IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MARYLAND, NORTHERN DIVISION

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CLASSEN IMMUNOTHERAPIES, INC.

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Plaintiff,

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v. CIVIL NO.: WDQ-04-2607

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BIOGEN IDEC, *et al.*,

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Defendants.

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MEMORANDUM OPINION

Classen Immunotherapies, Inc. ("Classen") sued Biogen Idec ("Biogen") and GlaxoSmithKline ("GSK") (collectively the "defendants") for patent infringement. Pending is claim construction. On June 7, 2013, the Court held a claim construction hearing.

I. Background[1]

Classen is the assignee of John B. Classen, M.D. ("Dr. Classen") inventor of the patents in suit. Biogen has licensed patents "relating to recombinant hepatitis B virus vaccines." ECF No. 207 ¶ 6. GSK and its affiliates manufacture and market several vaccines, including ROTARIX, CERVARIX, BOOSTRIX, PEDIARIX, INFANRIX, and ENGERIX-B. ECF No. 211 ¶ 6.

[1] The factual background is from the Third Amended Complaint.

Each of the three patents in suit is entitled "method and composition for an early vaccine to protect against both common infectious diseases and chronic immune mediated disorders or their sequelae." *See* ECF Nos. 219-1 to 219-3. According to the abstracts, each discloses "a method of immunization . . . provided for substantially preventing or reducing the symptoms of at least one infectious disease and at least one chronic immune mediated disorder." *Id.* The patents have the same specification.

The '139 patent has 70 claims, and the '739 patent has 113 claims. Each has two essential steps, (I) screening two or more immunizations schedules, and (II) immunizing according to the lower risk schedule. '139 patent col. 52-53; '739 patent col. 52. The '790 patent has 213 claims and three essential steps: (I) considering the association between an immunization schedule and one or more chronic immune mediated disorders, (II) screening one or more potential recipients, and (III) immunizing according to the considerations. '790 patent col. 51.

B. Procedural History

On August 10, 2004, Classen filed suit asserting infringement of the '139, '739, and two other patents. ECF No. 1. This Court dismissed Biogen and GSK under 35 U.S.C. § 271(e)(1) and granted summary judgment for the defendants, holding that the '139 and '739 sought to patent unpatentable

subject matter, *see, e.g.*, ECF Nos. 76, 151, 152. On December 22, 2008, the Federal Circuit affirmed. ECF No. 157. However, the Supreme Court granted certiorari, vacated, and remanded to the Federal Circuit. The Federal Circuit, over Judge Moore's dissent, affirmed in part, reversed in part, vacated in part, and remanded in part, holding that Biogen and GSK were not entitled to § 271(e)(1) safe harbor and the '139 and '739 were not ineligible for patenting. ECF No. 159. On December 8, 2011, the mandate issued.

On February 3, 2012, Classen filed an amended complaint. ECF No. 172. On May 29, 2012, the Court granted GSK's motion to dismiss contributory and willful infringement claims and denied as to other claims.[2] ECF No. 195. On August 9, 2012, the Court granted reconsideration but denied dismissal. ECF No. 214. On September 10, 2012, the parties filed the joint claim construction statement and opening briefs. ECF Nos. 219-221. On November 13, 2012, responsive briefs were filed. ECF Nos. 231-232.

On September 12 and 13, 2012, GSK filed requests for inter partes reexamination of the patents in suit at the Patent and Trademark Office ("PTO"). ECF Nos. 234-4 at 6, 234-6 at 5, 234-8 at 5. On October 24, November 19, and November 23, the PTO

[2] On June 20, 2012, Classen filed an amended complaint in accordance with this opinion. ECF No. 202.

granted the reexamination requests and issued First Office Actions rejecting all the asserted claims. See ECF Nos. 234-4 to 234-9.

On February 22, 2013, the Court denied the defendants' motion to stay pending reexamination, ordered Classen to serve infringement contentions compliant with Local Rule 804.1.a for 30 claims within 15 days of the claim construction ruling, and granted the defendants' motion for leave to file supplemental invalidity contentions. ECF No. 238.

On April 1, 2013, the defendants requested additional claim construction briefing because of alleged inconsistencies between Classen's representations to the PTO during reexamination and before this Court. ECF No. 241. Classen did not oppose the request. On April 18, 2013, the Court permitted the defendants to redepose Holohan and ordered supplemental briefing. On May 14, 2013, the defendants filed supplemental briefing. ECF No. 244. On May 28, 2013, Classen filed its brief. ECF No. 249.

On June 7, 2013, the Court held a claim construction hearing. Dr. Classen, Thomas V. Holohan, M.D., and Steven N. Goodman, M.D., M.H.S., Ph.D. testified.

## II. Analysis

### A. Legal Standard

Claim construction is a question of law, to be determined by the Court. *Markman v. Westview Instruments, Inc.*, 517 U.S.

370, 384 (1996). Specifically, "[c]laim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy."[3] Therefore, "district courts are not . . . required to construe every limitation present in a patent's asserted claims." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008). For instance, terms that are "commonplace" or that "a juror can easily use [] in her infringement fact-finding without further direction from the court" need not be construed because they "are neither unfamiliar to the jury, confusing to the jury, nor affected by the specification[4] or prosecution history[5]."[6]

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[3] *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997), *cert. denied*, 522 U.S. 950 (1997).

[4] The "specification" is "[t]he part of a patent application describing how an invention is made and used, the best mode of operation of the claimed invention, and the inventor's claims." *Black's Law Dictionary* 1528 (9th ed. 2009).

[5] Also termed "file wrapper," the prosecution history is "[t]he complete record of proceedings in the [PTO] from the initial application to the issued patent or trademark; specif[ically], a patent or trademark-registration application together with all documentation, correspondence, and any other record of proceedings before the PTO concerning that application." *Id.* at 704.

[6] *Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 528 F. Supp. 2d 967, 976 (N.D. Cal. 2007).

"Although a claim is not to be construed in light of the accused device, it must inevitably be construed in the context of the accused device." *Pulse Med. Instruments, Inc. v. Drug Impairment Detection Servs., Inc.*, No. DKC 07-1388, 2009 WL 6898404, at *2 (D. Md. Mar. 20, 2009). "It is only *after* the claims have been *construed without reference to the accused device* that the claims, as so construed, are applied to the accused device to determine infringement." *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1118 (Fed. Cir. 1985) (en banc) (emphasis in original).

