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

This patent dispute presents a question of first impression with respect to the subject matter eligibility of a urine or other biological sample for drug screening and compliance protocols under 35 U.S.C. § 101, as well as related issues of enablement under § 112. The analysis is made more challenging by the state of flux in the treatment of competing goals inherent in § 101 challenges in recent years, and even in recent months. *See Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012); *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014); *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245 (Fed. Cir. 2014); *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709 (Fed. Cir. 2014). Of course, this debate reflects a broader tension in patent law between what is legitimate invention in need of the incentives of patent law and what is merely description of the natural world for which no further incentive is required than our desire to understand it better -- a tension recognized virtually from the outset of the American patent system. *See Le Roy v. Tatham*, 55 U.S. 156, 159 (1852). Justice Breyer's relatively recent opinion in *Mayo* attempts to reconcile the goal of ensuring that patents do not "impede innovation more than it would

tend to promote it," and the axiomatic notion that "all inventions, at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Id.* at 1293. Thus, Justice Breyer cautions that "too broad an interpretation of the exclusionary principle could eviscerate patent law." *Id.*

Here, plaintiffs Ameritox, Ltd., and Marshfield Clinic, LLC allege that defendant Millennium Health, LLC infringes two of their patents: 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 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).) Defendant Millennium seeks summary judgment of non-infringement and invalidity as to both patents. (Dkt. #126.) The parties also ask the court to construe various terms common to both patents, including most notably "known normative data" and "quantifying the concentration." (Def.'s Opening Br. (dkt #130); Pl.'s Opp'n (dkt. #172).) For the reasons that follow, the court will deny Millennium's motion for summary judgment of non-infringement and invalidity with respect to the '680 patent and grant the motion with respect to the '895 patent, finding the patent invalid for lack of enablement under § 112. For many of the same reasons, the court finds the '895 patent is vulnerable to the application of the exclusionary principle under § 101, while the '680 patent is substantially less so.

UNDISPUTED FACTS

I. The Licensing Agreement

Plaintiff Marshfield Clinic is a health care and research organization. Marshfield is also the assignee of the patents-in-suit from the inventors, Dr. Michael Larson and Dr. Thomas Richards.

Plaintiff Ameritox Ltd. is in the field of pain medication monitoring, including a provider of urine drug testing ("UDT") services. Ameritox is the exclusive licensee of the patents-in-suit pursuant to an exclusive license agreement between Ameritox and Marshfield dated March 15, 2010. In exchange for an exclusive license, Ameritox agreed to make certain royalty payments to Marshfield and to use good faith commercial efforts to develop, market, and sell a drug testing service based on the asserted patents.

II. The Testing Protocols

Ameritox tests urine samples on behalf of doctors, nurses, and other health-care providers who prescribe pain medications to treat chronic pain. (Am. Compl. (dkt. #106) ¶ 7.) Ameritox describes its UDT service as being able to "help clinicians assess whether patients are correctly taking medications and whether the prescription should be adjusted." (Dr. Paul J. Orsulak Infringement Report ("Orsulak Infringement Rept.") (dkt. #117) ¶ 27.) Healthcare professionals periodically use Ameritox's services to monitor drug levels in their patients in order to help assess their patients' therapeutic response to medications and adherence to the treatment plan, as well as to detect

aberrant behaviors (*e.g.*, illegal drug use) that may complicate treatment. ('680 patent at 2:17-20.)[1]

On May 16, 2011, Ameritox launched its current Rx Guardian CD service, which Ameritox asserts is based on the patents-in-suit.[2] The testing protocol for Rx Guardian CD has three phases. (Dr. Paul J. Orsulak Rebuttal Report ("Orsulak Rebuttal Rept.") (dkt. #118) ¶¶ 246-56.) First, Ameritox performs a series of laboratory tests to detect and measure the amount of drug and drug metabolites in a patient's urine sample (the "detection" steps, which are reflected in steps (a)-(d) of the '680 patent). Second, Ameritox "normalizes" or "adjusts" urine drug levels for a patient's hydration status by determining the metabolite/creatinine ratio of the patient (the "normalization" step, as reflected in step (e) of the '680 patent).[3] Third, the Rx Guardian CD protocol compares a patient's normalized test results to a range of "normative data" collected from other clinical patients on the same medication, who Marshfield carefully monitored to insure

[1] When citing to the patent, the number before the colon refers to the column number, and the number or numbers after the colon refer to the line number or line range.

[2] The court outlines Ameritox's patented services here purely for illustrative purposes. Ameritox's services have no bearing on claims construction or the court's infringement analysis. *See Zenith Labs. v. Bristol–Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994) ("As we have repeatedly said, it is error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process; the only proper comparison is with the claims of the patent.").

[3] Creatinine is a by-product of muscle metabolism excreted in urine in relatively constant amounts throughout the day. ('680 patent at 1:63-2:1.) The patents-in-suit teach calculating a "drug metabolite/creatinine ratio" to adjust for patient hydration; in other words, measuring the value of the drug metabolite and the creatinine in the urine sample and then dividing the former by the latter to obtain a normalized value. (*Id.* at 5:34-39.) According to Ameritox, urine creatinine had never been used successfully to develop a urine drug screen that allowed for comparison and identification of proper and improper use of prescribed medications. (*See id.* at 2:55-3:3.)

adherence to their prescribed opioid regimen (the "determining" step, as reflected in step (f) of the '680 patent).

By comparing the patient's normalized value to a range of values for other clinical patients believed to be prescribed and taking the same medication properly, the health care provider can better assess whether a patient is likely to be taking the prescribed drug in a manner consistent with the prescribed regimen. The three steps outlined above largely truncate the steps outlined in claim 1 of the '680 patent, which states:

> 1. A method for quantifying at least one metabolite in a biological sample comprising the steps of:
>
> (a) providing one biological sample obtained from a patient on a prescribed medication regimen, wherein the sample comprises at least one test metabolite, *wherein in the sample is urine*;
>
> (b) providing one set of known normative data specific to a reference metabolite, wherein the set of data is collected from a population that is on a prescribed medication regimen;
>
> (c) contacting the biological sample with an analytical device;
>
> (d) detecting the presence of at least one test metabolite in the biological sample with the device, wherein the device is capable of measuring the concentration of the test metabolite in the sample;
>
> (e) normalizing the biological sample to adjust for changes in the patient's hydration status by determining the metabolite/creatinine ratio of the patient; and
>
> (f) quantifying the concentration of at least one test metabolite in the biological sample by comparing a ratio between the concentration of the test metabolite from the patient to the set of known normative data specific to the reference metabolite concentration.

('680 patent at 21:9-32.)

III. The Specification, Prosecution History and Reexamination Certificates

The patents-in-suit have a priority date of August 28, 2003, and cover a method to monitor medication usage and to detect aberrant drug usage patterns, including over-use and under-use of prescribed medications. ('680 patent at ABSTRACT.) The patents share the same specification, which states that adherence to a prescribed medication regimen is important to the success of most treatments, "particularly in patients in drug abuse or chronic pain programs." (*Id.* at 1:21-24.) The specification further describes a number of sources used by health care professionals to monitor medication usage, including interviews with patients, medical records, pill counts, prescription monitoring programs, and testing of biological samples, such as urine. (*Id.* at 1:42-48, 15:11-15.) The specification also states that urine drug screens available in 2003 were limited to reporting a positive or negative result because of "the large amount of variability in urine drug concentrations, mostly due to variations in hydration and urinary output volume." (*Id.* at 1:50-53.)

Both patents highlight problems with purely "up or down" test results. In particular, so long as patients took some amount of medication, their test results were positive and patients who overused or underused their medications continued to receive the same prescription:

> To date, a test *is purely negative or positive as to the presence or absence of a drug metabolite in the urine*. Accordingly, it would be useful to develop a method to assess with confidence patient adherence to prescribed drug treatment regimens.

(*Id.* at 2:61-3:3 (emphasis added).) In light of the problems in the prior art, the specification goes on to state that:

> [t]he method of the present invention enables improved clinical accuracy of protocols used in testing biological samples, such as, urine testing [and] the present invention can *substantially improve the ability of a clinician to monitor and confirm whether a patient has been using the medication in a manner which is consistent with the prescription*.

(*Id.* at 3:17-19, 4:50-54) (emphasis added).) The specification thus describes a method to "improve" or "enhance" medication monitoring and seeks to identify aberrant drug use. (*Id.* at 3:17-19.)

The description of the invention is also reflected in the prosecution history, including the inventors' statement that:

> Applicants developed a normative database for the drug metabolite hydration corrected ratio that allows statistical analysis of drug metabolite level in urine to determine if the medication is utilized in a manner consistent with the prescription or what the potential dose may have been.

(Declaration of Rebecca C. Mandel ("Mandel Decl."), Ex. 24 (dkt. #129-24) pp.14-15); *see also id.*, Ex. 17 (dkt. #129-17) p.9.) By contrasting the invention with prior art references, the invention is better elucidated. For example, the inventors submitted to the Patent Office that the "Kell [reference] focuses on adulteration of the urine sample, whereas applicants' method [a] focuses on identification of the urine, [b] correction of hydration in order to reduce variability and then [c] comparison of that corrected drug metabolite to a normative database to identify appropriate or inappropriate" drug use. (*Id.*, Ex. 24 (dkt. #129-24) p.15.) The inventors further represents that "none of the patent publications from the Kell portfolio anticipate or render the claims obvious." (*Id.*)

The Patent Office agreed with the inventors' submission leading to issuance of both patents. The patents also survived two more recent reexaminations, with the Patent Office issuing: the first reexamination certificates for the patents-in-suit in May and June

2013, leaving each of the challenged claims intact and issuing additional claims, and a second set of reexamination certificates on May and July 2014 -- again leaving each of the challenged claims intact. (*See id.*, Ex. 1 (dkt. #129-1) pp.27-30; *id.*, Ex. 2 (dkt. #129-2) pp.26-29.)

IV. Prior Art[4]

There are several references cited in the prosecution history (and by the parties themselves) that constitute prior art so well known by the "scientific community" at the time of the invention that it assists in determining whether the combination of elements in '680 patent constitute inventive concept. *See Mayo*, 132 S. Ct. at 1298 (patent is invalid if any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community). In reviewing these references, the court is mindful that when prior art is put into evidence -- either existing as part of the prosecution history or cited in expert reports -- the reference must be considered in its entirety, *i.e.*, as a whole, including portions that would teach or steer away from the claimed invention. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983).

One of the most relevant prior art references in this case is the George Article. S. George & R.A. Braithwaite, *A Pilot Study to Determine the Usefulness of the Urinary Excretion*

[4] Relevant prior art references are outlined at this juncture not only to provide the lens through which a person skilled in the art would construe the claims, but because Millennium makes the representation at the beginning of its brief that "[t]he patents-in-suit attempt to employ [a] prior art creatinine-normalization method to detect whether a patient is abusing or diverting his/her drug by predicting the dosage of medication taken by the patient." (Def.'s Opening Br. (dkt. #130) 21.) This argument is central to Millennium's theory that the claims are invalid under 35 U.S.C. § 101.

of Methadone and its Primary Metabolite (EDDP) as Potential Markers of Compliance in Methadone Detoxification Programs, J. ANALYTICAL TOXICOL., Mar./Apr. 1999, at 81-85. (*See* Mandel Decl., Ex. 43 (dkt. #129-43).) The authors of the George Article investigate urinary excretion to determine whether "methadone or EDDP could be a simple and noninvasive marker of methadone compliance." (*Id.* at 83.) Testing was specifically performed "to try to resolve the issue of whether urinary excretion *could be* used *in place of plasma concentration* as a mechanism to monitor compliance during methadone replacement therapy for opiate addiction." (*Id.* (emphasis added).)

The George Article was cited before the Patent Office, and it is also cited at length in Dr. Wu's expert report, opining that the patents were invalid on §§ 101, 102 and 103 grounds.[5] Millennium further cites the George Article in support of the factual proposition that "normalizing urinary samples via metabolite/creatinine ratios [was] a routine and conventional practice" at the time of the invention. (Def.'s PFOFs (dkt. #127) ¶ 259.) The crux of the article, however, is best summarized by Ameritox's expert Dr. Orsulak who explains:

> One aim of the George article was to determine if quantitative urinary excretion data of methadone and EDDP may be used to distinguish between compliant and noncompliant subjects undergoing methadone detoxification. (George article at 83.) The George article discloses two datasets from different patient populations. One patient population consisted of 14 control subjects. A second patient population consisted of 56 drug abusers, including those suspected of missing dosages or topping up from other sources of methadone. (George article at 83.) The George article concludes, "there is too large of an interindividual variation to use

[5] While Millennium does not move for summary judgment on novelty and obviousness grounds, as evidenced by the George Article, "in evaluating the significance of additional steps, the § 101 patent-eligibility inquiry and the § 102 novelty inquiry might sometimes overlap." *Mayo*, 132 S. Ct. at 1304.

> urinary excretion concentrations of methadone or EDDP as markers of compliance." (George article at 83.)

(Orsulak Rebuttal Rept. (dkt. #118) ¶ 59.)

As Dr. Orsulak points out, the George Article "never compares the results from any of the 56 drug abusers to the 14 control subjects. Rather, to the extent any comparison is made, the George article only discloses comparing a patient's test result to earlier results from that *same* patient." (*Id.* at ¶ 86 (emphasis added).) "In other words, the George article discloses a straight historical results analysis, without any 95% inclusion range being involved, nor is any comparison to a known normative database disclosed." (*Id.*) Thus, the "only comparison disclosed in the George article is a single patient's test result to his/her own earlier test results." (*Id.*) These facts were not squarely controverted in Dr. Wu's opinion, nor is there anything else in the record that puts them into dispute.

The George Article offers further insights into what was well known at the time of the claimed invention:

- "there is too large of an interindividual variation to use urinary excretion concentrations of methadone or EDDP as markers of compliance";
- urinary excretion testing "would point to a lack of suitability of using urine concentrations of EDDP or methadone as markers of compliance"; and
- "the only reliable method available to monitor methadone compliance is the use of plasma methadone drug testing."

(Mandel Decl., Ex. 43 (dkt # 129-43) 84-85.) In each respect, the George Article supports a conclusion that at the time of the invention, blood testing was the only

reliable method to determine whether a patient was complying with a prescribed drug regimen.

