ. 1651(KBF)

I. BACKGROUND

Pursuant to this Court's Procedures for Patent Cases, Regeneron served its infringement contentions on May 19, 2014; motion practice followed.¹ After the parties met and conferred, Merus filed a letter on July 17, 2014 contending that Regeneron had failed to comply with the Court's rules by failing to break its claims into individual limitations. (Case No. 14-cv-1650, ECF No. 76.) Merus stated in the letter that "Regeneron has refused to correct this deficiency, stating every asserted claim should be read as one term" and called their approach "an absurd proposition." Regeneron rejected Merus's argument, which it characterized as asking them to "have broken up the asserted claims into more entries," as "bereft of legal support," and noted that during a telephone call "Regeneron explicitly asked Merus how it contended the claims should be broken out further." (Case No. 14-cv-1650, ECF No. 79.) Regeneron further stated in its letter that "Merus fails to cite any authority for the proposition that the elements of a claim are defined by each punctuation mark, preposition, and conjunction in the claim."

Based on Regeneron's position with respect to the infringement contentions and other positions it was taking at the time with regard to other discovery issues, the Court was concerned that there was gamesmanship afoot. From May 2014 to July 2014, the Court issued a series of discovery orders – Discovery Order No. 6

¹ The Court's rules provide that Regeneron must provide the defendants with: "A chart identifying specifically where each limitation of each asserted claim is found within each Accused Instrumentality . . . [and] the identity of the structure(s), act(s), or material(s) in the Accused Instrumentality that performs the claimed function." Individual Practices in Civil Cases, Attachment B (Judge Forrest's Procedures for Patent Cases) ("Individual Patent Rules"), Rule 1(a)(iii).

(dated July 22, 2014) concerned plaintiff's single limitation to infringement contentions. In that order, the Court stated:

The requirement for infringement contentions is a standard one; it allows for sensible and useful case preparation and trial. Parties are routinely held to their infringement contentions. Cases have been dismissed for inadequate contentions. The Court assumes the parties' familiarity with the case law in this area.

The Court will not force Regeneron to delineate elements in any particular way – but it will hold it to its stated position; here its position is that each claim has a single element and no delineation is necessary.

Breaking a claim with more than one limitation into its constituent elements is precisely what experienced practitioners in this area understand is required by infringement contentions. There are certainly claims with only one limitation; and there are certainly those with more. Here, Regeneron asserts one limitation per claim. If it is incorrect, this position has potential real ramifications for, inter alia, determinations of word surplusage, claim differentiation, and definiteness. The Court assumes Regeneron understands the implications of its position. The Court will not allow Regeneron to later claim individual elements or limitations.

Should Regeneron learn of additional detail relating to the Accused Instrumentality, it will not be able to use that information and only then delineate its own elements. In other words, the elements should be known to Regeneron now – but the Court accepts that it may learn more about the particular Accused Instrumentality. The latter can result in additional detail regarding the Infringement Contentions – but only within the framework Regeneron has previously established regarding its own claim elements.

Thus, to the extent that Regeneron determines that it will amend its Infringement Contentions by the date the Court has otherwise required, it may not alter how it breaks down its own claim into individual elements. It has staked out a position on that issue already. If defendants have, on that basis, additional motions to bring, so be it.

(Case No. 14-cv-1650, ECF No. 82.)

The parties appeared before the Court for a status conference shortly after this order was issued. (Case No. 14-cv-1650, ECF No. 92.) At that conference, the Court had an extensive discussion with counsel for Regeneron regarding its concern of gamesmanship – using as an example Regeneron’s position with regard to its infringement contentions. (Case No. 14-cv-1650, ECF No. 92, Tr. 14:14 – 19:23). At that conference, Regeneron asserted then, as it continues to assert now, that “it is a single limitation claim” (Tr. 7:13-14), noting that “I realize that we have gone in a different direction.” (Tr. 15:3-4.) Indeed, Regeneron said that breaking down the claim into constituents would be “difficult for us.” (Tr. 16:7-11.) This position made no sense then and it makes no more sense now – though Regeneron continues to assert a version of it in connection with the instant motion.