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude."[7] Thus, when construing a claim, a court should give its words their "ordinary and customary meaning" as would be understood by "a person of ordinary skill in the art in question at the time of the invention."[8]

"The claim should be read within the context of the entire patent, including the specification." *Pulse*, 2009 WL 6898404, at *2. The specification "is always highly relevant to the claim construction analysis. Usually it is dispositive; it is

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[7] *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted), *cert. denied*, 546 U.S. 1170 (2006).

[8] *Phillips*, 415 F.3d at 1313.

the single best guide to the meaning of a disputed term."[9] "The specification functions as a dictionary to explain the claimed subject matter and define the terms used in the claims[, but] is to be used only to interpret words or phrases of a patent claim, not to add to, or detract from, the language of the claims."[10] "In some instances, the ordinary meaning of a claim as understood by a person of skill in the art will be readily apparent from the words themselves and in those situations, general language dictionaries may be of assistance." *Pulse*, 2009 WL 6898404, at *2 (*citing Phillips*, 415 F.3d at 1314).

"In addition to consulting the specification . . . a court should also consider the patent's prosecution history, if it is in evidence." *Phillips*, 415 F.3d at 1317 (internal quotation marks omitted). "The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution."[11] "Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus

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[9] *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

[10] *C.M.L. s.r.l. v. Ineco Indus. Navarra de Equipos y Comercio, S.A.*, 177 F. Supp. 2d 442, 445 (D. Md. 2001) (internal citation omitted).

[11] *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995), *cert. denied*, 516 U.S. 987 (1995).

is less useful for claim construction purposes." *Phillips*, 415 F.3d at 1317.

"In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence." *Vitronics*, 90 F.3d at 1583. However, extrinsic evidence, including expert and inventor testimony, dictionaries, and learned treatises,

> may be helpful to explain scientific principles, the meaning of technical terms, and terms of art that appear in the patent and prosecution history. Extrinsic evidence may demonstrate the state of the prior art at the time of the invention. It is useful to show what was then old, to distinguish what was new, and to aid the court in the construction of the patent.

*Markman*, 52 F.3d 967, 980 (Fed. Cir. 1995) (internal quotation marks omitted), *aff'd*, 517 U.S. 370 (1996). "In sum, extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Phillips*, 415 F.3d at 1319.

B. Claims in this Case

There are three sets of disputed claims that the Court will address in turn: (1) the "supplemental" claims whose constructions are supported by evidence from the reexamination

process, (2) the original disputed claims, and (3) the "agreed" claims for which issues remain.

1. Supplemental Claims

The defendants request that the Court construe three additional claim terms because of Classen's statements at reexamination. *See* ECF No. 244. The defendants rely on the principle that litigants are bound by their statements at the reexamination proceedings.[12] Classen has substantively opposed the defendants' arguments. ECF No. 249.

Reexamination in this case has not been completed. Courts have generally "declined to consider material from unconcluded reexamination proceedings." *F5 Networks Inc. v. A10 Networks, Inc.*, No. 2:10-CV-00654-MJP, 2011 WL 2681182 at *4 (W.D. Wash. July 8, 2011); *see also BarTex Research, LLC v. FedEx Corp.*, No. 6-07-CV-385, 2009 WL 5061838, at *4 (E.D. Tex. Dec. 14, 2009).

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[12] *See also, e.g., Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) ("It is axiomatic that claims are construed the same way for both invalidity and infringement."); *CVI/Beta Ventures, Inc. v. Tura LP*, 112 F.3d 1146, 1158 (Fed. Cir. 1997) ("[S]tatements made during prosecution or reexamination . . . [are] then binding in litigation."); *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution. Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers." (citations omitted)).

However, in *Tesco Corp. v. Weatherford International, Inc.*, 722 F. Supp. 2d 737 (S.D. Tex. 2010), the court did consider reexamination materials in claim construction. *See, e.g., id.* at 743-44. Similarly in *BeneficialInnovations, Inc. v. Blockdot, Inc.*, Nos. 2:07-CV-263-TJW-CE, 2:07-CV-555-TJW-CE (E.D. Tex. June 3 2010), the Court reconsidered its claim construction ruling based on reexamination arguments, relying on *Tesco*.[13] *See id.* at 2.

*Tesco* relied on *Procter & Gamble v. Kraft Foods Global, Inc.*, 549 F.3d 842 (Fed. Cir. 2008) for the principle of looking to incomplete reexamination proceedings. *Tesco*, 722 F. Supp. 2d at 741. *Procter & Gamble*, however, did not concern standard claim construction. In that case, the Federal Circuit held that the district court had abused its discretion in denying a preliminary injunction when it had "expressly refused to consider" several of the relevant factors.[14] *Procter & Gamble*, 549 F.3d at 847. In remanding the case, the Federal Circuit stated that

> the district court's consideration of the four factors [for issuance of a preliminary injunction] may require it to interpret the claims, which are presently under review by the PTO. The district court should monitor the proceedings

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[13] The defendants have not relied on these cases in their briefing, but did bring them to the Court's attention at the hearing.

[14] Denials--or grants--of preliminary injunctions are immediately appealable. 28 U.S.C. § 1292(a)(1).

> before the PTO to ascertain whether its construction of any of the claims has been impacted by further action at the PTO or any subsequent proceedings.

*Id.* at 848. This is because a preliminary injunction requires a finding of likelihood of success on the merits, which, in that case, might have required some form of claim construction. *See id.* at 847-48. That is far from the typical claim construction process during which reexamination is pending. If claim construction were necessary for resolution of the likelihood of success on the merits factor, the analysis would have required a prospective determination of the evidence that would be presented at a proper construction and the final construction applied when the claims were addressed on the merits. Accordingly, by the time the case reached claim construction or final resolution of the case, the PTO proceedings very well could have ended; thus the reexamination materials would be proper evidence for consideration.

This case is different: typical claim construction is before the Court. The reexamination process has not been completed and development of that record there will continue. *Procter & Gamble* is inapplicable and *Tesco* is unpersuasive. This Court will follow several others in declining to consider the prosecution history of the pending reexamination. *See F6 Networks*, 2011 WL 2681182, at *4 (collecting cases). Because the defendants' arguments for supplemental constructions are

supported nearly entirely by evidence from the reexamination, see ECF No. 244, the Court will not construe those terms.[15] Similarly, the Court will not consider the defendants' evidence from reexamination in construing the disputed terms.