Another article that reflects the state of the art is the Haddow Article. Haddow, J., et al., *Replacing Creatinine Measurements with Specific Gravity Values to Adjust Urine Cotinine Concentrations*, CLINICAL CHEM. 562 (1994). (*See* Expert Report of Roger L. Bertholf, Ph.D. ("Bertholf Rept."), Ex. H (dkt. #209-8).) The Haddow Article evaluates the use of creatinine and specific gravity values in a study of environmental tobacco smoke exposure in non-smoking children with asthma. (*Id*. at 562.) Haddow uses a regression analysis of the logarithm of urinary cotinine and creatinine in a population of 116 children who were not exposed to environmental tobacco smoke. (*Id.*)

"[A]lthough measuring creatinine measurements to reflect hydration" was known, Haddow teaches that it adds "complexity and cost when such measurements are applied in routine and clinical practice." (*Id.*) This is why "specific gravity (relative density) measurements in urine samples from children with asthma" were used to "provide information equivalent to that from creatinine measurements." (*Id.*) Moreover, Haddow does not involve drug treatment or compliance with a prescribed drug regimen and no known normative database is developed. (*Id.* at 562-64.)

V. The Skilled Addressee[6]

For the purposes of identifying a person of ordinary skill in the art, the court agrees with Dr. Orsulak that the "relevant art of the subject matter claimed by the

[6] For the purposes of this opinion the terms "skilled addressee" or "skilled artesian" mean persons having ordinary skill in the art (often abbreviated POSITA or PHOSITA).

patents-in-suit is medication or therapeutic drug monitoring." (Orsulak Rebuttal Rept. (dkt. #118) ¶ 3.) Orsulak further opines that such a person would have a degree in a field "such as medicine, biochemistry, biology, clinical health psychology, clinical laboratory sciences, clinical toxicology, or pharmacology and several years of work experience related to medication or therapeutic drug monitoring, including drugs-of-abuse testing or substance abuse testing." (*Id.*) This characterization of the skilled addressee seems sensible; nothing in Millennium's materials alters this viewpoint; and the characterization is consistent with the field of the art applicable to the invention.[7]

VI. The Claims of the '680 and the '895 patent

The disputed claims in suit -- specifically claims 1, 2, 4-7, 10 and 16-18 of the '680 patent and claims 1, 4-5, 10-12 and 14 of the '895 patent -- generally disclose a series of six steps that culminate in a final comparison step between the drug collected from a patient's urine sample to "known normative data" collected from a patient population. Neither party disagrees with this characterization. As such, the asserted independent claims of the '680 patent (claims 1 and 4) and the '895 patent are represented below.

Claim 1 of the '680 patent states:

> 1. A method for quantifying at least one metabolite in a biological sample comprising the steps of:

[7] Millennium acknowledges in its briefing that the parties dispute the level of ordinary skill required in the art. Millennium further argues, however, that its assertions throughout its brief apply equally to both parties' proposed characterizations of the level of ordinary skill in the art. This strongly suggests, whether or not Millennium would still technically dispute it, that there is no *material* difference between the parties' characterizations of the level of knowledge of the skilled addressee.

(a) providing one biological sample obtained from a patient on a prescribed medication regimen, wherein the sample comprises at least one test metabolite, wherein in the sample is urine;

(b) providing one set of **known normative data** specific to a reference metabolite, wherein the set of data is collected from a population that is on a prescribed medication regimen;

(c) contacting the biological sample with an analytical device;

(d) detecting the presence of at least one test metabolite in the biological sample with the device, wherein the device is capable of measuring the concentration of the test metabolite in the sample;

(e) normalizing the biological sample to adjust for changes in the patient's hydration status by determining the metabolite/creatinine ratio of the patient; and

(f) **quantifying the concentration of at least one test metabolite in the biological sample by comparing a ratio between the concentration of the test metabolite from the patient to the set of known normative data specific to the reference metabolite concentration.**

('680 patent at 21:9-32 (terms in dispute have been bolded).)

Claim 1 of the '895 patent states:

A method for quantifying at least one metabolite in at least one biological sample comprising the steps of:

(a) providing at least one biological sample obtained from a patient on a prescribed medication regimen, wherein the biological sample comprises at least one test metabolite;

(b) providing one set of known normative data specific to a reference metabolite, wherein the set of data is collected from a population that is on a prescribed medication regimen;

(c) contacting the biological sample with an analytical device;

(d) detecting the presence of at least one test metabolite in the biological sample with the device, wherein the device is capable of measuring the concentration of the test metabolite in the at least one biological sample;

(e) normalizing the biological sample to adjust for changes in the patient's

> hydration status by determining the metabolite/creatinine ratio of the patient; and
>
> (f) quantifying the concentration of at least one test metabolite in the biological sample by comparing a ratio between the concentration of the test metabolite from the patient to the set of known normative data specific to the reference metabolite concentration.

('895 patent at 20:56-21:12.)

With regard to the disputed terms, the parties' preferred constructions are summarized in the following table:

Disputed Terms	**Plaintiff Ameritox's Preferred Construction**	**Defendant Millennium's Preferred Construction**
"known normative data" (all asserted claims)	Plain and Ordinary Meaning	Known dose-specific data that is related to the population it is intended to predict
"quantifying the concentration of at least one test metabolite in the biological sample by comparing a ratio between the concentration of the test metabolite from the patient to the set of known normative data specific to the reference metabolite concentration" (all asserted claims)	Plain and Ordinary Meaning	To the extent that this term can be construed, it means: predicting the dosage taken by a patient from at least one test metabolite in the biological sample by comparing the ratio based on the concentration of the test metabolite from the patient to the set of known normative data specific to the reference metabolite concentration

Millennium contends that the purpose of the patents is to quantify a specific dose. It argues that this purpose provides the proper context and is dispositive of what is meant by "known normative data." Similarly, with respect to the second disputed phrase -- "quantifying the concentration" -- Millennium argues in favor of a definition that

specifically predicts the dosage of the test metabolite. Ameritox contends that neither of these disputed terms should be so confined. More specifically, Ameritox argues that Millennium's construction seeks to import limitations from the specification to deviate from the plain and ordinary meaning of the claim terms.

OPINION

Analysis of patent infringement is a two-step process: "first, the scope of the claims are determined as a matter of law, and second, the properly construed claims are compared to the allegedly infringing device to determine, as a matter of fact, whether all of the limitations of at least one claim are present, either literally or by a substantial equivalent, in the accused device." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002); *Split Pivot, Inc. v. Trek Bicycle Corp*., 12-CV-639-WMC, 2013 WL 6564640, at *2-3 (W.D. Wis. Dec. 13, 2013).

I. Claim Construction

Claim terms "are examined through the viewing glass of a person skilled in the art." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). This provides an "objective baseline" from which to begin the claim analysis. *Innova, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). The inquiry is assessed at the time of the invention, where the words of a claim "are generally given their ordinary and customary meaning." *Phillips*, 415 F.3d at 1313.

Because an "ordinary and customary" meaning may not be readily apparent, and because "patentees frequently use terms idiosyncratically," courts look to the patent

specification, the prosecution history, and pertinent extrinsic evidence to construe disputed claim terms. *Id.* at 1314. The specification is typically considered the "best source for discerning the proper context of the claims." *Phillips*, 415 F.3d at 1315; *United States v. Adams*, 383 U.S. 39, 49 (1966) (describing as "fundamental that claims are to be construed in the light of the specification"). But when using the specification for the purposes of context, the skilled addressee must not improperly import a limitation from the specification into the claims themselves. *See Innova*, 381 F.3d at 1117 (district court improperly read limitations from the specification into the claims); *White v. Dunbar*, 119 U.S. 47, 51, (1886).[8]

Claim construction, therefore, requires a scalpel, not a sledgehammer because there is a thin line between *interpreting* the claims in view of the specification and improperly *reading* limitations from the specification into the claims. *See Innova*, 381 F.3d at 1117 (considering the contrasting nature of these axioms to be a "longstanding difficulty"); *see also Componex Corp. v. Electronics for Imaging, Inc.*, No. 13-CV-384-WMC, 2014 WL 3556064, at *7 (W.D. Wis. July 18, 2014).

A. "Known Normative Data"

The term "known normative" data is referenced in element (b) and element (f) of claim 1. (*See, e.g.*, '680 patent at 21:28-32.) The claim language expressly states that known normative data is "collected from a population that is on a prescribed medication

[8] Given the minor differences among the asserted claims, the court's construction for "known normative data" and "quantifying the concentration" applies equally to all of the asserted claims. This approach, noted in the parties' briefs, also seems sensible given that both patents share the same specification which informs claim meaning.

regimen." (*Id.* at 21:16-17.) In the abstract, known normative data is collected from a population and used as the invention's baseline so it may be compared to a patient's normalized urine sample to determine whether there is compliance with a prescribed medication regimen.

Millennium contends that the term known normative data is known "dose-specific data that is related to the population it is intended to predict." (Def.'s Opening Br. (dkt. #130) 20.) Millennium contends that its proposed construction is the only one that reflects the express function of the invention. That function, Millennium contends, is to determine the exact dosage taken by a patient (and thereby determining whether a patient is complying with the prescribed dosage). Much of Millennium's construction is based on passages and examples in the specification, with particular emphasis placed on the following passages:

- "This example describes how a drug metabolite/urine creatinine ratio . . . could be used to improve the ability of clinicians to predict appropriate use of prescribed medication, as well as detect and quantify inappropriate use." ('680 patent at 6: 58-62.)
- "The goal of the model was to be able to predict whether a patient had adhered to a prescribed dosage regimen." ('680 patent at 9:65-66.)

Arguing that these passages reflect the purpose of the patents -- "to predict the dosage taken by a patient" -- Millennium contends that the claim language should be construed in accordance with that purpose. (Def.'s Opening Br. (dkt. #130) 24.) In addition, Millennium points to Example 1 for support. That example "describes how a

drug metabolite/urine creatinine ratio in patients . . . could be used to improve the ability of clinicians to predict appropriate use of prescribed medication, as well as detect and quantify inappropriate use." ('680 patent at 6:58:62.) Specifically, Example 1 describes the collection of UDT data from a population of seven patients on "a specified methadone dosing regimen." (*Id.* at 7:7-8.) Such data is reflected in Table III in each of the patents. Example 1 thus teaches a "regression model for the prediction of methadone intake," namely statistical analysis of "known normative data" to predict the dosage of methadone taken by a patient. (*Id.* at 9:31-33.) From this, Millennium concludes that because the example is the "only detailed disclosure of the claimed invention in the patents-in-suit," it is instructive and should dictate claim meaning. (Def.'s Opening Br. (dkt. #130) 30.) The court, however, rejects Millennium's construction for several reasons.

To succeed, Millennium ignores a "'bedrock principle' of patent law that 'the claims of a patent define the invention.'" *Phillips*, 415 F.3d at 1312; *see also Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). Millennium also faces an uphill battle in negating the general rule that claims are given their customary and ordinary meaning. *See Teleflex, Inc. v.*, 299 F.3d at 1325 ("We indulge a 'heavy presumption' that a claim term carries its ordinary and customary meaning."). Specifically, courts should "only interpret a claim term more narrowly than its ordinary meaning under two circumstances: (1) when a patentee sets out a definition and acts as [its] own lexicographer, or (2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution history." *Aventis Pharma SA v. Hospira,*

Inc., 675 F.3d 1324, 1330 (Fed. Cir. 2012) (internal quotation omitted). "The standards for finding lexicography and disavowal are *exacting*." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014) (emphasis added). Neither of these circumstances applies here; nor is there any other canon of construction that allows Millennium to prevail.

First, Millennium points to no definitive definition of "known normative data" in the specification that supports its construction. When the skilled addressee turns to the specification the only definition that even comes close to the disputed phrase is the phrase: "normative database." ('680 patent at 5:60-65.) Notwithstanding the fact that "normative database" is worded differently to "known normative data" (the disputed term), Millennium's reliance on the former falls flat because the definition of "normative database" simply states "a collected set of data that is related to a specific population it is intended to predict." (*Id.* at 5:58-60.) Contrary to Millennium's position, there is no mention of dose specific data or dose specific regimen. Because none of the definitions in the specification supply claim meaning, Millennium's proposed construction must be rejected. *See Hospira, Inc.*, 675 F.3d at 1330; *Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1301 (Fed. Cir. 2013) ("Taken in context, this evidence does not support the trial court's interpretation, and certainly is not clear lexicography or disavowal.").

Second, there is no claim disavowal in the prosecution history. The best that Millennium can muster is the following passage:

> Applicants developed a normative database for the drug metabolite hydration corrected ratio . . . to determine if the medication is utilized in a manner consistent with prescription or what the [patient's] potential dose *may* have been.

(Def.'s Opening Br. (dkt. #130) 29 (emphasis altered).) Millennium's reliance on this passage is deficient for much the same reason as the first: the term normative database is used instead of the *actual* disputed term that is subject to the litigation (*i.e.*, known normative data). But even if the proper disputed phrase had been referenced above, the passage still supplies little to support Millennium's position. Indeed, the passage creates more questions than answers due to the permissive language used. Said another way, the word "may" preceded by the phrase "manner consistent with the prescription" is hardly verbiage that disavows the full scope of a claim term. Neither phrase is "exacting." *Stryker Corp.*, 755 F.3d at 1371. While Millennium argues that a person skilled in the art would equate the phrase "manner consistent with prescription" as meaning dose specific data, the court is not so convinced. *Id.* at 1372 ("Disavowal requires that the specification or prosecution history make clear that the invention does not include a particular feature.").

Third, Millennium provides no meaningful discussion for how references in the specification and the prosecution history narrowed claims scope to circumvent prior art. More specifically, nothing in the specification indicates that "dose specific data" is an essential feature of the claimed invention over the prior art. *See Liebel–Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906-09 (Fed. Cir. 2004) (distinguishing cases where the court narrowly construed an otherwise broad claim term).

To be fair, Millennium does argue that:

> [d]uring prosecution of the '680 patent, the patentees specifically used the known dose-specific element of "known normative data" to distinguish the claimed invention from the prior art. Specifically, the patentees asserted that "[a]pplicants are able to not only accurately analyze the level of drug

> metabolite, within a specific patient, but more importantly, across individuals on the same drug and drug dose."

(Def.'s Opening Br. (dkt. #130) 29 (emphasis omitted).) But, in the next sentence, and without supplying any further analysis, Millennium concludes that its construction "makes sense." (*Id*.) The problem with Millennium's argument is simple: it lacks depth. While an argument based on prosecution estoppel would tend to have traction in most cases, Millennium's argument here is only limited to the above mentioned passage -- perhaps because it had little to work with in the first place. This limited analysis contrasts starkly with a recent case in this court, finding that a *functional* definition was deliberately used by the patentees to avoid prior art. *See Componex Corp.*, 2014 WL 3556064, at *7 (holding that during the litigation, the definition could not be abandoned in order to expand the scope of its "patent beyond what was previously claimed").

