IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

AMERITOX, LTD., and
MARSHFIELD CLINIC, INC.,

Plaintiffs,

v.

MILLENNIUM HEALTH, LLC.,

Defendant.

OPINION AND ORDER

13-cv-832-wmc

In this case, plaintiffs Ameritox, Ltd., and Marshfield Clinic, LLC, claim that defendant Millennium Health, LLC infringes two of their patents: (1) U.S. Patents No. 7,585,680 ("the '680 patent"), purporting to describe a method for drug screening and compliance protocols for one sample of urine from a patient on a prescribed medication regimen; and (2) 7,785,895 ("the '895 patent"), purporting to describe a similar method for one biological sample generally. (*See* Am. Compl., Exs. A, B (dkt. ##106-1, 106-2).) On February 19, 2015, the court *granted* Millennium's motion for summary judgment as to the '895 patent and *denied* as to the '680 patent. (2/19/15 Op. & Order (dkt. #215).) Pursuant to Federal Rule of Civil Procedure 56(f), the court also directed Millennium to serve and file a response on or before March 2, 2015, as to why summary judgment should not be entered against it on the question of infringement of the '680 patent. Because Millennium's response offers no viable argument of law or fact that "all of the limitations" of claim 1 of the '680 patent are not found in Millennium's RADAR Report, *Innovention Toys, LLC v. MGA Entm't, Inc.*, 637 F.3d 1314, 1319-20 (Fed. Cir. 2011), the

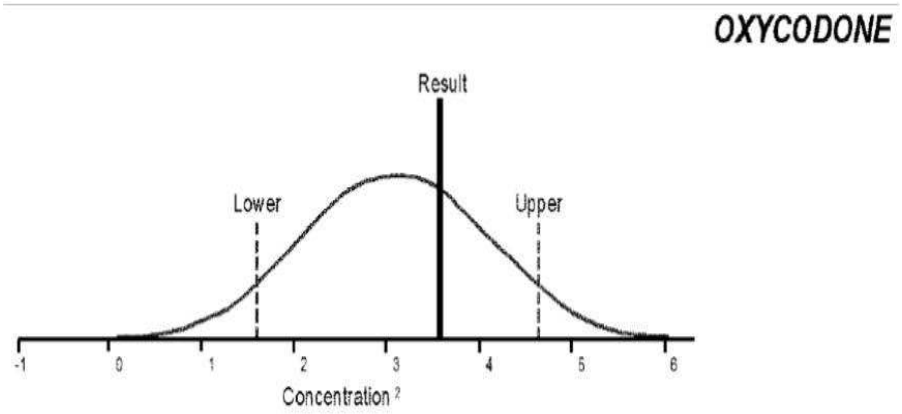
court will now grant summary judgment in favor of plaintiffs on their claim that Millennium infringes the '680 patent.

The court's summary judgment opinion observed the likelihood that "a trained toxicologist . . . familiar with clinical laboratory science" would find the comparative data in the RADAR Report as "falling within the plain and ordinary meaning of element (f)." (2/19/15 Op. & Order (dkt. #215) 74.) The court came to this conclusion because Millennium contracts for and produces RADAR Reports "that provide[] a comparison of the ratio between the concentration of a test metabolite from a patient to a set of normative data." (*Id.*) Indeed, Millennium's sample RADAR Report provides a comparison for oxycodone use, which is one of the specific drugs noted in the '680 patent specification. ('680 patent (dkt. #106-1) 12:18-13:48.)

Millennium's arguments to the contrary are wholly unpersuasive. *First*, Millennium repeats its already rejected argument for construing away from the plain and ordinary meaning of element (f) of claim 1. (Def.'s Resp. (dkt. #218) 1-2.) Contrary to Millennium's proposed narrow construction of element (f), the court found that element (f) should be given its broad meaning, which is consistent with a plain reading of the patents claims, as well as the varied aspects set forth in the patent's embodiments and described in its numerous and varied examples. (2/19/15 Op. & Order (dkt. #215) 24-27.) In particular, the court expressly rejected the notion that element (f) required use of known normative data from a population that is on the exact same regimen for a prescribed medication, much less that all members of the population actually *adhered* to that prescription regimen. Not prevailing in the construction debate on element (f) (as

well as element (b)) effectively foreclosed Millennium's only arguments against a finding of infringement of the '680 patent.[1]

As explained in the court's summary judgment decision, from the perspective of a person having ordinary skill in the art (a toxicologist), there is no reasonable factual dispute that the RADAR Report -- as best evidenced by the graph below -- reads upon element (f).



(Declaration of Rebecca C. Mandel (dkt. #129-29) p.4.)

[1] Millennium regularly uses the word "dose," rather than "prescribed medication" used in the patent claims themselves. The distinction is significant, since "dose" can refer to both "a quantity of medicine taken or recommended to be taken at a particular time," while "prescribed" is merely the act of a medical practitioner authorizing, usually in writing, "a patient to be provided a medicine or treatment." *New Oxford American Dictionary* pp. 518, 1381 (3rd ed. 2010). Millennium's own Rule 56(f) response recognizes this distinction itself by using the adjective "prescribed" or "actual" before dose when wanting to be more precise. To the extent that this extrinsic evidence from a dictionary adds to the reasoning of the court's earlier claim construction, it is entirely consistent with that reasoning:

> Language in the embodiment above tracks key language in claim 1 of the '680 patent as demonstrated here, only strengthening Ameritox's construction -- i.e., data that is not unknown, and certainly not limited to data that is dose specific. The view is fortified by the fact ***that when inventors knew how to specify dose*** in one of the patents' embodiments (Example 1), they did so. And by ***not doing the same in the claims, this tends to end the debate over the disputed term***. (*Compare* '680 patent at 9:65-66 (specification using the term "prescribed dosage regimen"), *with* id. at 21:16-1 (claim 1 using the phrase "prescribed medication regimen").)