2. Disputed Terms

There are 15 disputed claim terms. Several issues are relevant to multiple terms, and have in various documents been grouped by the parties according to issue. However, for the sake of clarity, the Court will address the terms by number, cross-referencing prior discussions when relevant. Differences in proposed constructions will be emphasized by underlining.

a. Terms 1 and 2

| **Claim Language** | **Classen's Proposed Construction**[16] | **The Defendants' Proposed Construction** |
|---|---|---|
| *"may be identified as a lower risk screened immunization schedule . . . with regard to the risk of developing said chronic immune mediated disorder(s)"*[17] | a screened immunization schedule which <u>is associated with a numerically lower rate of</u> chronic immune mediated | <u>may be identified whether or not that identification is actually made, as</u> a screened immunization |

[15] The Court's refusal to construe the term will not be an obstacle to the jury's understanding at trial. The defendants' proposed supplemental constructions are either explanatory parentheticals inserted into the claim language or additional language excluding certain types of studies. *See* ECF No. 244.

[16] Classen asserts that each of the terms does not require construction and should be given their plain and ordinary meaning, but generally gives an alternative construction.

[17] '139 patent, Claims 1(I(b)), 63(I(b)), 65(I(b)); '739 patent, Claims 1(I(b)), 71(I(b)), 96(I(b)).

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|---|---|---|
| | disorder(s) being compared which someone may or could interpret as a real risk (regardless of whether there is a statistically significant difference) | schedule which causes a decreased net risk of acquiring all the chronic immune-mediated disorders compared, such conclusion based upon the appropriate application or sound and recognized scientific and statistical principles |
| *"may be identified . . . as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s)"*[18] | a screened immunization schedule which is associated with a numerically higher rate of a chronic immune-mediated disorder(s) being compared which someone may or could interpret as a real risk (regardless of whether there is a statistically significant difference) | may be identified, whether or not that identification is actually made, as a screened immunization schedule which causes an increased net risk of acquiring all the chronic immune-mediated disorders compared, such conclusion based upon the appropriate application of sound and recognized scientific and statistical principles |

[18] '139 patent, Claims 1(I(b)), 63(I(b)), 65(I(b)); '739 patent, Claims 1(I(b)), 71(I(b)), 96(I(b)).

Classen asserts that no construction is required and the plain and ordinary meaning suffices. *See* ECF No. 219 at 28. As the parties' proposed constructions illustrate, there is significant ambiguity in the terms about what that process of identification requires. Accordingly, construction is required. *See U.S. Surgical Corp.*, 103 F.3d at 1568.

There are three main areas of disputes in the parties' construction of these related terms: (1) statistical principles, (2), causation, and (3) risk.

i. Statistical Principles

Classen asserts that the risk should be evaluated based on numerical difference,[19] not statistical significance. ECF No. 219 at 28-34. It bases this argument on the "practice of medicine" and notes that "[n]othing in the specification or the prosecution file history contradicts that." ECF No. 219 at 29. The defendants contend the specification reveals that statistical principles are to be used. *E.g.*, ECF No. 221 at 20-21.

The defendants are correct that the specification reveals significant reliance on statistical principles. For example:

- "In a preferred embodiment the size of the groups should allow determination of statistical significance during an acceptable period of time. Any *statistical method* that is deemed appropriate for the trial design

[19] For example, under Schedule A, 5 out of 10 patients developed diabetes, while under Schedule B, 4 out of 10 did.

by one skilled in the art may be acceptable." '139 patent, col. 29, ll.62-64 (emphasis added).

- "Given the desired change in incidence of disease one hopes to be able to detect, and *the statistical test one is employing*, one can determine the size of a population needed for the (*sic*) at least one treatment group and the one or more control groups to demonstrate *statistical significance* (p< or =0.05). '139 patent, col. 30, ll.2-7 (emphasis added).

- "The size of a group needed to determine if [a] dosing schedule provides protection against at least one infectious agent is generally smaller than that needed to detect an effect on reducing a chronic immune mediated disorder because the incidence of the former diseases are generally higher than the later diseases and the former may occur earlier in life than the later. If the end point of the study is the development of protective or neutralizing antibodies two hundred mammals or less may be sufficient. The trial preferably will utilize *any statistical method* that is acceptable and is congruent with the study design." '139 patent, col. 32, ll.19-29 (emphasis added).

- "At 16 weeks of age 54% of the untreated rats had developed diabetes and[/]or died compared to 20% in the vaccinated group. At 20 weeks of age 54% of the untreated rats had died compared to 25% in the vaccinated group. At 32 weeks the results were 54% versus 35% respective . . . which represents a 34% reduction in the incidence of diabetes. The difference between the two groups *were statistically significant* at 20 weeks (P=0.027). '139 patent, col. 41, ll.6-14 (emphasis added).

- "The data in Table I indicates that administration of vaccines after two months increases the incidence of diabetes while administration of vaccines at birth can prevent diabetes. The findings are *highly statistically significant.*" '139 patent, col. 42, ll.47-50 (emphasis added).

In contrast, the specification nowhere mentions "numerical difference," the construction sought by Classen. *Cf.* ECF No.

219 at 29 ("Nothing in the specification or the prosecution file history contradicts" Classen's proposed construction).

Even Bert Spilker's, *A Guide to Clinical Trials* (1991), on which Classen relies, supports the defendants' construction over Classen's. Spilker describes "Number Needed To Be Treated," on which Classen heavily relies as:

> Mathematically, the number of patients who must be treated to prevent one major adverse event is the reciprocal of the absolute risk reduction.[20] This number has a readily understood meaning to physicians and has numerous statistical advantages over the other expressions described above . . . . For example, for every seven patients treated with medicine X[,] one fewer patient will have a stroke.