Here, no effort is made by Millennium to show that the inventors deliberately abandoned claim scope to traverse prior art, let alone refer to the specific prior art references that inventors were seeking to distinguish in the prosecution history to provide a basis for estoppel. Without such analysis, Millennium's construction is far less persuasive. It is rejected accordingly. *Cf. Spectrum Int'l, Inc. v. Sterilite Corp*., 164 F.3d 1372, 1379-80 (Fed. Cir. 1998) ("By distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover.").

Fourth, Millennium's argument fares no better when it points to examples in the specification to construe the claims. Specifically, Millennium argues that known normative data must mean "dose specific" data because Example 1 expressly supplies such meaning when read in the context of both patents. To succeed in this argument,

Millennium must again overcome the presumption that favors plain and ordinary meanings of claim terms. In *Teleflex*, the Federal Circuit held that the district court erred when it imported a limitation from the specification, thereby straying from the ordinary meaning of the claim term "clip" by requiring a "clip" to have a "single pair of legs," even though the *only* embodiment in the specification disclosed a clip having a single pair of legs. 299 F.3d at 1327-28 (emphasis added). Thus, in *Teleflex*, the only embodiment in the specification supported the alleged infringer's position -- and the Federal Circuit still reversed.

Unlike *Teleflex*, *multiple* embodiments are provided in the '680 and '895 patents. Although Example 1 does provide a dose specific embodiment, other embodiments are not so confined. Ameritox directed the court to the following passage from the specification that is illustrative:

> The method [of the invention] is carried out by contacting the biological sample with a device capable of distinguishing between the test metabolite and a reference metabolite; detecting the presence of at least one test metabolite in a biological sample; and quantifying the concentration of at least one test metabolite in a biological sample by comparing a ratio between a ***set of unknown data*** from the test metabolite versus a set of ***known normative data*** specific to the ***reference metabolite***. The method of the present invention enables improved clinical accuracy of protocols used in testing biological samples, such as urine testing.

('680 patent at 3:6-18 (emphasis added).)

Even if *all* the embodiments described known normative data as including dose-specific data (and they do not), Millennium's construction would still stray impermissibly from the plain and ordinary meaning of the claim term. *Teleflex* states as much. 299 F.3d at 1325; *see also Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1301 (Fed. Cir.

2013) ("[E]ven if a specification has only one embodiment, its claims will not be confined to that example 'unless the patentee has demonstrated a clear intention to limit the claim scope using words or expression of manifest exclusion or restriction."' (quoting *Liebel-Flarsheim*, 358 F.3d at 906)); *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1334 (Fed. Cir. 2007) ("[A] fundamental principle of patent claims construction is that the court should not read limitations from the specification into the claim language; the specification can only be used to limit a claim if there has been 'a clear disclosure that the patentee intended the claims to be limited.'" (internal citation omitted)).

As the passage explains, the use of the phrase known normative data is deliberately juxtaposed with unknown data from the test metabolite. The juxtaposition is used to demonstrate that while the invention does require known normative data to provide a baseline from which to improve clinical urine testing, that data need not be a specific dosage. Indeed, had the patentee sought to limit the claim language in this way, it would have elected to do so. The lack of a limitation in the claims reinforces the case against a restrictive reading of the disputed term. *See ACTV Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003) ("[T]he analytical focus of claim construction must begin, and remain centered, on the language of the claims themselves.").

More specifically, element (b) of claim one expressly states: "providing one set of *known normative data* specific to a *reference metabolite*, wherein the set of data is collected from a population that is on a prescribed medication regimen." ('680 patent at 21:16-17 (emphasis added).) 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").)

Accordingly, because of the claim language conforms with embodiments cited in the specification and because there is no clear scope disavowal, the court rejects Millennium's proposed construction.

B. "Quantifying" (step (f))

Millennium argues that interpretation of step (f) is guided by the "intended purpose of the patents," which is "to predict or determine drug dosage taken by a patient." (Def.'s Opening Br. (dkt. #130) 44.) It follows, Millennium contends, "that any construction of the claim -- specifically step (f)'s comparison between the patient's ratio to the known normative data from a population -- must reflect the stated goal." (*Id.* at 45.) The court disagrees.

As an initial matter, the purpose of the patents is far broader than what Millennium maintains. Millennium's entire construction is predicated on the flawed assumption that that the patents' sole objective is to identify the specific dose of a patient.[9] This purpose is too narrowly drawn because the patents' specification and

[9] In the context of construing element (f), the focus is on the theory that the element is seeking to quantify a specific dose of the patient; whereas, the focus of the term in element (b), "known

prosecution history directs one skilled in the art to an invention that allows "analysis of drug metabolite level in urine to determine if the medication is utilized in a manner consistent with the prescription or what the potential dose may have been" -- a broader goal. (Mandel Decl., Ex. 24 (dkt. #129-24) pp.14-15; *see also id.*, Ex. 17 (dkt. #129-17) p.9.) Instead of being dose specific, the method of the "invention enables improved clinical accuracy of protocols used in testing biological samples, such as, urine testing." ('680 patent at 3:17-19.) This, as the inventors say, "can substantially improve the ability of a clinician to monitor and confirm whether a patient has been using the medication in a manner which is consistent with the prescription." (*Id.* at 4:50-54.)

When compared with pre-existing testing protocols, the state of the art sought to determine "a positive or negative result as to the presence or absence" of a drug. (*Id.* at 2:66-67.) In contrast, the '680 patent provides a method to "improve" and "enhance" medication monitoring and identify aberrant drug use. (*Id.* at 3:17-19.) While Millennium is correct in saying that courts look to the object or purpose of the invention, such analysis must be examined in the totality so to guard against the claims being pulled in different ways by the different embodiments in the specification. *See White*, 119 U.S. at 51-52 (patents are not "nose[s] of wax which may be turned and twisted in any direction by merely referring to the specification").

Millennium further contends that each of the examples indicate specific embodiments of the invention that seek to predict dosage based on the comparison applied in step (f). For reasons similar to that stated above, this argument must also be

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normative data," was that such data was based on a subject of specific known population where each subject's prescribed regimen was specifically known.

rejected. Two aspects of the claimed invention include: (1) "determine if the medication is utilized in a manner consistent with the prescription" and (2) "determine … what the [patient's] potential dose may have been." (Mandel Decl., Ex. 24 (dkt. #129-24) pp.14-15; *see also* '680 patent at 3:20-27.) The first aspect can be accomplished with or without definitive prediction of dosage. While the second aspect uses dose-specific data, the patent stops short of claiming that the invention definitively predict ingested dose, simply stating that the invention may be used to approximate what the "potential" dose "may have been." The multiple aspects of the patent demonstrate that the asserted claims do not require dose-specific data. As such, the asserted patents are prime examples for why the Federal Circuit "repeatedly warn[s] against confining the claims to [the] embodiments" of the specification. *Phillips*, 415 F.3d at 1323; *see also Teleflex*, 299 F.3d at 1325.

Claim language that is narrow would only limit the patents to determining potential or approximate doses, not whether medication is being used in a manner consistent with the prescription. The claim encompasses both these embodiments. A broader purpose afforded to the patented invention reflected in the actual claim language ensures a plurality of embodiments that fall within the claims. This broad reading of the claims is further fortified by the fact that the word "dose" and "dose-prediction" appear nowhere in the asserted claims. Like the previous disputed term, the lack of a limitation in the claims reinforces the case against a restrictive reading of the disputed term here. *See ACTV*, 346 F.3d at 1088 ("[T]he analytical focus of claim construction must begin, and remain centered, on the language of the claims themselves.").

Accordingly, Millennium's request that the court read a definitive dose-prediction limitation into the asserted claims finds no support in the actual claim language. Because of this, the court will decline Millennium's invitation to insert a limitation when canons of construction suggest otherwise. *See Phillips*, 415 F.3d at 1323; *MBO Labs., Inc.*, 474 F.3d at 1334.

II. Motion for Summary Judgment on Invalidity and Infringement

Summary judgment is warranted under Federal Rule of Civil Procedure 56 "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the burden of showing that the facts material to the motion are not in dispute. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The nonmoving party may not avoid summary judgment merely by showing that some facts are in dispute; rather, it must establish that there are factual issues that might affect the outcome of the suit under governing law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). Although the court must "take all facts and reasonable inferences in the light most favorable to" the nonmoving party, *Helman v. Duhaime*, 742 F.3d 760, 761 (7th Cir. 2014), the nonmoving party must still come forth with enough evidence to support a reasonable jury verdict in its favor, *Delta Consulting Grp., Inc. v. R. Randle Constr., Inc.*, 554 F.3d 1133, 1137 (7th Cir. 2009). Summary judgment is "not a dress rehearsal or practice run," but the "put up or shut up moment" in which a party must show what evidence it has to convince a trier of fact to accept its version of events. *Nichols v. Nat'l Union Fire Ins. Co. of Pittsburgh, PA*, 509 F. Supp. 2d 752, 760 (W.D. Wis. 2007) (quoting *Schacht v. Wis.*

Dep't of Corr., 175 F.3d 497, 504 (7th Cir. 1999)).

Because a patent is presumed valid, Millennium must prove invalidity by clear and convincing evidence. *See Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011). Thus, for Millennium to succeed in the instant motion for summary judgment, it must present clear and convincing evidence from which a reasonable jury could find that the patent is invalid. *See Nystrom v. TREX Co.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005); *see also CertusView Techs., LLC v. S & N Locating Servs., LLC*, No. 2:13cv346, 2015 WL 269427, at *14 (E.D. Va. Jan. 21, 2015).[10]

A. Section 101

Section 101 of the Patent Act defines patentable subject matter: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. The section defines four categories of patentable inventions: processes, machines, manufactures, and compositions of matter. Despite these broad categories, § 101 does *not* encompass all products of human effort and discovery. For example, "laws of nature, physical phenomena, and abstract ideas" constitute ineligible subject matter and are not patentable. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). All of these exceptions

[10] Other courts, along with some judges on the Federal Circuit, have suggested that it is inappropriate to require a party challenging validity on § 101 grounds to prove invalidity by clear and convincing evidence. *E.g., Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 720 (Fed. Cir. 2014) (Mayer, J., concurring) ("Although the Supreme Court has taken up several section 101 cases in recent years, it has never mentioned -- much less applied -- any presumption of eligibility. The reasonable inference, therefore, is that while a presumption of validity attaches in many contexts . . . no equivalent presumption of eligibility applies in the section 101 calculus."). Although certainly a closer question, the conclusions reached here would not change under either standard.

are well established. *See, e.g., Diamond v. Diehr*, 450 U.S. 175, 185 (1981); *Parker v. Flook*, 437 U.S. 584, 599 (1978) (Stewart, J., dissenting); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948); *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939); *Le Roy v. Tatham*, 55 U.S. 156 (1853).

1. Recent Legal Developments

The validity of many business and software patents has been called into question following the Supreme Court's decision in *Alice Corporation v. CLS Bank International*, 134 S. Ct. 2347 (2014).[11] Patents in the biotechnology and diagnostic fields have also come under scrutiny since the *Alice* decision was handed down in June of 2014, with some having already been found invalid. *See, e.g., In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014). As a result, courts and commentators are understandably seeking more concrete contours in the application of § 101, which instead of acting like the coarse "filter" it once was, now arguably imposes a "higher bar," invalidating numerous patents in district courts and *inter partes* proceedings before the Patent Office. *Cal. Inst. of Tech.*, 2014 WL 5661290, at *2; *see also Ultramercial*, 772 F.3d at 720. Accordingly, this court will follow the Supreme Court's

[11] A recent decision by Judge Mariana R. Pfaelzer surveys the many patents that have been invalidated since June 2014. *See Cal. Inst. of Tech. v. Hughes Commc'n*, No. 2:13-cv-07245-MRP-HEM, 2014 WL 5661290, at *8-11 (C.D. Cal. Nov. 3, 2014); *see also* Robert R. Sachs, *A Survey of Patent Invalidation Since Alice*, LAW360, Jan. 13, 2015, http://www.law360.com/articles/604235/a-survey-of-patent-invalidations-since-alice (noting that only 26% of all patents considered in district courts since the *Alice* decision have survived).

admonition in *Alice* to "tread[] carefully" in applying this reinvigorated exclusionary principle to the patents at issue here. 134 S. Ct. at 2354.

In *Alice*, the Supreme Court articulated a "framework" for determining whether 35 U.S.C. § 101 is met. 134 S. Ct. at 2355 (*citing Mayo*, 132 S. Ct. at 1296-97). First, a court determines "whether the claims at issue are directed to one of those patent-ineligible concepts" -- *i.e.*, whether the claims are directed to laws of nature, natural phenomena, and abstract ideas. *Id.* Second, if the claims are directed to patent-ineligible concepts, the process sought to be patented must include an additional element or a combination of additional elements that constitute "inventive concept'" -- *i.e.*, "an element *or* combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'" *Alice*, 134 S. Ct. at 2355 (quoting *Mayo*, 132 S. Ct. at 129); *see also Funk Bros.*, 333 U.S. at 130 ("If there is to be invention from [a discovery of a law of nature], it must come from the application of the law of nature to a new and useful end.").

Before applying the *Alice* framework to the patents-in-suit, a review of the Supreme Court's recent decisions in *Mayo*, which similarly dealt with drug level testing and diagnostic patents, as well as some of the post-*Alice* Federal Circuit decisions may be helpful. In *Mayo*, the patents-in-suit concerned the use of thiopurine drugs in the treatment of autoimmune diseases. In particular, doctors knew that such drugs could be helpful in treating Crohn's disease and that the drugs' toxicity or effectiveness could be measured relative to how thiopurine metabolized in the body. Before the filing date of the invention, however, it had been difficult for doctors "to determine whether for a

particular patient a given thiopurine dose was too high, risking harmful side effects, or too low, and so likely ineffective." *Mayo*, 132 S. Ct. at 1295. Said another way, the scientific community did not know the precise correlations between metabolite levels and likely harm or ineffectiveness.