In the instant motion, Regeneron seeks to amend its infringement contentions. It asserts that it has learned additional information regarding Merus’s accused MeMo mouse and now understands Merus’s position on claim construction. It still has not, however, conceded that its claims have several limitations. It continues with its odd position that each claim is but a single limitation. In addition, Regeneron seeks to add infringement contentions pursuant to the doctrine of equivalents.

Merus has opposed Regeneron’s motion to amend both on the basis that the amendments violate Discovery Order No. 6 and as untimely; Ablexis opposes the motion to the extent that it is inconsistent with Discovery Order No. 6.

In its memorandum in support of the instant motion, Regeneron continues to maintain that its infringement contentions were properly laid out, noting “[t]he amended contentions do not change Regeneron’s infringement read; they simply add technical support for those contentions . . .” (Case No. 14-cv-1650, ECF No. 145, at 2.) In response to questions laid out in an order by the Court (Case No. 14-cv-1650, ECF No. 166; Case No. 14-cv-1651, ECF No. 109), Regeneron on October 9, 2014 reiterated that its original infringement contentions satisfy the Court’s rules as “Regeneron formatted its original infringement contentions in a manner that it believed was sensible and straightforward given the language of the claims.” (Case No. 14-cv-1650, ECF No. 169.) Of course, as Regeneron’s experienced patent counsel knows full well, this is not a formatting issue. Merus noted in its letter from the same date that Regeneron should be held to the strategic position it has held for the past six months “particularly given the significant prejudice Merus has experienced and would continue to experience should Regeneron be permitted to change now.” (Case No. 14-cv-1650, ECF No. 168.) Ablexis similarly noted in its letter that the issue before the court is “whether Regeneron should now be allowed to avoid the consequences from its own strategic decision.” (Case No. 14-cv-1651, ECF No. 113.) The Court agrees.

II. DISCUSSION

Claim construction is a question of law for the Court. Markman v. Westview Instruments, Inc., 517 U.S. 370, 388-90 (1996). When parties disagree as to how a claim should be construed, it is the Court’s role to resolve the issue. Id.

Claim construction is generally conceived as defining the meaning of claim terms. Id. at 388. Its purview is, however, broader than that. Claim construction is more generally concerned with how a claim is to be presented to the finder of fact for a determination, inter alia, of infringement. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Infringement – whether literal or on the basis of the doctrine of equivalents – is determined element-by-element. See Warner-Jenkinson Company, Inc. v. Hilton Davis Chemical Co., 520 U.S. 17, 40 (1997); Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 935 (Fed. Cir. 1987). At times, courts must determine whether certain language in a claim represents an individual element or limitation. The Court is required, as part of this motion, to make such a determination here.

A. Doctrine of Equivalents

The Court’s determination of the individual elements of a claim has particular importance with respect to the doctrine of equivalents. Warner-Jenkinson Company, Inc. v. Hilton Davis Chemical Co., 520 U.S. 17 (1997).

In Warner-Jenkinson, the Supreme Court left no doubt that the doctrine of equivalents requires a court to ask whether the accused product contains elements equivalent to each claimed element of the patented invention. Id. at 40. The “determination of equivalence should be applied as an objective inquiry on an element-by-element basis.” Id. The focus on elements maintains particularized attention to whether each specific element has been infringed and prevents a finding of infringement based only a generalized perception about a device. Id. “An

analysis of the role played by each element in the context of the specific patent claim will thus inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element.” Id.; see also Abbott Laboratories v. Sandoz, Inc., 566 F.3d 1282, 1296-97 (Fed. Cir. 2009).

In Abbott, the Federal Circuit stated unambiguously, “In no cases, however, may the doctrine of equivalents ignore the individual claim elements.” Id. at 1297 (citing Warner-Jenkinson, 520 U.S. at 40).