ECF No. 221-3 at 47. Spilker's focus in describing this way to portray the information is "in a way that practicing physicians can easily understand." *Id.* That does not necessarily mean, that statistical principles do not underlie the analysis. Further, Spilker specifically states that Number Needed To Be Treated, as an expression, "has numerous *statistical advantages*." *Id.* Clearly, Spilker did not comprehend this method to be the renunciation of statistics that Classen appears to contemplate. *See* ECF No. 219 at 32. Given the lack of evidence supporting Classen's contention that only numerical

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[20] Spilker describes Absolute Risk Reduction as: "the difference in adverse event rates for two groups, usually control and treatment. The number is usually a decimal and does not make inherent sense to practicing physicians as a basis for making a choice among therapies." ECF No. 221-3 at 47.

difference is required, the specification is clear that use of statistical principles is required. The "scientific" principles to which the defendants refer are unclear, as is the "sound and recognized" modifier. The requirement of statistical analysis from the specification is sufficiently specific, without the "sound" or "scientific" modifiers.

The Court is mindful that it should not "import[] limitations from the specification into the claim." *Phillips*, 415 F.3d at 1323. Because "understanding how a person of ordinary skill in the art would understand the claim terms" is the Court's focus, *id.*, these passages of the specification inform interpretation of the claim terms. As Dr. Goodman has indicated, statistical principles are necessary for interpretation even of a coin toss. If two coins--each with an equal chance of showing heads or tails--are tossed, after 10 tosses, there is an 82% chance of the number of heads of the two coins being different; for 100 tosses, the chance is 94.4%. *See* ECF No. 221-13 ¶ 5; *Hr'g.* Without an understanding of the statistical principles involved, a person with ordinary skill in the art would be unable to "asses[] the possible contribution of the role of chance." ECF No. 221-13 ¶ 5. Accordingly, rather than adding limitations, the specification reflects the meaning of the claims to a person with ordinary skill in the art. *See Phillips*, 415 F.3d at 1323.

Classen also asserts the doctrine of claim differentiation for the proposition that statistical principles are not required in these terms. ECF No. 219 at 32. "Under the doctrine of claim differentiation, dependent claims are presumed to be of narrower scope than the independent claims from which they depend." *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003). Claim 51 of the '139 patent is "[t]he method of claim 20[21] where there is a statistically significant difference in the incidence of diabetes between the first and second groups or between a group of said subjects and a control group."

Claim 51 is clear that "a statistically significant difference is required." Statistical significance is a particular finding, unlike the mere application of statistical principles. *See* ECF No. 221-13 at ¶ 5 ("Assessing the role of chance does not absolutely require a threshold of statistical significance, but it does require some threshold for rejecting chance."). Accordingly, the presumption of claim differentiation is inapplicable.

ii. Causation

Despite their divergent proposed constructions--and their apparent belief as evidenced in the briefing--the parties

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[21] Claim 20 is "[t]he method of Claim 1 where the incidence of diabetes is compared."

actually *agree* that the *possibility*--as opposed to a requirement--of causation is required.[22] The specification--and Dr. Classen's declaration from earlier in this case--confirm that the possibility of causation is intended:

- "The data presented in the present specification shows that such an immunization schedule can *cause* or at least *substantially contribute* to the develop of chronic immune mediated disorders . . ." '139 patent, col. 4, ll.19-23 (emphasis added).

- "The present invention relates to the discovery that when one or more immunogens . . . is first administered at an early age . . . it can *substantially decrease* the incidence, frequency, prevalence or severity of, or prevent, at least one chronic immune mediated disorder . . . ." '139 patent, col. 7, ll.35-40 (emphasis added).

- "[E]arly administration of immunogens can cause the release of lymphokines that may accelerate the maturation of the immune system in a manner which reduces the likelihood of development of a chronic immune mediated disorder." '139 patent, col. 7, ll.49-53.

- "In contrast, the late administration of an immunogen *can cause* the release of lymphokines which may act as grow factors enabling autoimmune inducing cells to grow." '139 patent, col. 8, ll.4-6 (emphasis added).

- "The immunization schedules of the present invention induce an immune response in the subject sufficient to reduce at least one measure selected from the group consisting of incidence, prevalence, frequency

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[22] *See* ECF No. 219 at 25 ("The patent claims pertain to 'risk' which is the ***possibility*** of causation ***not proof*** of causation." (emphasis in original)); ECF No. 221 at 25 ("Defendants' prosed constructions, like the inventor's own understanding . . . require a practitioner to identify the 'possibility of causation' using sound and recognized scientific and statistical principles appropriate to the analysis at issue.").

at severity of at least one chronic immune mediated disorder . . . ." '139 patent, col. 11, ll.36-40.

- "Comparison of data from the one or more control groups to data from the (*sic*) at least one treatment group may be performed to determine if the treatment schedule *can modulate* at least one measure in at least one chronic immune mediated disorder." '139 patent, col. 29, ll.55-59.

- "The patent claims pertain to 'risk evaluation' which is the *possibility* of causation not *proof* of causation." ECF No. 66 at 48 (Dr. Classen's declaration in support of opposition to motion for summary judgment) (emphasis in original).

Nevertheless, the parties' proposed constructions do not adequately encompass the possibility of causation. Classen seeks construction of the claim terms to include "association," which it defines as "the connection or relationship between ideas, concepts or physical things."[23] ECF No. 220 at 16. Although a possible causal link is clearly an "association," that word does not connote the specificity necessary to fulfill the purposes of claim construction.[24] *See U.S. Surgical*, 103 F.3d at 1568.

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[23] Classen cites www.merriam-webster.com as a source for this definition, but the Merriam-Webster site does not contain this definition. *See http://www.merriam-webster.com/dictionary/association* (last accessed August 22, 2013).

[24] *See, e.g.*, ECF No. 221-13 ¶ 7. ("For example, it can be said that tobacco-stained fingers are 'associated with' lung cancer. However, such an association is meaningless to a practitioner who wishes to treat lung cancer. It would be absurd to suggest that one can treat lung cancer by washing one's hands to remove the tobacco-stains; therefore, the 'association' is meaningless.").

The defendants' proposed use of "causation" is similarly problematic. Although one could read the entire proposed construction as applying "may be identified" to mean that causation is not actually required, that is not the natural reading and would likely not convey to the jury the appropriate meaning. Because neither of the parties' proposed constructions is adequate, the Court will adopt a construction including the phrase "possible causation."

iii. Risk

The parties also propose divergent adjectives for describing "risk" as used in the claim terms. Classen proposes using "real risk," while the defendants propose "net risk." Neither of these terms is contained within the intrinsic evidence.