The Supreme Court found that this is where the patent addressed a need, with claims directed to "processes embodying researchers' findings that identified these correlations with some precision."[12] *Id.* While the Court had not yet adopted the two-step framework later set out in *Alice*, the *Mayo* analysis certainly reflected the first step of the *Alice* framework while suggesting the second. Specifically, upon coming to the conclusion that the patent was directed to ineligible subject matter, the Court asked rhetorically: "What else is there in the claims before us?" *Id.* at 1297. This provided the segue to what is now the second part of the *Alice* framework: the search for inventive

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[12] The representative claim provided:

> A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
>
> (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointesti-nal disorder; and
>
> (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointesti-nal disorder,
>
> wherein the level of 6-thioguanine less than about 230 pmol per 8x10 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and
>
> wherein the level of 6-thioguanine greater than about 400 pmol per 8x10 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Id. at 1295.

concept. At that juncture, the representative claim was divided into an "administering" step, a "determining" step, and a "wherein" step. *Id.*

To begin, the Supreme Court held that the "administering" step" did not supply inventive concept because the "step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs." *Id.* The "determining" step was treated with equal disdain because it simply "tells the doctor to determine the level of relevant metabolites in the blood, through whatever process the doctor . . . wishes to use." *Id.* Justice Breyer found *that* step "nothing more [than] well-understood, routine, conventional activity previously engaged in by scientists who work in the field." *Id.* To support this conclusion, Justice Breyer cited admissions in the patent itself that the processes for determining the level of metabolites in a patient's blood were "well known in the art." *Id.* at 1298.[13] As to the "wherein" step in *Mayo*, the Supreme Court found those clauses simply "tell the relevant audience about the laws while trusting them to use those laws appropriately where they are relevant to their decision-making (rather like Einstein telling linear accelerator operators about his basic law and then trusting them to use it where relevant)." *Mayo*, 132 S. Ct. at 1298.

Next, the Court addressed the patentability of the *combination* of these steps. The Court found that "to consider the three steps as an ordered combination adds nothing to

[13] While no specific prior art reference outside the four corners of the specification was cited in support, Justice Breyer presumably relied on undisputed facts in the prosecution history (the intrinsic administrative record) to determine whether these steps in the process were inventive in the context of section 101. *Cf. Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015) ("[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law.").

the laws of nature that is not already present when the steps are considered separately." *Id.* Justice Breyer's opinion distinguished the decision from the Court's previous holding in *Diamond v. Diehr*, 450 U.S. 175 (1981). To Justice Breyer, nothing in *Diehr* suggests that the steps of the claimed process or their combination "were in context obvious, already in use, or purely conventional," as had been found to be true with respect to the claimed process in *Parker v. Flook*, 437 U.S. 584 (1978).[14] *Mayo*, 132 S. Ct. at 1299 ("[I]t was nowhere suggested that all the steps [in Diehr's invention], or at least the combination of those steps were . . . conventional."). Because of this, Justice Breyer concluded that "the patentees [in *Diehr*] did not seek to pre-empt the use of [the] equation, but sought only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process." *Id.* (internal quotations omitted). In Justice Breyer's view, these other steps apparently added to the formula in *Diehr* something that had significance in terms of patent law's objectives – "they transformed the process into an *inventive application* of the formula." *Id.* at 1299 (emphasis added.).

Finally, Justice Breyer expressly addressed the risk of preemption, stating that "the Court has repeatedly emphasized the concern that patent law [must] not inhibit further discovery by improperly tying up the future use of laws of nature." *Mayo*, 132 S. Ct. at 1301. For this reason, Justice Breyer cautioned against patents that would "foreclose[]

[14] *See* John M. Golden, *Flook Says One Thing, Diehr Says Another: A Need for Housecleaning in the Law of Patentable Subject Matter*, 82 GEO. WASH. L. REV. 1765, 1790-91 (2014) (providing an-in depth analysis of the *Mayo* Court's explanation of its holding).

more future invention than the underlying discovery could reasonably justify." *Id.*[15] Justice Breyer concluded that, as in *Benson*, where the claimed mathematical formula had "no substantial practical application except in connection with a digital computer," the claims in *Mayo* were overly broad because they "did not differ significantly from a claim that just said apply the algorithm." *Id.* (citing *Benson*, 409 U.S. at 71).

Since *Mayo* and *Alice*, the Federal Circuit has continued to develop the standard for what constitutes patentable subject matter. In particular, two recent decisions provide insights into what constitutes an "inventive concept" under *Alice's* second step. In *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245 (Fed. Cir. 2014), for example, the Federal Circuit reviewed patents "directed to systems and methods of generating a composite web page that combines certain visual elements of a host website with content of a third-party merchant." 773 F.3d at 1248. Judge Chen found that the patents were directed toward more than an abstract idea or fundamental business practice; they solved a problem particular to the internet. *Id.* at 1257. "Instead of the computer network operating in its *normal, expected manner* . . . the claimed system generate[d] and direct[ed] the visitor to [a] hybrid web page that presents product information from the third-party and visual 'look and feel' elements from the host website." *Id.* at 1258-59 (emphasis

[15] *Cf.* Mark A. Lemley, *Point of Novelty*, 105 NW. U. L. REV. 1253 1279 n.12 (2011) ("[T]here is good reason to worry about overbroad patent claims that lock up a wide swath of potential future applications. But the enablement and written description doctrines largely address that concern."); *see also* Michael Risch, *Everything is Patentable*, 75 TENN. L. REV. 591, 598–606 (2008) (offering examples of patentable subject matter cases that could be reframed through the lens of other patentability doctrines, such as novelty, utility, and adequate disclosure); Anna B. Laakmann, *An Explicit Policy Lever for Patent Scope*, 19 MICH. TELECOMM. & TECH. L. REV. 43, 53-54 (2012) ("Although they are treated as distinct patentability criteria, the disclosure requirements are conceptually linked both to each other and to the PSM doctrine.").

added). Because the patents were directed toward solving a new problem, particular to the internet, and solved the problem beyond "routine or conventional use of the internet," Judge Chen found that the patents were significantly more than just an abstract idea. *Id*. at 1259.[16]

More recently, the Federal Circuit examined whether gene sequences known as BRCA1 and BRCA2 could overcome a § 101 challenge. *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014). The case involved Myriad Genetics, Inc. suing Ambry Genetics Corporation for infringement of U.S. Patent No. 5,753,441 and U.S. Patent No. 5,747,282. In the 1990s, Myriad had discovered the precise locations and sequences of the BRCA1 and BRCA2 genes, mutations linked to hereditary breast and ovarian cancers. Myriad was then able to determine the typical sequences of the genes most often found in humans (*i.e.*, the "wild-type" sequence for each), as well as mutations that depart from these two sequences. Some mutations were harmless, while other mutations correlated with an increased likelihood of developing particular cancers. By testing for the presence of these mutations, doctors could determine whether a patient is particularly prone to developing breast or ovarian cancer.

As in the present case, the method claims involved comparison steps. Ambry, however, argued that *Mayo* was directly on point because these claims "simply identif[ied] a law of nature (the precise sequence of the BRCA genes, and comparisons of wild-type BRCA sequences with certain mutations of those gene sequences found in the test subject) and appl[ied] conventional techniques." *Id.* at 762. In a slight twist, the

[16] Among other things, this case is of note for being the first Federal Circuit case using the *Alice* framework that upheld eligibility of a patent under 35 U.S.C. § 101.

Federal Circuit declined to decide whether *Mayo* applied to the process patents "because the method claims suffer[ed] from a separate infirmity: they recite[d] abstract ideas." *Id.* In analyzing claims 7 and 8, the court noted that both were similar and dependent from claim 1. In applying the two-step framework of *Alice*, the court dissected the claims to a first set of paragraphs, "which describe the comparison of wild type genetic sequences with the subject's genetic sequence and correspond to the first step of *Alice*" and the second set of paragraphs, "which describe the techniques to be used in making the comparisons and correspond to the second step of *Alice*." *Id.* at 763.

Holding that the first paragraphs -- the comparison step -- amounted to an abstract idea, the court turned to the second paragraphs in claim 7 and claim 8, respectively. *Id.* The court found that the second paragraph of claim 7 described the way in which the "sequences are compared: they are compared by 1) hybridizing a BRCA gene probe and 2) detecting the presence of a hybridization product." *Id.* at 764. Similarly, the court said that "claim 8 requires 1) amplification of the BRCA1 gene and 2) sequencing of the amplified nucleic acids." *Id.* The court found that "claims 7 and 8 do not add 'enough' to make the claims as a whole patent-eligible." *Id.* This holding was predicated on the unchallenged finding by the district court that the elements of the second paragraphs of claims 7 and 8 "set forth well-understood, routine and conventional activity engaged in by scientists at the time of Myriad's patent applications." *Id.* (quotations omitted). The court concluded:

> The second paragraphs of claims 7 and 8 do nothing more than spell out what practitioners *already knew* -- how to compare gene sequences *using routine, ordinary techniques.* Nothing is added by identifying the techniques to be used in making the comparison because those comparison techniques

> were the well-understood, routine, and conventional techniques that a scientist *would have thought of* when instructed to compare two gene sequences.

Id. (emphasis added).

Just as Justice Breyer tethered the notion of well-understood, conventional steps to "activity already engaged in by the scientific community" in *Mayo*, 132 S. Ct. at 1298, the Federal Circuit in *BRCA1* tethered the notion of well-understood, conventional steps to "techniques that a scientist would have *thought*" to use when deciding to engage in experiments that were directed to the invention, 774 F.3d at 764 (emphasis added). Both of these articulations amount to the same concept: whether the scientific community *would have thought to do something* at the time of invention is very much dependent on *what activities scientists had already been engaged in at the time*.

Of course, the inverse concept also is true: if inventors engage in activities that run *counter* to scientific thought, those activities can hardly be considered conventional under § 101. This latter concept would similarly apply when a patent involves a combination of elements that the scientific community would not have thought to use or implement to deliver a new, improved and useful result. 35 U.S.C. § 100 ("The term 'process' means process, art or method, and includes a new use of a known process."). Indeed, the new and useful result of a combination patent resides precisely in a combination that neither existed in the prior art, nor was the possibility of such a combination well known in the art at the time of the invention.

When invention is based on the combination of elements that cuts against the

grain of scientific thought, this heightens the novelty of invention itself.[17] This is not to say that all inventions must cut against the grain to supply inventiveness. Far from it. This was not taught in *DDR*, nor was it in the *California Institute of Technology* case. The common thread in both those cases was that both inventions were directed towards a specific problem in the art and improved functionality. By doing so, both patents contributed to the art. *See, e.g.*, *Cal. Inst. of Tech.*, 2014 WL 5661290, at *20 ("Caltech's patents improve a computer's functionality by applying concepts unique to computing (like using a linear transform operation to encode data) to solve a problem unique to computing (data corruption due to noise)."). Solving those problems was not said to preempt because the elements in each invention were combination patents and created new and useful results that did not foreclose the use of other means to arrive at that same result: "it at least must be true that § 101 protects a unique computing solution that addresses a unique computing problem." *Caltech*, 2014 WL 5661290, at *20.

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[17] The Supreme Court recognized the potential for overlap between § 101 and § 102 in *Mayo*, 132 S. Ct. at 1304 ("the § 101 patent-eligibility inquiry and, the § 102 novelty inquiry might sometimes overlap"). This is also borne out by the legislative history that states expressly that § 102 is an amplification and definition of "new" in § 101. Specifically, the Senate Report associated with the 1952 Patent Statute stated:

> Section 101 sets forth the subject matter that can be patented, 'subject to the conditions and requirements of this title.' The conditions under which a patent may be obtained follow, and section 102 covers the conditions relating to novelty.

S. Rep. No. 82-1979, 1952 U.S.C.C.A.N. 2349, 2399. Later, the same Report observes:

> Section 102, in general, may be said to describe the statutory novelty required for patentability, and includes, in effect, an *amplification and definition of 'new' in section 101*.

Id. (emphasis added). Of course, this amplification of § 101 does not mean that 101 and 102 are the same. Perhaps a better analogy is that the sections "overlap," much like two circles in a Venn diagram. *Mayo*, 132 S. Ct. at 1304.

While not expressly referenced in the *Alice* framework, an underlying concern is general preemption. That concern was underscored in *Mayo*. As previously discussed, what lies at the core of preemption is the question of whether the patent "forecloses more future invention than the underlying discovery could reasonably justify."[18] *Id.* at 1301. For example, a well-tailored invention seeking to solve a specific problem with specific claim limitations should not typically trigger preemption concerns, at least where the invention is new and useful.[19]

To satisfy the framework laid out in *Alice*, therefore, the invention must "supply a "'new and useful'" application of the idea in order to be patent eligible." *Alice*, 134 S. Ct. at 2357; *see also Le Roy v. Tatham*, 55 U.S. 156, 159 (1852) ("There can be no doubt that, if this combination is new, and produces a new and useful result, it is the proper subject of a patent. The result is a new manufacture. And even if the mere combination of machinery in the abstract is not new, still, if used and applied in connection with the practical development of a principle, newly discovered, producing a new and useful result, the subject is patentable.").

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[18] A non-conventional application of an abstract idea will tend not to preempt. This is how Justice Breyer attempted to reconcile *Diehr* with *Flook* -- explaining that in *Diehr,* "the patentees did not seek to pre-empt the use of [the] equation, but sought only to foreclose from others the use of that equation in *conjunction with all of the other steps in their claimed process*." *Mayo*, 132 S. Ct at 1299 *(*quoting *Diehr* 450 U.S. at 187) (emphasis added); *see also Cal. Inst. of Tech.*, 2014 WL 5661290, at *15 ("Although many of these limitations are mathematical algorithms, these algorithms are narrowly defined, and they are tied to a specific error correction process. These limitations are not necessary or obvious tools for achieving error correction, and they ensure that the claims do not preempt the field of error correction. The continuing eligibility of this patent will not preclude the use of other effective error correction techniques. Therefore, all of the asserted claims are patentable.").

[19] Of course, all valid patents foreclose use and preempt. That's their purpose. *See* Bernard Chao, *Finding the Point of Novelty in Software Patents*, 28 BERKELEY TECH. L.J. 1217, 1235-36 (2013) ("Almost any claim can be characterized as too broad if the concept is defined narrowly.").