In the absence of a particularized position taken by the plaintiff on the constituent elements of his patent, there is simply no way to assess equivalency. In effect, by failing to break down a multi-element claim into constituent elements, a party has failed to provide adequate infringement contentions for a doctrine of equivalents analysis. If it were otherwise, the combination of inadequate infringement contentions and an assertion of the doctrine of equivalents would leave defendants in an untenable position of having to defend against such a claim as if Warner-Jenkinson and its progeny did not exist. It does exist and it is the law. See Freedman Seating Co. v. American Seating Co., 420 F.3d 1350, 1358 (Fed. Cir. 2005) (the “all limitations” rule holds that an accused product or process is not infringing unless it contains each limitation of the claim, either literally or by equivalence. This has implications for the doctrine of equivalents); see also Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1349 (Fed. Cir. 1998). To prove infringement under the doctrine of equivalents, the accused product or process

“must be shown to include an equivalent for each literally absent claim limitation.”

See Dawn Equip. Co. v. Kentucky Farms Inc., 140 F.3d 1009 (Fed. Cir. 1998).

B. Regeneron’s Single Limitation Position

Regeneron’s position that each claim in its ‘018 Patent has a single limitation is, at the very least, odd. It is also possibly a colossal tactical blunder. Perhaps at the outset of this litigation Regeneron had no choice but to take the positions it took because at the time infringement contentions were due, it was unsure of precisely whether or how the defendants’ product(s) infringed. It is ultimately of no concern to the Court why Regeneron has taken this position. The bottom line is the same: The Court meant what it said on July 22, 2014 when it issued Discovery Order No. 6; it meant what it repeated at the in-person conference that it held on July 24, 2014; and it will again reiterate its determination and the impact of that determination on these proceedings now: the Court perceives Regeneron as engaging in gamesmanship with regard to its infringement contentions. The Court does not believe that Regeneron – represented by experienced patent counsel – believes that their claim has only a single limitation. Regeneron’s position that the whole issue is about “formatting” is untenable, unacceptable and rejected.

As a matter of law, there is no doubt that each of the claims that Regeneron has asserted defendants have infringed contain more than one element. As an example, claim 1 states:

A genetically modified mouse, comprising in its germline human unrearranged variable region gene segments inserted at an endogenous mouse immunoglobulin locus.

(’018 Patent, 29:24-27.) This breaks down into as many as the following elements:

1. A genetically
2. Modified
3. Mouse
4. Comprising in its germline
5. Human
6. Unrearranged
7. Variable region
8. Gene segments
9. Inserted
10. At
11. An endogenous mouse immunoglobulin locus.

There may well be other ways to break down the claim; what is clear is that Regeneron’s single limitation position is incorrect as a matter of law. The Court finds that, as a matter of law, claim 1 contains multiple elements. As a result, Regeneron has not provided proper infringement contentions. It has therefore not provided infringement contentions asserting the doctrine of equivalents in proper form, and it is now too late to do so. Its motion to amend to add contentions pursuant to the doctrine of equivalents is therefore denied. To hold otherwise would ignore the holding and rationale of Warner-Jenkinson, and its progeny, and to reward Regeneron for its failure to comply with this Court’s rules.

C. Timing

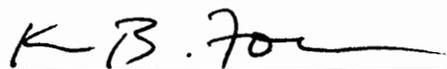
Separately, Regeneron asserts that its remaining amendments provide additional technical detail and are timely. The Court will allow those portions of the amendment other than as discussed above. While infringement contentions are not and cannot be moving targets to be amended as discovery progresses, the Court will allow this single amendment. The Court will not, however, allow any further amendments. The defendants are entitled to have certainty as to the scope of the claim against which they are defending. Now they do. See O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc., 467 F.3d 1355, 1366 (Fed. Cir. 2006).

III. CONCLUSION

For the reasons set forth above, the defendants' motion is GRANTED in part and DENIED in part.

SO ORDERED.

Dated: New York, New York
October 17, 2014


KATHERINE B. FORREST
United States District Judge