Classen's conception of "real risk" is unclear, but Holohan implies that it does not require statistical significance.[25] *See* ECF No. 219-5 at 9, 14, 23. "[I]t is something that may determine that you would choose or not choose a particular intervention. And what I'm talking about in terms of someone with skill in the art being able or could interpret as a real risk, it's in the eye of the beholder. Not every clinician would agree on the number of untoward events that would require

[25] Holohan did not elaborate at the hearing. However, Goodman testified that real risk is "risk you've established; not raw numbers." *Hr'g*.

them to change their practice." ECF No. 23-2 at 26-27, Tr. 124:21-125:5. The ambiguity of this term counsels against its use in the construction.

The defendants seek a construction including "net risk." They contend that a single risk must be considered with regard to all the disorders being screened in the schedules based upon the claim language--"said chronic immune mediated disorder(s)." ECF No. 221 at 17.

The defendants are correct that a single comprehensive risk for assessing all the screened disorders is necessary. As the parties note, the harms caused by some chronic immune mediated disorders--e.g., schizophrenia, or diabetes--are far greater than others--such as hay fever. *See* ECF Nos. 219 at 35, 221 at 17. The defendants' language of "net risk," however, does not indicate how the comparison is to be made, nor does it indicate how--if at all--the different chronic immune mediated disorders are to be weighed. "Net" is often used to mean some mathematical subtraction has been undertaken, but can also mean "balanced, final, [or] conclusive." *See* Oxford English Dictionary, net, *adj.* (3d ed., 2003). As either connotation is reasonable in this context, "net risk" only adds an additional word without diminishing the ambiguity.

Additionally, the defendants rely on Goodman's declaration that "a person of ordinary skill would have understood the term

to require evaluation of the net risk of acquiring all the chronic immune-mediated disorders *being compared.*" ECF No. 221-13 ¶ 8; *see* ECF No. 221 at 17. Accordingly, the word "all" in their proposed construction is superfluous. The definite article "the" already refers to the chronic immune mediated disorders being screened--whether there is one or multiple disorders being screened. Use of "net risk" and "all" does nothing to assist in the construction of the terms, and they will not be used.

| **Claim Language** | **Court's Construction** |
|---|---|
| *"may be identified as a lower risk screened immunization schedule . . . with the risk of developing said chronic immune mediated disorder(s)"* | may be identified, whether or not that identification is actually made, as a screened immunization schedule which possibly causes a decreased risk of acquiring the chronic immune mediated disorder(s) being compared, such conclusion based upon the application of statistical principles |
| *"may be identified . . . as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s)"* | may be identified, whether or not that identification is actually made, as a screened immunization schedule that possibly causes an increased risk of acquiring the chronic immune mediated disorder(s) being compared, such conclusion based upon the application of statistical principles |

b. Term 3:

| Claim Language | Classen's Proposed Construction | The Defendants' Proposed Construction |
|---|---|---|
| *"evaluating the association between said immunization schedule and one or more chronic immune mediated disorders"*[26] | evaluating the correlation between the immunization schedule and one or more chronic immune mediated disorders | evaluating the causal relationship, which is based upon the appropriate application of sound and recognized scientific and statistical principles, between said immunization schedule and one or more chronic immune mediated disorders |

For this term, the parties rely on their arguments about whether a causal relationship is required. ECF Nos. 219 at 39-40, 221 at 27-28. As discussed above, a possible causal relationship is the appropriate standard for the evaluation, and the use of statistical principles is required in the construction. *See supra*.

| Claim Language | Court's Construction |
|---|---|
| *"evaluating the association between said immunization schedule and one or more chronic immune mediated disorders"* | evaluating the possible causal relationship, which is based upon the application of statistical principles, between said immunization schedule and one or more chronic immune-mediated disorders |

[26] '739 patent, Claim 109(I).

c. Term 4

| Claim Language | Classen's Proposed Construction | The Defendants' Proposed Construction |
|---|---|---|
| "*comparing the incidence, prevalence or frequency of a chronic immune mediated disorder in a group . . . to that in a control group*"[27] | comparing the incidence, prevalence or frequency of the chronic immune-mediated disorder(s) being evaluated in a first group relative to the incidence, prevalence or frequency of the same chronic immune-mediated disorders in a control group | comparing the incidence, prevalence or frequency of all the chronic immune-mediated disorders being evaluated in a first group relative to the incidence prevalence or frequency of the same one or more chronic immune-mediated disorders in a control group |

The parties generally agree on the construction of this term but dispute whether the comparison is of "all" the chronic immune mediated disorders being screened or only a single one. *See* ECF Nos. 219 at 42, 221 at 10. Related to this dispute is Classen's attempt to change the agreed construction for Term 18. *See infra*.

The dispute of "all" arises from the inartfully drafted claim itself. Although part of disputed Term 3, rather than Term 4, step (I) of Claim 109 is "evaluating the association between said immunization schedule and *one or more* chronic immune mediated disorders by:." '739 patent col. 61, ll.41-42.

[27] '739 patent, Claim 109(I(a)).

This is immediately followed by substep (a), which includes Term 4: "comparing the incidence, prevalence or frequency of *a* chronic immune mediated disorder." '739 patent col. 61, ll.44-45. This is followed by the alternative substep (b), Term 5, *infra*: "comparing the risk of *said* chronic immune mediated *disorder*." '739 patent col. 61, ll.51-53. Because of this ambiguity, construction is necessary. Classen seeks to remedy the ambiguity by requesting "disorder(s)" in this term. The defendants seek to impose a requirement of "all" disorders.

The problem with the defendants' proposed construction is that it is internally inconsistent. It is not clear why the word "all" is used at the beginning of the term--for the first group--but "one or more" appears at the end--for the control group. In light of the Court's rejection of "all" in Terms 1 and 2, *see* supra, use of "all" could confuse the jury when only one chronic immune mediated disorder is being compared between the schedules. Use of "all" is inappropriate.