2. Analysis of the '680 patent

In what amounts to a conspiracy of silence, while Millennium challenges both the '680 patent *and* the '895 patent under § 101, both parties focus their § 101 analysis narrowly on the more tailored '680 patent, likely because Millennium must prevail in its challenge with respect to both and plaintiffs are happy to argue § 101 using the stronger of its two patents. Because the '895 patent is invalid for lack of enablement, the analysis here will also focus on the '680 patent, although the likely implications for a similar analysis with respect to the '895 patent may at times be obvious.[20] For the reasons set

[20] While the '680 patent is valid under both §§ 101 and 112, the '895 patent claims too much under either section. Not restricted to urine screening, the claims in the '895 patent extend to blood, saliva, *etc.*, while at the same time failing to enable one skilled in the art to properly understand the invention. Indeed, there is not only overlap between §§ 101 and 102/103, as Justice Breyer suggests in *Mayo,* the preemption concern bridges the divide between §§ 101 and 112. 132 S. Ct. at 1301. *See* Mark A. Lemley, *et al.*, *Life After Bilski*, 63 STAN. L. REV. 1315, 1329-30 (2011) (noting similarities and some of the nuanced differences between enablement and patentable subject matter regarding issues relevant to the time of filing). Even so, the court will follow the Supreme Court's lead in *Mayo* and decline an invitation to forego any analysis of the '895 patent, 132 S. Ct. 1304, while acknowledging that a dispute exists in the Federal Circuit and lower courts as to whether this is necessary. *Compare Ultramercial, Inc. v. Hulu, LLC*, 772 F.,3d 709, 718 (Fed. Cir. 2014) (Mayer, J., concurring) ("Just as a court must assure itself of its own jurisdiction before resolving the merits of a dispute, it must likewise first assess whether claimed subject matter is even *eligible* for patent protection before addressing questions of invalidity or infringement.") (internal citation omitted), *I/P Engine, Inc. v. AOL Inc.*, 576 F. App'x 982, 995-96 (Fed. Cir. 2014) (Mayer, J., concurring) ("Until it is determined that claimed subject matter is even *eligible* for patent protection, a court has no warrant to consider subordinate validity issues such as non-obviousness under 35 U.S.C. § 103 or adequate written description under 35 U.S.C. § 112."), *and SmartGene, Inc. v. Advance Bio. Labs., SA*, 852 F. Supp. 2d 42, 51-52 (D.D.C. 2012) (treating the § 101 inquiry as the "threshold inquiry for patent validity"), *with MySpace, Inc. v. GraphOn Corp.*, 672 F.3d 1250, 1260 (Fed. Cir. 2012) (noting that "courts could avoid the swamp of verbiage that is § 101 . . . and insist that litigants initially address patent invalidity issues in terms of the conditions of patentability defenses as the statute provides, specifically §§ 102, 103, and 112), *and Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1335 (Fed. Cir. 2012) (Plager, J., concurring in part and dissenting in part) ("[T]his court should exercise its inherent power to control the processes of litigation and insist that litigants, and trial courts, initially address patent invalidity issues in infringement suits in terms of the defenses provided in the statute: 'conditions of patentability,' specifically §§ 102 and 103, and in addition §§ 112 and 251, and not foray into the jurisprudential morass of § 101 unless absolutely necessary.").

forth below, the court ultimately concludes that the claims in the '680 patent are patent eligible, while finding the broader claims in the '895 patent foreclose more future inventions than the inventors narrow discovery could reasonably justify.

a. Step One of the *Alice* Framework

At step one, the court determines "whether the claims at issue are directed to ineligible subject matter." *Alice*, 134 S. Ct. at 2355. Millennium argues that the claims as a whole are directed to an abstract idea, but places particular emphasis on element (b) and element (f) of claim 1 and the related claims. The latter recites a comparison "of a person's metabolite/creatinine ratio to 'known normative data' (a population of metabolite/creatinine ratios)." (Def.'s Opening Br. (dkt. #130) 63-64.) Ameritox counters by pitching the invention at a more specific level, arguing that the claims are directed "to quantifying a metabolite concentration by adjusting the concentration for the patient's hydration status and then statistically comparing the adjusted concentration to a set of known normative data."[21] (*Id.* at 87.) This, Ameritox argues, reflects the purpose of the invention -- providing a method to improve medication monitoring and identifying aberrant drug use.

The court finds Millennium's position more persuasive. While the skilled addressee would view comparative analysis of the invention as one that seeks to achieve a new and useful result over prior urine screening protocols, this new and useful result still

[21] Millennium criticizes Ameritox's characterization, stating that it merely parrots claim 1 itself, but in more generalized form. Since the court adopted the plain and ordinary meaning of the claims here, Ameritox can hardly be criticized for adopting at step one of *Alice* precisely what the plain and ordinary meaning of the claims provides.

rests upon an abstract idea, at least at some level. This finding is consistent with the recent *BRAC1* decision, which also involved method claims. Specifically, the claims identified "a law of nature ([*i.e.*] the precise sequence of BRCA genes and *comparisons* of wild-type BRCA sequences with certain mutations of those genes found in the test subject) and applied conventional techniques" to determine a patient's propensity to cancer. *See BRCA1*, 774 F.3d at 761. In finding in favor of the defendant, the *BRAC1* court held that the comparative analysis of the invention "recite[d] abstract ideas." *Id.* at 762.

Because the present case involves a comparative analysis like that found in *BRCA1*, Millennium satisfies step one of the *Alice* framework. *Id.; see also Bilski*, 561 U.S. at 611-12 (characterizing abstract idea as "the concept of hedging" where claim limitations described initiating transactions and identifying market participants); *Alice*, 134 S. Ct. at 2356 (characterizing abstract concept as "intermediated settlement" despite claim elements reciting use of shadow credit records and debit records); *buySAFE Inc. v. Google, Inc.*, 765 F.3d 1350, 1354-55 (Fed. Cir. 2014) (holding that "[t]he claims are squarely about creating a contractual relationship" despite presence of more specific claim limitations); *Ultramercial,* 772 F.3d at 715 (holding that "the concept embodied by the majority of the limitations describes only the abstract idea of showing an advertisement before delivering free content" despite presence of other limitations).[22]

[22] Millennium also argues that element (e) of the claimed process in particular -- "normalizing the biological sample to adjust for changes in the patient's hydration status by determining the metabolite/creatinine ratio of the patient" -- is a natural law that satisfies step one of the *Alice* analysis. (Pl.'s Opp'n (dkt. #172) 87.) Whether Millennium intends to advance this theory in the alternative to the abstract nature of the claims as a whole is unclear, but the issue is moot

But as Millennium must readily acknowledge and as previously discussed, it would be a *rare* case where a patent is *not* directed to ineligible subject matter under § 101. *See Mayo*, 132 S. Ct. at 1293 ("[A]ll inventions, at some level . . . apply laws of nature, natural phenomena or abstract ideas."); *cf. AutoForm Eng'g GMBH v. Eng'g Tech. Assocs., Inc.*, No. 10-14141, 2014 WL 4385855, at *3-4 (E.D. Mich. Sept. 5, 2014); *Ameranth, Inc. v. Genesis Gaming Solutions, Inc.*, No. 11-00189, 2014 WL 7012391, at *6 (C.D. Cal. Nov. 12, 2014) (explaining that the cotton gin could sound abstract if one uses broad enough terms); *see also* Michael V. Risch, *Everything is Patentable*, 75 TENN. L. REV. 591 (2008). No doubt, this is precisely why § 101 has traditionally been considered a "threshold test" under the statute. *See, e.g.*, *Diehr*, 450 U.S. at 188 ("that process is at the very least not barred at the threshold by 101"); *Alexsam, Inc. v. IDT Corp.*, 715 F.3d 1336, 1348 (Fed. Cir. 2013) (Mayer, J., dissenting) ("Whether claims are directed to statutory subject matter is a "threshold" question.").

b. Step Two of the *Alice* Framework

Holding that the claims are directed to an abstract idea, however, does not win the day for Millennium. As noted at the outset, an invention is not rendered ineligible

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since Millennium succeeds at step one regardless. Moreover, the process of normalizing a urine sample by determining the metabolite/creatinine ratio is not necessarily a natural law, at least on this record. (Orsulak Rebuttal Rept. (dkt. #118) ¶¶ 237-238 (finding a ratio is not a law of nature).) Creatinine normalization is a process that the inventors considered and then implemented. The ratio is simply the end result. This ratio can hardly be considered a natural law in isolation. The ratio more closely resembles an abstract idea (if at all). Perhaps realizing that its natural law theory was unsound, and inappropriately dissects the claims at step one of the *Alice* analysis, Millennium makes this very argument in its reply brief. (Def.'s Reply (dkt. #183) 47.) Moreover, because it was not raised in its opening brief, Millennium has waived this argument, at least for purposes of summary judgment. *Gold v. Wolpert*, 876 F.2d 1327, 1331 n.6 (7th Cir. 1989); *Shlay v. Montgomery*, 802 F.2d 918, 922 n.2 (7th Cir. 1986).

simply because it involves an abstract idea. Applications of concepts ''to a new and useful end'' remain eligible for patent protection. *Alice*, 134 S. Ct. at 2354 (quoting *Benson*, 409 U.S. at 67). To meet this second step under *Alice*, claims directed to an abstract idea must contain an "inventive concept," that is "an *element or combination of* elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." *Id.* at 2355 (emphasis added).

Claim 1 of the '680 patent states:

> 1. A method for quantifying at least one metabolite in a biological sample comprising the steps of:
>
> (a) providing one biological sample obtained from a patient on a prescribed medication regimen, wherein the sample comprises at least one test metabolite, *urine*;
>
> (b) providing one set of known normative data specific to a reference metabolite, wherein the set of data is collected from a population that is on a prescribed medication regimen;
>
> (c) contacting the biological sample with an analytical device;
>
> (d) *detecting* the presence of at least one test metabolite in the biological sample with the device, wherein the device is capable of measuring the concentration of the test metabolite in the sample;
>
> (e) *normalizing* the biological sample to adjust for changes in the patient's hydration status by determining the metabolite/creatinine ratio of the patient; and
>
> (f) *quantifying* the concentration of at least one test metabolite in the biological sample by comparing a ratio between the concentration of the test metabolite from the patient to the set of known normative data specific to the reference metabolite concentration.

('680 patent at 21:9-32.) For ease of reference, elements (a)-(d) will be described as the "detection" steps. Element (e) will be described as the "normalization" step. Element (f) will be described as the "comparative" step.

Millennium argues that the claims are conventional because they "direct medical professionals to measure the level of a drug metabolite, to normalize data via a creatinine ratio, and then to compare that value against the creatinine ratios of a population of individuals." (Def.'s Opening Br. (dkt. #130) 78.) Millennium further argues that because these elements are conventional, the invention lacks an "inventive concept" beyond the abstract idea itself.

Ameritox's position is more nuanced. Ameritox argues that the claim elements are unconventional because the asserted claims are drawn to specific methods of monitoring medication through normalization and quantification of metabolites in a urine sample. Ameritox contends that these steps contain an inventive concept because the process described seeks to implement a novel solution to a pre-existing problem in the field. (Pl.'s Opp'n (dkt. #172) 99.) Indeed, much of Ameritox's argument centers on the fact that: (1) the invention *produces* an improved result over existing technology; and (2) the necessary inventive concept is *combining* the normalization step with the detection and comparative steps. As to the '680 patent, the court agrees.

First, when the invention is examined as an ordered combination, the combination of steps produces a new and useful result. 35 U.S.C. § 101 (the patent statute provides protection for "any new and useful process"). The instant case shares similarities with *Diehr* in this respect. In both cases, the subject patents are directed to abstract ideas that improve pre-existing technology. Specifically, like the rubber curing improvements taught in the *Diehr* patent, new improvements are similarly taught in the '680 patent (albeit with respect to drug compliance monitoring). Indeed, each additional step taught

directs the skilled addressee to an invention that allows quantifiable analysis of urine samples to determine a patient's compliance with a prescribed drug regimen. This type of improvement in existing technology is the type of invention that the statute seeks to encourage, not dismiss. 450 U.S. at 183; *see also Alice*, 134 S. Ct. at 2359 (looking at improvements in the "functioning" of a computer and the "technical field"); *Bilski*, 561 U.S. at 601 ("Congress took this permissive approach to patent eligibility to ensure that ingenuity should receive a liberal encouragement.") (internal quotation marks omitted).

In *DDR*, Judge Chen similarly upheld under § 101 scrutiny, an invention that addressed the challenge of retaining website visitors that was specific to the internet, as opposed to the "performance of a business practice known prior to the 'pre-internet world.'" *DDR,* 773 F.3d at 1257. Although the patent claimed a solution "rooted in computer technology," Judge Chen found the hybrid functionality of the invention constituted inventive concept. *Id.* This holding was reinforced by the fact that the claims addressed the problem of retaining website visitors otherwise instantly transported away from a website after "clicking" on an advertisement. *Id.* While the invention at issue in *DDR* was in the software field, that decision establishes that inventive concept can be established by something more than "conventional functioning" that targets and improves existing technological processes for a specific problem in field of the invention. *Id.*; *see also Wavetronix LLC v. Iteris, Inc.*, No. A-14-CA-970-SS, 2015 WL 300726, at *6 (W.D. Tex. Jan. 22, 2015) (citing *Alice*, 134 S. Ct. at 2358).

Here, the '680 specification states that previous urine protocols were restricted in their application because they could only test for positive or negative results as to the

"presence or absence of a drug metabolite in urine." ('680 patent at 2:64-67.) This problem was described as a "major difficulty" in the art because of the "large amount of variance in urine drug concentrations, mostly due to variations in hydration and urinary output volume." ('680 patent at 1:51-52.) In addressing the problem, the inventors coupled the normalization step with the comparative step, allowing for more accurate assessment of aberrant drug use. Nothing in Millennium's summary judgment materials rebuts what was plainly identified on the face of the specification as a problem in the field, nor directly rebuts the solution that the patent provided. This is telling.[23] Just as the patent in *DDR* was deemed eligible because it solved a "problem specifically arising in the realm of computer networks," so, too, does the '680 patent solve a unique problem with respect to drug testing technology. *See DDR,* 773 F.3d at 1257; *Cal. Inst. of Tech.*, 2014 WL 5661290, at *20 ("§ 101 protects a unique computing solution that addresses a unique computing problem"); *cf. Alice*, 134 S. Ct. at 2359 ("The method claims do not . . . purport to improve the functioning of the computer itself.").

[23] In this case, what is referred to in the specification actually helps the patentee for 35 U.S.C. § 101 purposes because the prior art in the "background of the invention" demonstrates the problems faced by those in the field, since those problems appear to have been significant and solved by solutions specifically tailored in the applicant's invention. *See generally DDR*, 773 F.3d at 1257 (explaining that the patent claimed a specific solution addressing a specific problem that was "rooted in computer technology"). Indeed, it is the admissions on the face of the specification that assist the patentee in more clearly elucidating the specific problem that is then solved by the patented invention so to meet § 101 requirements. This is in contrast to other recent district court decisions that have noted how the admissions in the specification tend to hurt the patentee in the § 101 context. *See McRO, Inc. v. Namco Bandai Games Am., Inc.*, No. CV 12-10327-GW (FFMx), 2014 WL 4749601, at *11 (C.D. Cal. Sept. 22, 2014) ("And the patent's casual—and honest—description of the prior art was made at a time when, under the then-prevalent interpretation of the law, such admissions were unlikely to be harmful. One unintended consequence of *Alice*, and perhaps of this and other decisions to come, is an incentive for patent applicants to say as little as possible about the prior art in their applications.").