(2/19/15 Op. & Order (dkt. #215) 23-24.)

Indeed, this is precisely what Millennium's product does as represented by the bell curve reflected in the RADAR Report and internal correspondence of its employees. Millennium never controverts the fact that the comparative graph in the RADAR Report is based on statistical analysis (*i.e.* frequency distribution). Indeed, in its response to Ameritox's proposed findings of facts, infringement of claim 1 is arguably best reflected in Millennium's ***own*** description:[2]

> The cited RADAR Report merely states *that* graph "present[ing] the current UDT results[] in relation to the frequency distribution of positive UDT values for all patients with a reported prescription tested by Millennium" and "[s]et against the bell curve is the patient's individual creatinine-corrected concentration for the given drug indicated by a single vertical line labeled 'Result.'"

(Def.'s Resp. to Pl.'s PFOFs (dkt. #185) ¶ 240 (quoting Mandel Decl., Ex. 29 (dkt. #129-29) pp.4, 9.) In short, the RADAR Report quantifies a patient's *likely* adherence to (*i.e.*, whether it is consistent with) a prescription medication regimen by comparing his or her test results to a set of known normative data.

Although less than clear in its Rule 56(f) response, Millennium nevertheless seems to argue that its product falls outside the claim scope because its putative normative data is based on "both adherent and non-adherent" usage and, therefore, the graphical data cannot assess appropriate or inappropriate drug usage. (Def.'s Resp. (dkt. #218) 3). In

[2] Of course, this acknowledgment was made well before the court rejected Millennium's narrow construction of the claim terms -- suggesting that all their eggs relevant to the infringement defense were placed in the legal basket (*i.e.* claim construction) -- nevertheless, the acknowledgement above only further supports that the RADAR Report falls within a broad reading of the claim terms.

making this argument, Millennium ignores its own internal emails stating unambiguously that:

(1) One of the benefits of the graphed results added to the RADAR report is that it provides "the vertical lines labeled 'Lower' and 'Upper' indicat[ing] the 95% inclusion interval. The inclusion interval represents the universe of patients tested for the named medication. Ninety-five percent of the patients in the ML database who tested positive for the named drug (with a reported prescription) fall within the lower and upper limits shown. Two and a half percent of patients fall below the lower limit and another 2.5% of patients fall above the upper limit shown . . . A result closer to the middle of the frequency distribution indicates that the patient's urinary concentration is comparable to the bulk of ML patients with a reported prescription that was tested for the named medication . . . Atypical urinary concentrations, those found at the low or high end of the range may motivate clinicians to investigate anomalies in the way a patient is taking their medications." (Mandel Decl., Ex. 29 (dkt. #129-29) p.9.);

(2) "The Comparative Results graph [in the RADAR Report] assists clinicians with determining whether the patient's result is consistent with or similar to those of other patients prescribed and taking the same medication, unrelated to dosage." (*Id.*, Ex. 33 (dkt. #129-33) p.3.).

(3) "An individual patient's test result below the 'Lower Limit' of the 95% inclusion range can show possible '[m]edication non-adherence,' including 'hoarding' or 'diversion.'" (*Id.* at p.4.).

In the end, Millennium's argument for non-infringement is nothing more than another attempt to read back into element (f) a limitation that is just not in the patent claims. Indeed, elements (b) and (f) merely refer to a "set of known normative data" from a population prescribed the subject medication, not that the data reflects a population prescribed the same dose -- and certainly not data where each person's adherence to the dose prescribed is confirmed. While these shortcomings in the data used in Millennium's RADAR Report may well make for an inferior product, they do not render the product non-infringing.

Once Millennium's "specific dosage" construction is rejected, all that remains is a plain and ordinary meaning of the claim language -- a set of known normative data that (1) is "specific to the reference metabolite" and (2) allows for "compari[son]" with a "test metabolite" drawn from a creatinine-normalized biological sample. (*Id*. at 21:28-32.) Since Millennium offers no material facts undermining the court's finding of infringement consistent with the court's expressed claim construction, after having been given an opportunity to do so pursuant to Rule 56(f), the court now finds that Millennium infringes all of the asserted claims of the '608 patent.[3]

[3] Of course, as Millennium points out, this still leaves its invalidity defenses to be decided during the liability phase of the upcoming trial. Millennium also appears to suggest that it lacked an opportunity pursuant to Fed. R. Civ. P. 56(f) to respond fully on the issues of enablement and utility before having summary judgment entered against it. On this, it is simply mistaken since the court only denied *defendant's* motion.

ORDER

IT IS ORDERED that partial summary judgment is AWARDED in plaintiff's favor with respect to its claim that Millennium infringed claims 1, 2, 4-7, 10 and 16-18 of the '680 patent.

Entered this 6th day of March, 2015.

BY THE COURT:

/s/

William M. Conley
District Judge