Nevertheless, the plain and ordinary meaning of this term will not suffice. Step I (Term 3) clearly provides for comparison of "one or more chronic immune mediated disorders," *see* '739 patent col. 61, ll.41-43, and substeps (a) (Term 4) and (b) (Term 5) are alternative parts of the method, *see* '739 patent col. 61, ll.44-53. In light of the specification's summary that the invention discovers "decreas[ing] the

incidence, frequency, prevalence or severity of, or prevent, *at least one* chronic immune mediated disorder," '739 patent, col. 7, ll.41-44, and the other independent claims in the '739 patent referring to chronic immune mediated disorder(s), *see*, '739 patent col. 52, l.47, col. 62, l.36, the best reading of this claim is that at least one disorder is contemplated. Accordingly, the Court will adopt Classen's proposed construction, with all references to "disorder" as "disorder(s)."

| **Claim Language** | **Court's Construction** |
|---|---|
| "*comparing the incidence, prevalence or frequency of a chronic immune mediated disorder in a group . . . to that in a control group*" | comparing the incidence, prevalence or frequency of the chronic immune-mediated disorder(s) being evaluated in a first group relative to the incidence, prevalence or frequency of the same chronic immune-mediated disorder(s) in a control group |

d. Term 5

| **Claim Language** | **Classen's Proposed Construction** | **The Defendants' Proposed Construction** |
|---|---|---|
| "*comparing the risk of said chronic immune mediated disorder associated between two or more immunization schedules*"[28] | comparing the numerical rate(s) of occurrence of the same chronic immune mediated disorder in two or more immunization schedules | comparing the risk of acquiring all the same chronic immune-mediated disorders being evaluated which are caused by immunizations schedules, such conclusion based upon the |

[28] '739 patent, Claim 109 (I(b)).

| | | |
|---|---|---|
| | | appropriate application of sound and recognized scientific and statistical principles |

The parties' arguments for this term are substantially the same as for Terms 1 and 2. *See* ECF Nos. 219 at 43, 221 at 27. Accordingly, the Court will construe the terms using similar language of causation and statistical principles.

| Claim Language | Court's Construction |
|---|---|
| *"comparing the risk of said chronic immune mediated disorder associated between two or more immunization schedules"* | comparing the risk of acquiring the same chronic immune-mediated disorder(s) being evaluated which are possibly caused by immunizations schedules, such conclusion based upon the application of statistical principles |

e. Term 6

| Claim Language | Classen's Proposed Construction | The Defendants' Proposed Construction |
|---|---|---|
| *"safe immunization . . . reflective of the analysis from I"*[29] | an immunization schedule which the immunizer believes is associated with an acceptable risk of inducing the chronic immune-mediated disorder | immunization which causes a decreased net risk of acquiring all the chronic immune-mediated disorders evaluated in (I), such conclusion based upon the appropriate application of |

[29] '739 patent, Claim 109(II).

| | | |
|---|---|---|
| | | sound and recognized scientific and statistical principles |

The parties' arguments are largely the same as those for Terms 1 and 2. *See* ECF Nos. 219 at 44-45, 221 at 29. Here, Classen introduces the term "acceptable risk" without providing any evidence in support.[30] Because the language of risk appropriately describes the analysis to be undertaken, the Court will construe this term as in Terms 1 and 2. *See supra*.

| Claim Language | Court's Construction |
|---|---|
| "*safe immunization . . . reflective of the analysis from I*" | immunization which possibly causes a decreased risk of acquiring the chronic immune-mediated disorders evaluated in (I), such conclusion based upon the application of statistical principles |

f. Term 7

| Claim Language | Classen's Proposed Construction | The Defendants' Proposed Construction |
|---|---|---|
| "*comparing the incidence, prevalence or frequency of at least one chronic* | Comparing the relative incidence, prevalence or | comparing the incidence, prevalence or frequency of one |

[30] *Cf.* ECF Nos. 219-5 (Holohan supplemental report) ("[A]n acceptable risk to a physician or clinician would often fall short of statistical causation or even statistical significance."), 232 (Classen's responsive brief) ("Determining what an 'acceptable risk' is implicates the practice of medicine--or rather the art of medicine--which is not always the exact science . . . .").

| | | |
|---|---|---|
| *immune-mediated disorder in said first and second groups"*[31] | frequency of the same one or more chronic immune-mediated disorders between said first and second group | or more chronic immune-mediated disorders in a first group relative to the incidence, prevalence or frequency of the same one or more chronic immune-mediated disorders in a second group |

The parties' constructions for this term are fairly similar. To the extent a construction is required, Classen asserts that its "proposal is simpler, less confusing, and more closely aligned with the original claim language, and is thus more readily understood." ECF No. 219 at 46. The defendants contend that Classen's proposal introduces "a new concept which has no place in the claim: relative risk,"[32] and argue that their construction "identifies with precision what must be compared." ECF No. 221 at 31.

A construction is required for this term because the claim language could be construed as separate comparisons within the groups--not between them. Although the Court--unlike the defendants--does not read "relative risk" in Classen's proposal,

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[31] '739 patent, Claim 110(I(b)).

[32] Although the parties have not provided a definition for "relative incidence, prevalence or frequency," Spilker defines "relative risk reduction" as the "control rate minus treatment group rate, divided by the control rate." *See* ECF no. 221-3 at 47.

the placement of "relative" within the proposed construction does create the new term of "relative incidence, prevalence or frequency," which is undefined and ambiguous. Accordingly, the Court will use the defendants' construction.

| Claim Language | Court's Construction |
|---|---|
| *"comparing the incidence, prevalence or frequency of at least one chronic immune-mediated disorder in said first and second groups"* | comparing the incidence, prevalence or frequency of one or more chronic immune-mediated disorders in a first group relative to the incidence, prevalence or frequency of the same one or more chronic immune-mediated disorders in a second group |

g. Terms 8 and 9

| Claim Language | Classen's Proposed Construction | The Defendants' Proposed Construction |
|---|---|---|
| *"lower risk screened immunization schedule . . . with regard to the incidence or severity of said chronic immune mediated disorder(s)"*[33] | a screened immunization schedule which is associated with a lower numerical rate of cases or a lower numerical rate of severe cases of the chronic immune-mediated disorder(s) being compared | screened immunization schedule which causes a decreased net risk of incidence or severity of all the chronic immune-mediated disorders being compared, such conclusion based upon the appropriate application of sound and recognized scientific and statistical |

[33] '739 patent, Claim 110(I(b)).