Second, Millennium's analysis of the second *Alice* step to the '680 patent is flawed. As an initial matter, Millennium argues that the comparative step must be filtered out of the analysis when looking at a combination patent, because it is either a "known method" or "an unpatentable . . . process." (Def.'s Opening Br. (dkt. #130) 78.) But there is nothing in *Alice* suggesting that any steps are "filtered out" when considering a combination patent. To the contrary, the invention in *Alice* was considered as "a whole" when assessing the second step of the framework. 134 S. Ct. at 2359 ("Considered as an ordered combination [and] . . . [v]iewed as *a whole*, petitioner's method claims simply recite the concept of intermediated settlement as performed by a generic computer." (internal quotations omitted, emphasis added)).

Alternatively, Millennium argues that instead of ignoring the comparative step, the detection and normalization steps must be discounted because they exist in the prior art, leaving only an abstract idea at the comparative step. (Def.'s Opening Br. (dkt. #130) 78.) Essentially, Millennium appears to assert that any additional steps beyond the abstract idea do not elevate the claim to "inventive concept," because each step was either "established" or "conventional." (*Id.*) Not so under *Alice*.

Specifically, looking at the normalization step, Millennium merely relies on its proposed finding that: "Normalizing urine samples [had] been routine and conventional practice for over 40 years." (Dr. Alan H. Wu Invalidity Report ("Wu Invalidity Rept.") (dkt. #115) ¶ 112.) To support this proposed finding, Millennium infers that because creatinine normalization was mentioned in the George article, someone skilled in the art would know to simply combine the normalization step with the detection and

comparative steps. Millennium argues that this finding is also supported by Dr. Wu, who opined that for § 101 purposes, "neither the individual claim steps of the patented methods nor the series of claim steps in the patented methods are novel." (*Id.*)

In reviewing the experts' reports, however, there is nothing that supports a finding that the *combination* of the steps is routine and conventional.[24] For example, Dr. Wu merely isolates the prior art in disparate references, but provides no meaningful rationale for why they would be combined. Even more telling, Wu cherry-picks aspects of the George article while wholly ignoring those sections that steer away from the combination claimed in the '680 patent.

When looking at a combination patent, what courts most want to know is: who would have thought to combine the known elements in the first place and why?[25] Providing such evidence is even more important for a moving party in the summary judgment context, where all "reasonable inferences" are made in the light most favorable to "the nonmoving party." *Helman v. Duhaime*, 742 F.3d 760, 761 (7th Cir. 2014). When, as here, Millennium is asking the court to infer that the combination of elements is conventional, it must supply *some* evidence to convince the trier of fact to accept its

[24] In contrast, Dr. Larson testified that aspects of the invention were novel concepts "within the urine screen testing world" in combination with the other steps of the invention. (Deposition of Michael Larson ("Larson Dep.") (dkt. #114) 60).

[25] At step two, *Alice* expressly requires that the elements be viewed in "combination." 134 S. Ct. at 2359 ("Considered as an ordered combination [and] . . . [v]iewed as a whole."). *See generally Parks v. Booth*, 102 U.S. 96, 102 (1880) ("Modern inventions very often consist merely of a new combination of old elements or devices, where nothing is or can be claimed except the new combination."). This echoes what was said in *Mayo*, 132 S. Ct. at 1298 ("to consider the three steps as an ordered combination"). In contrast to *Mayo*, Millennium has offered nothing in the prior art that indicates that the scientific community would have combined the steps of the '680 patent.

version of events. Since those facts are lacking here, Millennium's position is necessarily rejected. *See Schacht*, 175 F.3d at 504 (explaining that summary judgment is "not a dress rehearsal or practice run," but the "put up or shut up moment" in which a party must show what evidence it has to convince a trier of fact to accept its version of events). In the end, Millennium does not approach its burden of producing "clear and convincing" evidence that the combination taught in the '680 patent was known.

Third, and a close corollary of the second, evidence of combination helps to guard against hindsight bias. To ignore this concern would provide a 'blank check' to all those who challenge patents without sufficient legal or evidentiary basis. Given that *Alice* now expressly requires that courts look at patented elements in *combination* when assessing inventive concept (as did *Mayo*), the concern of hindsight bias has as much relevance to a § 101 challenge as it does a § 103 challenge. *See generally Mayo*, 132 S. Ct. at 1299 ("at least the combination of those steps, were in context obvious, already in use, or purely conventional"). Where, as here, § 101 is effectively being used as a *de facto* § 103 challenge, some *rational basis* for combination must be proffered, particularly in a case like this where the patent has survived prosecution and two further rounds of re-examination, as plaintiffs point out (repeatedly) in briefing. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417-18 (2007) (noting the need to "be cautious of arguments reliant upon ex post reasoning"); *Scientific Plastic Prods., Inc. v. Biotage AB*, 766 F.3d 1355, 1362-63 (Fed. Cir. 2014) (Moore, J., dissenting); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest

that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.").

Finally, having had the benefit of claims construction and viewing the claims through the lens of the skilled addressee, the court is well versed in the state of the art at the time of the invention. In many ways, claim construction has confirmed the basic subject matter of the invention. There would seem no reason why the state of the art should not also be used to analyze claims in the § 101 context when evaluating the "significance of the additional steps" for the purposes of assessing inventive concept. *Mayo*, 132 S. Ct. at 1304. Like other provisions of the statute, it is the state of the *art* that provides the objective baseline for the analysis. Section 101 should be no exception. *Id*.; *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014) ("[A] patent's claims, viewed in light of the specification and prosecution history, [need only] inform those skilled in the art about the scope of the invention with reasonable certainty."); *Graham v. John Deere Co.,* 383 U.S. 1, 17-18, 86 (1966) (skilled addressee in the obviousness context); *Innova, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004) (using prior art as an "objective baseline" from which in claims construction); Lemley, *supra* note 20, at 1330.

Here, Millennium can point to *no* reference demonstrating the existence of or even suggesting the *combination* of the comparative step with the additional steps of the invention. And there is certainly nothing in the art that demonstrates that such a combination was well-known. This provides indicia that the '680 patent is inventive for § 101 purposes. *See Mayo*, 132 S. Ct. at 1297-99. Indeed, in *Mayo*, Justice Breyer

explained that the invention in *Diehr* was patentable because the "ordered combination" of the steps of the claimed invention were "nowhere suggested" to be "in context obvious, already in use, or purely conventional." *Id.* at 1299; *see also Oleksy v. Gen. Elec. Co.*, No. 06-C-01245, 2013 WL 3233259, at *5 (N.D. Ill. June 26, 2013) ("Oleksy's process is patentable despite its reliance on mathematical equation because of the way the equation is integrated into a process that also uses steps that are not obvious, already in use or purely conventional"); *France Telecom S.A. v. Marvel Semiconductor Inc.*, No. 12-cv-04967-WHO, 2014 WL 1478850, at *8-9 (N.D. Cal. Apr. 14, 2014) (finding the claims are "narrow and they confine and tie down the otherwise abstract processes cited" and provide "'inventive concepts' that exceed the prior art, namely coding in parallel and a novel method of iterative coding").

Moreover, Millennium has failed to offer any evidence that someone in the scientific community would have even "thought" to combine the claimed elements. *BRCA1*, 774 F.3d at 764. For § 101 purposes, this makes the claims new and useful over the prior art. *Id.*; *see also Diehr*, 450 U.S. at 188 ("[A] new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made."); *Ultramercial*, 772 F.3d at 715 ("[A]ny *novelty* in implementation of the idea is a factor to be considered only in the second step of the *Alice* analysis." (emphasis added)); *Parks v. Booth*, 102 U.S. 96, 102 (1880).

As stated previously, the George Article is indicative of routine and well-known techniques at the time of the invention in the urine testing world. Not only was it

frequently cited in the prosecution history, but both parties' experts rely upon the article for purposes of §§ 101, 102 and 103, *and* Millennium expressly put the article into evidence to support its position on § 101. The article also predated the invention by four years, making it indisputably well known before the patent's filing date. The purpose of the study as described in the George Article was to find a noninvasive way of testing for drug compliance.

At the end of the study, the article expressly concluded that creatinine normalization was problematic and "[f]or practical purposes . . . the only reliable method available to monitor methadone compliance is the use of plasma methadone drug testing." (Mandel Decl., Ex. 43 (dkt. #129-43) 85.) Indeed, the George Article not only indicates that use of creatinine normalization was anything but routine and commonplace in the urine drug testing protocols, but suggests that it was viewed as *unreliable*. *Cf. Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007) ("Applying modern electronics to older mechanical devices has been commonplace in recent years."). Instead, blood testing at the time of the invention was considered the only reliable method to determine whether a patient was complying with a prescribed drug regimen.[26]

[26] Similarly, the Haddow Article, which was cited in the specification and formed part of the prosecution history, teaches that although the use of "creatinine measurements to reflect hydration" was known, it adds "complexity and cost when such measurements are applied in routine and clinical practice." (Bertholf Rept., Ex. H (dkt. #209-8) 562.) This is why "specific gravity (relative density) measurements in urine samples from children with asthma" were used to "provide information equivalent to that from creatinine measurements." (*Id*. at 562-63.) Moreover, Haddow neither involves drug treatment nor compliance with a prescribed drug regimen, nor any known normative database.

If the seminal reference in the art at the time stated that blood sampling was by far preferable to urine normalization, because of the latter's unreliability, why would anyone in the industry have thought to use a normalization step for urine in drug protocols? *Cf. BRCA1*, 774 F.3d at 764 (addressing what a "scientist would have thought of" with respect to gene sequences). Regardless, a normalization step that others skilled in the art had rejected as unreliable can hardly be considered conventional in the § 101 context.[27] Moreover, it is this normalization step that distinguishes the present patent's claims from the *Mayo* patent claims. The fact that the claims in the '680 patent are even more specific -- limiting their reach to *creatinine* normalization -- further narrows their scope, especially since there were *other* means to adjust for changes in a patient's hydration status.[28]

Because the inventors cut against scientific thought at the time of the invention, and because the invention targeted a specific problem in the field of urine testing, the court finds that there is sufficient inventive concept in the '680 patent for the purposes of meeting the threshold test of section 101. *BRAC1*, 774 F.3d at 764; *Ultramercial*, 772 F.3d at 715.

While *each* of the reasons above address Millennium's section 101 challenge in isolation, Millennium also fails to proffer any meaningful evidence to support a finding of

[27] Further compounding Millennium's position is that it supplies no meaningful evidence that a scientist would have thought to use creatinine normalization in combination to achieve the new and useful results produced by the invention over the prior art.

[28] Articles noting these other means are cited in the patent specification itself, and there are even more specific limitations in the dependent claims of the '680 patent. *See, e.g.*, '680 patent at 22:19-48 (claim 4).

preemption for the '680 patent. *See Helios Software, LLC v. SpectorSoft Corp*., No. 12-081-LPS, 2014 WL 4796111, at *17 (D. Del. Sept. 18, 2014) (finding that because defendant "provided no support" the court could not find "that the patents-in-suit were drawn to [eligible subject matter]"). This further suggests that the limitations in the '680 patent do not have preemptive effect, something reinforced by Dr. Orsulak, who noted several other methods besides blood sampling that the patent also did not preempt. These examples were not controverted by Millennium's expert witnesses or in its briefing. (Def.'s Reply (dkt. #183) 56-58.)

None of this can be said with respect to the '895 patent. On the contrary, the sweeping claim to "a method for quantifying at least one metabolite in at least one biological sample" refers to nothing more than the claimed discovery of a method for "quantifying the concentration of at least one test metabolite in the biological sample" against an *unspecified and undisclosed* "known normative data specific to the reference metabolic concentration." Unlike element (e) of the claims in the '680 patent, there is no teaching against the art well-known at the time with respect to the use of creatinine concentration in urine, no specification of a similar test metabolite in other biological samples, or unique relationships between at least one biological sample obtained from a patient and a set of known normative data specific to the referenced metabolite concentration. In short, the '895 patent merely deletes the limitation of the biological sample of urine leaving a sweeping claim to biological samples consisting of "blood, salvia, sweat, spinal and brain fluids." ('895 patent at 4:58-60.) Not only does the patent not provide enablement for biological samples other than urine under § 112 for reasons

discussed below, but it amounts to nothing more than speculative claims that purport to preempt similar discoveries with respect to other biological samples. This would appear exactly the kind of preemption strongly disfavored by the United States Supreme Court because it "forecloses more future invention than the underlying discovery could reasonably justify." *Mayo*, 132 S. Ct. at 1301; *see also* Lemley, *supra* note 20, at 1329-30 ("The abstract ideas exception should disallow those claims to ideas unmoored to real-world applications, taking into account the extent to which the claim forecloses after-arising embodiment of the idea, the nature and extent of the *prior art*, and the level of *disclosure* by the inventor.").

Indeed, as detailed already, it is the very combination of integers in the '680 patent that supplies the inventive concept to that invention. By stark contrast, the '895 patent makes one of those elements redundant -- namely element (e) -- effectively seeking to broaden that patent because there is one less limitation that must be met when seeking infringement with respect to, for *e.g.*, blood. Said another way, and to draw an analogy with a mechanical patent, element (e) provides a pivot point between the detection steps ((a) - (d)) and the comparative step (f) that is essential to invention described in the '680 patent. Rendering that pivot point irrelevant to the combination of the '895 patent -- for example, because blood does not require creatinine-normalization -- cuts away from the novelty and inventiveness of the patent itself, which in turn, cuts away from any justification for allowing the broad claim scope of the '895 patent. *Mayo*, 132 S. Ct. at 1301. Accordingly, without restriction to urine screening, the claims in the

'895 patent are invalid under § 101, and for reasons that are foreshadowed here, invalid under § 112 (a).

B. Section 112 and Other Invalidity Challenges

Regardless of the court's conclusions on claim construction and § 101, Millennium argues that the patents-in-suit are invalid under § 112. Specifically, Millennium argues that the claims of both patents are invalid under the doctrines of indefiniteness and enablement. Since both patents share the same specification, the court addressed the patents together, just as Millennium did in briefing.

1. Indefiniteness

Because the court has earlier found that the claims *can* be construed by a person having ordinary skill in the art, much of Millennium's indefiniteness argument falls flat, but the court will briefly address why, beginning with § 112 itself. Paragraph 2 of § 112 provides that a patent's specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter [that] the applicant regards as [the] invention." 35 U.S.C. § 112, ¶ 2. In *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014), the Supreme Court recently explained that under § 112, ¶ 2, "a patent's claims, viewed in light of the specification and prosecution history, [need only] inform those skilled in the art about the scope of the invention with *reasonable certainty*." *Id.* at 2129 (emphasis added). The Supreme Court further explained in *Nautilus* that indefiniteness requires a "delicate" balance:

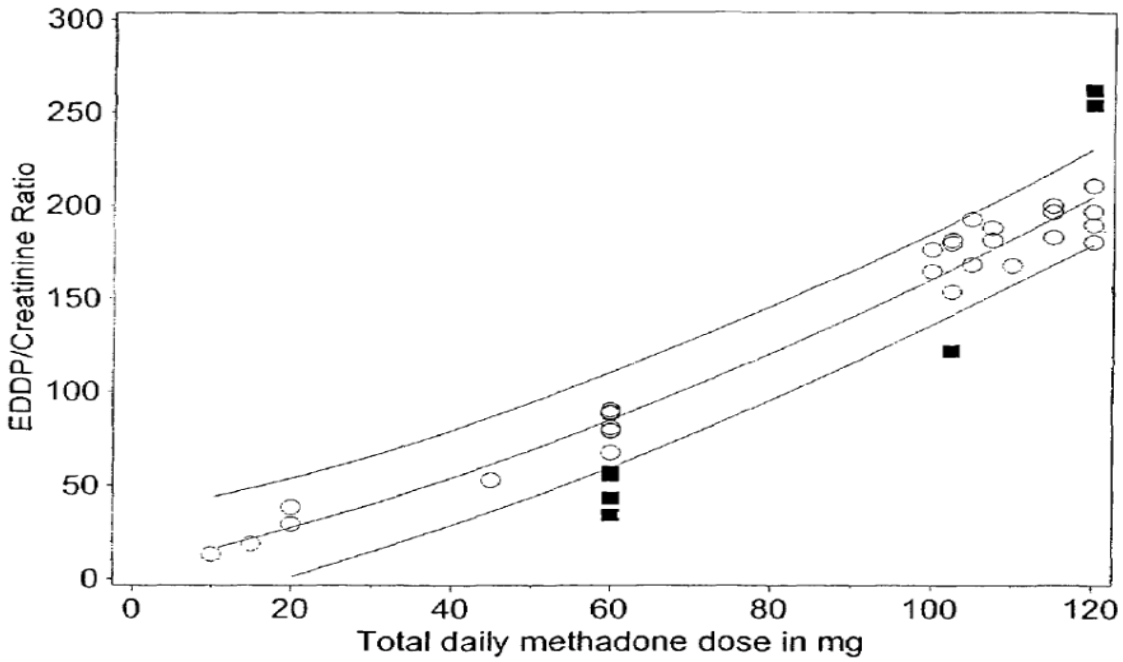
> On the one hand, the definiteness requirement must take into account the inherent limitations of language. Some modicum of uncertainty . . . is the

> price of ensuring the appropriate incentives for innovation. . . . At the same time, a patent must be precise enough to afford clear notice of what is claimed.

Id. at 2128-29 (internal citations and quotation marks omitted). Accordingly, the definiteness requirement "mandates clarity," while recognizing that absolute precision is "unattainable." *Id.* at 2129.

Here, Millennium primarily challenges the validity of Ameritox's construction of a term in element (f) of each of the independent claims in the patents-in-suit -- "quantifying the concentration." Millennium argues that under this now adopted construction, the independent claims are all rendered indefinite. Under § 112 ¶ 2, however, Millennium must provide clear and convincing evidence that the claims fail to provide reasonable certainty as to the scope of the patent. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011). That threshold has not been satisfied here, particularly in light of what is stated in the specification and the prosecution history.

With respect to the former, Example 1 provides a detailed summary of the invention, which is cross-referenced to Figure 4. The example explains how the claimed invention will "improve the ability of clinicians to predict appropriate use of prescribed medication" and "detect and quantify inappropriate use." ('680 patent at 6:58-62.) The inventors further teach how this is achieved with respect to element (f) via statistical analysis of normative data establishing "95% prediction intervals" to identify aberrant medication. (*Id.* at 6:30-35.) That data, as the specification suggests, can then be translated into prediction limits, which are depicted in Figure 4 of the patent:



('680 patent at FIG. 4.) The circles represent normative data. The black squares reflect "known outliers" or "aberrant results." The graph demonstrates that quantifying a urine sample quickly identifies instances of nonadherence. (*Id.* at 4:6-10; *see also id*. at 11:11-12 ("The data used in this study was sufficient to yield a highly significant regression analysis that allowed the demonstration of known outliers.").)

Examples 2, 5, 6, 7, 8, 12, and the "Summary of the Invention," likewise describe ranges, confidence intervals, and regression equations, established from normative data to compare patient information and to "identify aberrant drug use patterns." (*Id.* at 3:20-28, 45-54; *id*. at Exs. 2, 5, 6, 7, 8, 12.) These examples provide objective data that the skilled addressee could rely upon to determine the scope of the patented claims. *Compare DDR*, 773 F.3d at 1259-60 (finding that the term "look and feel" satisfied § 112 because it "had an established, sufficiently objective meaning in the art"), *and Augme Techs., Inc. v. Yahoo! Inc.*, 755 F. 3d 1326, 1340 (Fed. Cir. 2014) (finding that the term "receiving, by

an ingest server, the unique identifier to the digital content" satisfied § 112 because it was "clear on its face"), *with Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370-71 (Fed. Cir. 2014) (finding that the term "unobtrusive manner" was indefinite under § 112 because it was "highly subjective," "provide[d] little guidance to one of skill in the art," and "offer[ed] no objective indication of the manner in which content images are to be displayed to the user").

Moreover, when the skilled addressee views the prosecution history, she would readily appreciate the inventors' explanation that element (f) "allows statistical analysis of the drug metabolite level in the urine to determine if the medication is utilized in a manner consistent with the prescription or that the potential dose may have been." (Mandel Decl., Ex. 24 (dkt. #129-24) pp.14-15; *id.*, Ex. 17 (dkt. #129-17) p.9.) The use of well-known statistical models in the prosecution history is consistent with the teachings in the specification itself -- and, when read together, this would confirm to the skilled addressee with reasonable certainty both how the patented invention works and the "scope of the invention" itself. *Nautilus*, 134 S. Ct. at 2129.

Millennium raises two more arguments that at least deserve mention. *First*, Millennium emphasizes the term "quantifying the concentration" is not "expressly defined anywhere in the specification or prosecution history of the patents-in-suit." (Def.'s Opening Br. (dkt. #130) 30.) However, whether the inventors "expressly defined" a claim term is not the test for indefiniteness. *See Bancorp Serv., L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1373 (Fed. Cir. 2004) ("The failure to define the term is, of course, not fatal, for if the meaning of the term is fairly inferable from the

patent, an express definition is not necessary."). At some level, ambiguity resides in the claims of most (if not all) patented inventions, but as the Supreme Court explained in *Nautilus*, "[s]ome modicum of uncertainty is the price of ensuring the appropriate incentives for innovation." 134 S. Ct. at 2128-29.

Second, Millennium argues that the claims are indefinite because one of the inventors, Dr. Larson, misunderstood what was meant by the "quantifying" step at his deposition. While Millennium placed heavy emphasis on this point, the Federal Circuit has long recognized that an inventor, represented by counsel during the application process, may not understand the meaning of a precise claim in a patent as issued.

> [C]ommonly the claims are drafted by the inventor's patent solicitor and they may even be drafted by the patent examiner in an examiner's amendment (subject to the approval of the inventor's solicitor). While presumably the inventor has approved any changes to the claim scope that have occurred via amendment during the prosecution process, it is *not unusual for there to be a significant difference between what an inventor thinks his patented invention is and what the ultimate scope of the claims* is after allowance by the PTO.

Markman v. Westview Instruments, Inc., 52 F.3d 967, 985-86 (Fed. Cir. 1995) (emphasis added); *see also Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1380 (Fed. Cir. 2000); *Componex Corp.*, 2014 WL 5361946, at *8.

In light of the above, both the specification and the prosecution history supply enough notice so that the skilled addressee would understand the scope of the claims with reasonable certainty.[29] As such, the court finds that the claims meet the

[29] Millennium, through its technical expert, Dr. Alan Wu, also maintains that the term "ratio" as used in the asserted claims is indefinite. Ameritox correctly points out that this new invalidity theory was not included in Dr. Wu's invalidity report, which was due and served on August 11, 2014. Rather, it was first raised in Dr. Wu's rebuttal infringement report, to which plaintiffs'

requirements of 35 U.S.C. § 112, ¶ 2.

2. Enablement

The enablement requirement provides that:

> The specification shall [describe] the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the [invention].

35 U.S.C. § 112(a) (emphasis added).

To be enabling, "the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1380-81 (Fed. Cir. 2012) (citations omitted). "The enablement determination proceeds as of the effective filing date of the patent." *Id.* (citation omitted). "Enablement serves the dual function in the patent system of ensuring adequate disclosure of the claimed invention and of *preventing claims broader than the disclosed invention*." *Id.* (citation omitted, emphasis added). A court may consider the following factors when determining if a disclosure requires undue experimentation: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and

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expert never had a chance to respond. The court rejects Millennium's attempt to inject a new invalidity theory through a rebuttal expert report. *See Ruppert v. Alliant Energy Cash Balance Pension Plan*, No. 08-cv-127, 2010 WL 2518853, at *2 (W.D. Wis. June 18, 2010) (excluding expert's new theory offered in deposition for the first time because "to allow testimony on a matter beyond the scope of the expert report would be improper"). Regardless, the court has reviewed this new invalidity theory, as well as plaintiff's sur-reply, and finds that it does not change the analysis under § 112, ¶ 2.

(8) the breadth of the claims. *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010).

Millennium addresses enablement at two levels. On one level, Millennium argues that had the court adopted its proposed construction of element (f), then the claims in *both* patents are invalid for lack of enablement. Even accepting the court's construction, on another level, Millennium argues that the '895 patent is still invalid due to its failure to teach the claimed methods directed to *non-urine* biological samples. Since the court did *not* adopt Millennium's construction, the first argument obviously falls away, but the second of these arguments is persuasive.

As discussed earlier, one skilled in the art would readily appreciate that the claims in the '895 patent are not limited to urine samples, which contrasts starkly with similar claims in the '680 patent. Unlike that patent, the '895 patent claims expressly extend to other biological samples, including "blood, saliva, sweat, and spinal and brain fluids, or a combination thereof." ('895 patent at 4:58-60.) Tellingly, Ameritox neither disputes this contrast, nor explains how the '895 patent teaches the practice of the claimed invention as to any of these non-urine samples except in the broadest possible terms. The court finds this terminal to Ameritox's chances of succeeding with respect to the '895 patent. *See, e.g.*, *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1378-79 (Fed. Cir. 2007) (holding that the patentee must provide a "reasonable enablement of the scope *of the range*" of the patented embodiments (emphasis added)); *Gen. Elec. Co. v. SonoSite, Inc.*, 641 F. Supp. 2d 793, 817 (W.D. Wis. 2009) (explaining that although a patentee need not describe "how to make and use every possible variant of the claimed

invention," where claims are "open-ended," the patent would need to be supported by "reasonable enablement of the scope of the range").

In basic patent parlance, the teaching of how to practice the claimed invention supplies the "*quid pro quo* of the patent bargain." *Liebel-Flarsheim*, 481 F.3d at 1380; *see also Promega Corp. v. Life Technologies Corp.*, 773 F.3d 1338, 1347 (Fed. Cir. 2014) (stating that the "scope of the claims" must be "commensurate" with the specification). In this respect, the '895 patent does not live up to its promise. The *only* biological sample in the specification is the same urine samples already disclosed and claimed in the '680 patent. Indeed, the bulk of the '895 patent is primarily directed to explaining how creatinine normalization plays a critical role in accounting for hydration when testing urine samples, not unlike the '680 patent. This lack of disclosure as to the *other* biological samples is enough to defeat the '895 patent on enablement grounds given that undue experimentation would obviously be required to determine how non-urine samples work in conjunction with creatinine normalization so to provide a new and useful result. *Id.*; *see also MagSil*, 687 F.3d at 1380-81 ("To be enabling, the specification of a patent must teach . . . without [the need] for undue experimentation.").

Reinforcing the strength of Millennium's argument is the fact that applying creatinine normalization to other biological samples (*e.g.,* blood) makes no sense. As Millennium's unrebutted expert report explained, hydration does *not* need to be accounted for in non-urine, biological samples, since fluids, like blood, do not reflect variations in hydration like urine. (Wu Invalidity Rept. (dkt. #115) ¶ 100) (noting that, with respect to non-urine biological samples, "[t]he body already has a defense

mechanism in place to prevent wide variation in hydration and dehydration").

While the enablement inquiry also allows assessment of the state of the art and the relative skill of those scientists involved in the industry, the patent fares no better when considering these sources at the time of the '895 patent filing. On the contrary, the lack of teachings in the specification is not saved by what was known outside the specification -- *i.e.* what was common general knowledge or commonplace. When turning to these sources, the skilled addressee would find references such as the George Article that make *no* reference to how blood applies creatinine normalization to achieve more accurate results. Most likely, this is because, as Dr. Wu opines, it makes no difference since blood has built-in mechanisms to prevent wide variations in hydration. (*Id.*)

Not only is this not controverted in the parties' summary judgment materials, Ameritox goes so far as to say that the case is not about blood, it's about urine samples. Specifically, Ameritox concludes that because non-urine samples are not relevant to the other issues of this case -- in particular, infringement -- the court should ignore Millennium's contention that the '895 patent is invalid for lack of enablement. (Pl.'s Opp'n (dkt. #172) 63-64.) At the same time, Ameritox seems to be conceding that the '895 patent is irrelevant to the current lawsuit, it neither offers to withdraw the patent from these proceedings nor cite law as to how the much broader claims of the '895 patent satisfy an enablement inquiry.