| | | |
|---|---|---|
| | | principles |
| *"higher risk screened immunization schedule with regard to the incidence or severity of said chronic immune mediated disorder(s)"*[34] | a screened immunization schedule which is associated with a higher numerical rate of cases or a higher numerical rate of more severe cases of the chronic immune-mediated disorder(s) being compared | screened immunization schedule which causes an increased net risk of incidence or severity of all the chronic immune-mediated disorders being compared, such conclusion based upon the appropriate application of sound and recognized scientific and statistical principles |

The parties' arguments for these terms are the same as those for Terms 1 and 2. *See* ECF Nos. 219 at 47-50, 221 at 221 at 15-26. Accordingly, the Court's analysis above on causation, risk, and statistical principles will be applied to these terms.

| **Claim Language** | **Court's Construction** |
|---|---|
| *"lower risk screened immunization schedule . . . with regard to the incidence or severity of said chronic immune mediated disorder(s)"* | a screened immunization schedule which possibly causes a decreased risk of incidence or severity of the chronic immune-mediated disorder(s) being compared, such conclusion based upon the application of statistical principles |
| *"higher risk screened* | a screened immunization |

[34] '739 patent, Claim 110(I(b)).

| | |
|---|---|
| *immunization schedule with regard to the incidence or severity of said chronic immune mediated disorder(s)"* | schedule which possibly causes an increased risk of incidence or severity of the chronic immune-mediated disorder(s) being compared, such conclusion based upon the application of statistical principles |

h. Term 10

| **Claim Language** | **Classen's Proposed Construction** | **The Defendants' Proposed Construction** |
|---|---|---|
| *"considering the association between said immunization schedule and one or more chronic immune mediated disorders"*[35] | considering the correlation between the immunization schedule and one or more chronic immune mediated disorders | considering the causal relationship, which is based upon the appropriate application of sound and recognized scientific and statistical principles, between said immunization schedule and one or more chronic immune-mediated disorders |

With the substitution of "considering" for "evaluating" this term is the same as Term 3, *supra*. Accordingly, the parties rely on the same arguments. *See* ECF Nos. 219 at 50, 221 at 28. The Court will construe this term as with Term 3.

[35] '790 patent, Claim 1(I).

| Claim Language | Court's Construction |
|---|---|
| *"considering the association between said immunization schedule and one or more chronic immune mediated disorders"* | considering the possible causal relationship, which is based upon the application of statistical principles, between said immunization schedule and one or more chronic immune-mediated disorders |

i. Term 11

| Claim Language | Classen's Proposed Construction | The Defendants' Proposed Construction |
|---|---|---|
| *"considering the risk of said chronic immune mediated disorder associated with said immunization schedule relative to at least one other immunization schedule"*[36] | considering the numerical rate(s) of a chronic immune mediated disorder associated with an immunization schedule, relative to the numerical rate(s) of occurrence of the same chronic immune-mediated disorder associated with at least one other immunization schedule | considering the risk of all the chronic immune-mediated disorders caused by the immunizations schedule, such conclusion being based upon the appropriate application of sound and recognized scientific and statistical principles, relative to the risk of the same one or more chronic immune-mediated disorders caused by at least one other immunization, such conclusion being based upon the appropriate |

[36] '790 patent, Claim 1(I(b).

| | | |
|---|---|---|
| | | application of sound and recognized scientific and statistical principles |

The parties' arguments for this term concern the same "all," causation, and statistical principles issues as in Terms 1 and 2. *See* ECF Nos. 219 at 53-54, 221 at 27. Accordingly, the Court will construe this term in accordance with the analysis above.

| Claim Language | Court's Construction |
|---|---|
| *"considering the risk of said chronic immune mediated disorder associated with said immunization schedule relative to at least one other immunization schedule"* | considering the risk of the chronic immune-mediated disorder(s) possibly caused by the immunizations schedule, such conclusion being based upon the application of statistical principles, relative to the risk of the same one or more chronic immune-mediated disorders possibly caused by at least one other immunization, such conclusion being based upon the application of statistical principles |

j. Term 12

| Claim Language | Classen's Proposed Construction | The Defendants' Proposed Construction |
|---|---|---|
| *"identifying at least one human subject who would be expected to be immunized safely with said one or more* | identifying at least one human subject who the immunizer expects to have an | identifying at least one human subject whom a practitioner would reasonably expect, |

| | | |
|---|---|---|
| *immunogens according to said immunization schedule reflective of the analysis from (I)"*[37] | acceptable risk of developing a vaccine induced chronic immune-mediated disorder if said human subject were immunized with one or more immunogens according to one of said schedules based upon the analysis in part (I) | based on the causal relationship concluded in (I), to have a decreased net risk of acquiring all the chronic immune mediated disorders considered in (I) if said human subject is immunized with said one or more immunogens |

The parties' arguments for their proposed constructions are based upon those for Terms 1, 2, and 6. *See* ECF Nos. 219 at 54-55, 221 at 29. The Court will construe this term accordingly.

| Claim Language | Court's Construction |
|---|---|
| "*identifying at least one human subject who would be expected to be immunized safely with said one or more immunogens according to said immunization schedule reflective of the analysis from (I)*" | identifying at least one human subject whom a practitioner would reasonably expect, based on the possible causal relationship concluded in (I), to have a decreased risk of acquiring the chronic immune mediated disorder(s) considered in (I) if said human subject is immunized with said one or more immunogens |

[37] '790 patent, Claim 1 (II).

k. Term 13

| Claim Language | Classen's Proposed Construction | The Defendants' Proposed Construction |
|---|---|---|
| *"immunizing said subject"*[38] | No construction required--plain and ordinary meaning | Immunizing said subject after said screening |

Classen asserts that this term is clear and there is no reason for the defendants' additional language. ECF No. 219 at 56. The defendants contend that the claim language and specification are clear that immunization must occur after screening. ECF No. 221 at 32-34.

"As a general rule the claim is not limited to performance of the steps in the order recited, unless the claim explicitly or implicitly requires a specific order." *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1345 (Fed. Cir. 2008). Each of the Claims containing this term has the same structure: Step I contains screening and Step II addresses immunizing. *See* '139 patent claims 1, 63, 65; '739 patent claims 1, 71, 96. As a general matter it is logical that immunization would occur after screening. Viewed in the context of the structure alone, it is not certain that screening must happen first: one could immunize and then screen to see if the immunization was proper.