Instead, Ameritox relies principally (really exclusively) on *Takeda Pharm. Co. Ltd. v. Zydus Pharm. USA, Inc.*, 743 F.3d 1359 (Fed. Cir. 2014), for the proposition "that the enablement requirement is met if the description enables any mode of making and using

the invention." *Id*. at 1369-70 (internal quotation omitted). More specifically, Ameritox contends that because Millennium does not dispute the "claims are . . . enabled and operable with regards to urine . . . [, t]hat is enough." (Pl.'s Opp'n (dkt. #172) 105.

Just as Millennium's application lacked depth with respect to construction, Ameritox suffers from the same vice with respect to enablement on the '895 patent. *First*, Ameritox makes no effort to square what is said in *Takeda* -- regarding use of the word "mode" -- with the well-established rule that the patent must teach how to practice the full scope of an invention. *See Wyeth & Cordis Corp. v. Abbott Labs*., 720 F.3d 1380, 1384 (Fed. Cir. 2013) (citing *MagSil Corp.*, 687 F.3d at 1380-81) ("not enabled when . . . one of ordinarily skill in the art could not practice their full scope without undue experimentation"); *see also Edwards Lifesciences AG v. CoreValve, Inc.*, 699 F.3d 1305, 1309 (Fed. Cir. 2012) ("The enablement defense does not require an intent to withhold; all that is required is a failure to teach how to practice the *full scope* of the claimed invention." (emphasis added)).

To use the language of *Takeda*, if the putative mode does not provide means on how to make and use other embodiments of the invention, then it can hardly be considered a mode that allows the skilled addressee to "practice the full scope of the claimed invention." *Edwards Lifesciences*, 699 F.3d at 1309. This is precisely the case here: there is nothing in the evidence to show how the urine embodiment -- Ameritox's putative mode -- supplies enough information to the skilled addressee to make and use the invention with respect to samples of blood, saliva, sweat, spinal and brain fluid. Accordingly, the '895 patent is invalid for lack of enablement.

Second, Ameritox's two sentence "analysis" ignores that, as Millennium points out, the *Takeda* case is factually inapposite to the present. In *Takeda*, the defendant argued that because the specification only disclosed one method of measuring the drug particles' diameter to determine whether the invention was infringed, the patent did not enable the claims for other methods of measuring drug particles. 743 F.3d at 1369. "[B]ecause the patent identifie[d] laser diffraction as a viable measurement technique, and there [was] no dispute that a skilled artisan would know how to use laser diffraction to measure particle diameter," the Federal Circuit found that the patent "sufficiently *enabled the full scope* of the claims." *Id.* (emphasis added). Thus, to satisfy the enablement requirement, the patentee was only required to show that there was at least one mode to determine how differing embodiments (*i.e.*, different sizes of a drug particle) of the invention could infringe.

The present patent claims differ in kind from the patent claims in *Takeda* in several respects. For instance, while the '895 patent extends to the use of blood samples to quantify drug metabolites, it cannot be said that blood (or any of the other biological samples) are being used as a universal measuring device, as laser diffraction was in the *Takeda* case. In particular, laser diffraction was a mode for measuring whether an infringing embodiment fell within the full scope of the claims. In contrast, here, each biological source represents an alternative embodiment of how the '895 patent can be implemented. Urine is one embodiment, while blood is another entirely. Because blood is not taught in the specification, blood stretches the scope of the '895 patent beyond its description in the patent. Saliva, sweat, spinal and brain fluids are further embodiments

that each expand the scope further. Moreover, each of these biological samples are embodiments of the invention unto themselves, expanding the scope of the '895 patent far beyond what is disclosed in the '680 patent.

In expanding its scope dramatically, Ameritox was required to ensure that the disclosure was "commensurate" with the specification. Its failure to provide the necessary *quid pro quo* results in the '895 patent being held invalid. *See Promega Corp. v. Life Techs. Corp.*, 773 F.3d 1338, 1347 (Fed. Cir. 2014); *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195-96 (Fed. Cir. 1999) ("[T]he public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims . . . [being] less than or equal to the scope of enablement.").

Similarly, there is nothing in the specification that teaches how creatinine-normalization can be combined with blood (much less other biological samples) to determine the scope of the '895 patent. *MagSil Corp.*, 687 F.3d at 1381 ("The specification must contain sufficient disclosure to enable an ordinarily skilled artisan to make and use the entire scope of the claimed invention at the time of filing."). As addressed earlier, the skilled addressee would also be of no assistance. *Id.* at 1381. Nor does Ameritox's briefing or affidavits even attempt to reconcile these obvious differences between *Takeda* and the present case.

A more apt case than *Takeda* is *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, (Fed. Cir. 2007). On appeal in that case, the patentee unsuccessfully argued as Ameritox does here that the teaching of *one* embodiment was enough for enablement purposes:

> Liebel contends that the court erroneously considered whether an injector without a pressure jacket was enabled . . .Because it is undisputed that

> Liebel provided an enabling disclosure of what it calls its preferred embodiment, viz., an injector with a pressure jacket, Liebel asserts that the court should have held that the disclosure was enabling for the full scope of the claims.

Id. at 1378. In construing the claims, however, the Federal Circuit concluded the claims in *Liebel-Flarsheim* were "not limited to an injector with a pressure jacket." *Id*. at 1379. And, therefore, "the full scope of the claimed inventions include[d] injectors *with* and *without* a pressure jacket." *Id*. (emphasis added).

As for the enablement question, and turning to the specification, the Federal Circuit then held that "nowhere does the specification describe an injector with a disposable syringe without a pressure jacket." *Id*. at 1379. In fact, the Federal Circuit noted, "the specification teaches away from such an invention." *Id*. When turning to the skilled addressee, the Federal Circuit found that "undue experimentation" would be required "to make and use the injector without a pressure jacket." *Id*. at 1380. Because the specification did not teach how to make an embodiment of the invention -- an injector *without* a pressure jacket -- and because the skilled artesian could not "fill the gaps," the Federal Circuit held the "claims were invalid for lack of enablement." *Id.*

Strong parallels exist between the present claims in the '895 patent and the claims in the *Liebel-Flarsheim* patent.[30] Just as nowhere in the specification of the *Liebel-Flarsheim* patent did the patentee describe an injector without a pressure jacket, nowhere in the

[30] For example, the Federal Circuit noted, as is true here, "[t]he irony of this situation is that Liebel successfully pressed to have its claims include a jacketless system, but, having won that battle, it then had to show that such a claim was fully enabled, a challenge it could not meet. The motto, 'beware of what one asks for,' might be applicable here." *Liebel-Flarsheim*, 481 F.3d at 1380.

'895 specification did the patentee describe embodiments of the invention based on blood, saliva, brain fluid or the other claimed biological samples. Moreover, and consistent with *Liebel-Flarsheim* the skilled addressee in this case would be unable to "fill the gaps" in the specification so that invention could meet the enablement requirement. *Id.* Because of the similarities between instant case and *Liebel-Flarsheim*, among others, the court has little hesitation in finding the '895 patent invalid. *See* 35 U.S.C. § 112, ¶ 1 (providing in pertinent part that the specification shall describe "the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the [invention]"); *see also Stirick v. Dreamworks LLC* , 516 F.3d 993, 999-1000 (Fed. Cir. 2008) (affirming summary judgment that claims were invalid for lack of enablement when the claims encompassed both video games and movies, but the specification did not enable the invention for use in movies); *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1285 (Fed. Cir. 2007) (affirming summary judgment that the claims were invalid for lack of enablement when the specification did not enable one of the embodiments).

In sum, because of this fairly blatant overreach and because Millennium has demonstrated through clear and convincing evidence that the '895 patent captures far more than what is taught in the specification, the court grants Millennium's motion for invalidity as to the '895 patent pursuant to § 112(a) of the statute. *See Edwards Lifesciences AG v. CoreValve, Inc.*, 699 F.3d 1305, 1309 (Fed. Cir. 2012).

3. Utility

Finally, Millennium argues that each of the patents lack utility. Given that the '895 patent does not constitute eligible subject matter and is invalid for lack of enablement, this analysis will be strictly limited to the '680 patent. The threshold of utility "is not high: An invention is 'useful' . . . if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1365 (Fed. Cir. 1999). To fail the utility requirement, the claims must be totally inoperable. *See Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992) ("To violate § 101 the claimed device must be totally incapable of achieving a useful result."). As previously discussed, Millennium fails to prove this is so here.

Millennium repeats its argument that the asserted claims are not useful because they require definitive dose prediction. Specifically, Millennium asserts that "it is scientifically impossible to predict or determine the dosage of medication taken by a patient from a metabolite/creatinine ratio", the patent lacks utility. (Def.'s Opening Br. (dkt. #130) 59.) At the outset, Millennium's argument only succeeds if the court adopts its construction of element (f): "quantifying the concentration." That construction, as addressed earlier, was rejected, since it was founded on the flawed premise that the purpose of the patents was to provide a definitive dosage prediction. In order to provide such a result, the invention would have been required to teach the skilled addressee how to correct or adjust for *all* sources of variability in urine drug concentrations -- not just through creatinine normalization.

Nowhere in the '680 patent is this promise made. In fact, the specification

expressly acknowledges that the claimed method does not attempt to account for all sources of variability. ('680 patent at 11:11-19.) Because Millennium's utility argument is wedded to the erroneous premise that the invention seeks to predict dosage definitively, when it does not, its argument is rejected.

Contrary to Millennium's understanding of the' 680 patent, the claimed invention is directed to providing a method that allows for improvement in a doctor's ability to determine whether a patient has been taking medication as prescribed. As addressed earlier, and prior to the claimed invention, the only information gained from urine drug testing was the presence or absence of a drug (*i.e.*, the urine samples could only provide for positive or negative testing result). The invention here does more than this; it provides doctors with information that allows assessment of whether a patient "has been using the medication in a manner which is consistent with the prescription." (*Id.* at 3:17-19; *see also id.* at 4:50-54 (emphasis added).) The examples in the specification further demonstrate this.

On review of Millennium's briefing, there is nothing by way of evidence that establishes that the invention could *not* deliver on the new and useful improvements that are stated in the '680 specification. *See Juicy Whip*, 185 F.3d at 1365. This is Millennium's burden, even more so in the context of summary judgment.[31] While there is certainly room for argument that the invention could not predict or determine the dosage of medication, evidence proffered to support this point is only applicable had the court adopted Millennium's claim construction (which it did not). Because Millennium's

[31] *Schacht v. Wis. Dep't of Corr.*, 175 F.3d 497, 504 (7th Cir. 1999) (describing summary judgment as the "put up or shut up moment").

claim construction was not adopted -- and since there is no evidence to suggest that the invention does not deliver the claimed improvements over the prior art -- the '680 patent meets at least one objective in the specification and satisfies the utility requirement. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958 (Fed. Cir. 1983) ("When a properly claimed invention meets at least one stated objective, utility under § 101 is clearly shown.").

C. Infringement

Based on the undisputed positions of the parties on summary judgment and the rulings by the court above, there would appear to be just one arguable issue left for trial as to infringement: whether Millennium's RADAR Report infringes (f) of the '680 patent claims? Even more refined, there would appear to be a single factual dispute: whether the RADAR Report compares "a ratio between the concentration of the test metabolite from the patient to the set of known normative data specific to the reference metabolite concentration."

Even as to this narrow issue, Ameritox and Millennium both maintain that there is no material factual dispute, although they would draw opposite legal conclusions from those facts. Contrary to Millennium's position, however, the undisputed facts would seem to compel the conclusion that it infringes step (f) by use of the RADAR software:

> 1. Millennium is a clinical laboratory that competes in the medication-monitoring industry. (Pl.'s PFOFs (dkt. #163) ¶ 1.)

2. Millennium tests urine samples on behalf of doctors, nurses, and other health care providers who prescribe pain medications to treat chronic pain. (Pl.'s PFOFs (dkt. #163) ¶ 2.)

3. Healthcare professionals use Millennium's services to test specimens and monitor drug levels periodically in their patients to whom medications are prescribed. (Def.'s Resp. to Pl.'s PFOFs (dkt. #185) ¶ 3.)

4. The test results are provided to the requesting doctor via a detailed written report which Millennium calls "Rapid Assessment Drug Adherence Report" or "RADAR Report." (Pl.'s PFOFs (dkt. #163) ¶¶ 4, 5.)

Despite these undisputed facts, Millennium still argues in reply that there are two factual distinctions relieving it of any finding of infringement: (1) the health care provider, *not* Millennium, makes the comparison; and (2) an individual patient's doctor ultimately decides whether the comparison provided in the RADAR Report has any bearing on assessing a patient's over or under dosing based on a variety of other independent factors. (Def.'s Reply (dkt. #183) 62-65.)

The first distinction would appear contradicted by the undisputed facts, since Millennium contracts and produces the RADAR Report that provides a comparison of the ratio between the concentration of a test metabolite from a patient to a set of normative data, as laid out by the reasoning and facts outlined in Ameritox's opposition brief. (Pl.'s Opp'n (dkt. #172) 79-81.) Indeed, Millennium has provided RADAR Reports providing this comparative data for oxycodone. The court finds it difficult *not* to conclude that the skilled addressee (a trained toxicologist, who is familiar with clinical laboratory science) would view this comparative data as falling within the plain and ordinary meaning of element (f).

The second distinction morphs with the first and strikes the court as equally

meaningless, since the possibility that a doctor *may* ultimately decide to disregard whether an individual falls inside or outside the 95% confidence range established by the RADAR Report does not mean the report does not infringe, any more than a manufacturer of a thermometer could claim its product does not infringe because a doctor may discount the results of a low or high thermometer reading. Similarly, the fact that the "RADAR Report includes an explicit disclaimer, warning physicians that Millennium makes no interpretations regarding the patient through the RADAR Report" (Def.'s Reply (dkt. #183) 72), does not mean the Report did not convey the comparison contemplated by (f) of the '680 claims.

Even so, only Millennium actually moved for summary judgment on infringement. Pursuant to Federal Rule of Civil Procedure 56(f), therefore, the court will give Millennium ten days to advise in a supplemental brief why summary judgment should not be entered against it on the question of infringement of the '680 patent. No further briefing or oral argument will be allowed except by express order of the court.

ORDER

IT IS ORDERED that:

1) defendant Millennium Health, LLC's motion for summary judgment (dkt. #126) is GRANTED as to the '895 patent and DENIED as to the '680 patent as set forth above;

2) plaintiff Ameritox, Ltd.'s motion to file sur-reply (dkt. #192) is GRANTED; and

3) Millennium may have until March 2, 2015, to serve and file its response as to why summary judgment should not be entered against it on the question of infringement of the '680 patent.

Entered this 18th day of February, 2015.

BY THE COURT:

/s/

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William M. Conley
District Judge