[38] '139 patent, Claims 1(II), 63(II), 65(II); '739 patent, Claims 1(II), 71(II), 96(II).

However, the language of Step II implicitly requires that the screening must occur first. Each limitation contains at least one reference to "screened immunization schedule." *See* '139 patent Claim 1 col. 53, ll.18, 22; Claim 63 col. 58, ll.16-17; Claim 65 col. 59, ll.3, 5; '739 patent Claim 1 col. 52 l.57; Claim 71 col. 57, l.5, 9-10; Claim 96 col. 59, l.27, 31-32. The use of the past participle "screened" requires that the screening already has been done at the time of immunization. *See Tuna Processors, Inc. v. Hawaii Int'l Seafood, Inc.*, 327 F. App'x 204, 209-190 (Fed. Cir. 2009). Accordingly, to clarify that the steps must be performed in order, the Court will adopt the defendants' proposed construction.

| **Claim Language** | **Court's Construction** |
|---|---|
| *"immunizing said subject"* | immunizing said subject after said screening |

*1.* Term 14

| **Claim Language** | **Classen's Proposed Construction** | **The Defendants' Proposed Construction** |
|---|---|---|
| *"immunizing said humans . . . by a method identified in (I)"*[39] | No construction required--plain and ordinary meaning | immunizing said human by a method already having been identified in (I) |

[39] '790 patent, Claim 1(III).

The dispute over this term is similar to Term 13. *See* ECF Nos. 219 at 56-57, 221 at 33. However, the analysis for Term 13 does not directly apply here: the step containing the term contains no past participle; it reads in full "immunizing said human against one or more infectious disease by a method identified in (I)." '790 patent col. 51, ll.46-47.

Nevertheless, this step requires that Step I be undertaken first. One cannot logically use an identified method if that method has not yet been performed. *See Rambus Inc v. Rea*, No. 2012-1480, 2013 WL 3242241, at *8 ("It would make no sense for the second step to be performed first--telling the memory device to begin sampling write data--before the memory device was even instructed to perform a 'write' operation."). Accordingly, the defendants are correct that the method of Step I must have already been performed.

Nevertheless, in this case, no construction is necessary because the term itself is clear. As discussed, it would be illogical to use the method for immunization before performing it. This would be clear to a jury hearing the term. Accordingly, the Court will not adopt a construction for this term, and rely on the plain and ordinary meaning.

| **Claim Language** | **Court's Construction** |
|---|---|
| *"immunizing said humans . . . by a method identified in (I)"* | Plain and ordinary meaning |

m. Term 15

| Claim Language | Classen's Proposed Construction | The Defendants' Proposed Construction | The Defendants' Hybrid Construction |
|---|---|---|---|
| *"chronic immune-mediated disorder"*[40] | a disorder which is slow to develop, is persistent and with some diseases is recurring, and results from the abnormal functioning of the body's immune system, such as when it overreacts to a threat, or attacks the body's own cells and does not include (a) permanent sequela of acute immune response diseases, (b) diseases associated with live viral infections, or (c) sequela caused by chronic infections | disorder(s) in which the immune system is involved in the pathogenesis, which last longer than two months, and do(es) not include (a) permanent sequela of acute immune response diseases, (b) diseases associated with live viral infections, or (c) sequela caused by chronic infections | Disorder(s) which result from the abnormal function of the immune system, which last(s) longer than two months, and do(es) not include (a) permanent sequela of acute immune response diseases, (b) diseases associated with live viral infections, or (c) sequela caused by chronic infections |

[40] Also included are derivative terms such as "said disorder", "the disorder", and "that disorder." *See* ECF No. 220 at 44. '139 patent, Claims 1, 36, 37, 63, 65; '739 patent, Claims 1, 2, 3, 35, 42, 53, 66, 71, 72, 73, 96, 97, 109, 110; '790 patent, Claims 1, 2, 7, 10-19, 136-64, 191, 192, 196, 199, 200, 205, 206.

The parties' proposed constructions of this term are quite similar. Classen asserts that the defendants' addition of the phrase "which lasts longer than two months" is unsupported. ECF No. 219 at 58. The defendants contend that the two-month limitation is from the specification. ECF No. 221 at 35. They have also added "the word 'pathogenesis' which indicates that the disorder arises from the immune system, and reflects the meaning of '*immune mediated*' within this term." ECF No. 221 at 35. At the hearing, the defendants offered a hybrid construction using Classen's language of "abnormal function of the immune system" with which they do not disagree. *Hr'g.*

The specification defines "chronic immune mediated disorder" as

> one which lasts longer than two months, but does not include permanent sequela of acute immune response disease such as seizures and anaphylaxis, nor do such disorders include disease associated with live virus infections as in subacute sclerosing panencephalitis induced by measles vaccine. Chronic immune mediated disorders does not include sequela caused by chronic infections by live vaccines.

'139 patent, col. 9, ll.44-51. The defendants have not provided any other evidence for this definition.[41] The defendants assert that because Classen has defined this term, the Court should use Classen's definition. ECF No. 221 at 35.

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[41] The defendants did not seek Goodman's expert opinion on this term. *See* ECF No. 221-12 ¶ 11 (listing terms).

The defendants misconstrue the doctrine. One of the two exceptions to the rule giving claim terms "their ordinary and customary meaning as understood by a person of ordinary skill in the art" is "when a patentee sets out a definition and acts as his own lexicographer." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). "To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term' other than its plain and ordinary meaning." *Id.* (*quoting CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). The patentee "must clearly express" his intent to do so "in the written description." *Helmsderfer v. Bobrick Washroom Equip, Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008).

The defendants have not provided any evidence of the plain and ordinary meaning of this term. Similarly, there is no indication that the definition in the specification is an intended departure. Because the Court must not "import[] limitations from the specification into the claim," *Phillips*, 415 F.3d at 1323, and there is no other evidence for the two month limitation, the Court will not so construe this term. Because of the lack of evidence for construction of this term--and the parties agree about the majority of the construction--the Court will construe the term according to the defendants' hybrid proposal, with the exception of "two months."

| Claim Language | Court's Construction |
|---|---|
| *"chronic immune-mediated disorder"* | disorder(s) which result from the abnormal function of the immune system and do(es) not include (a) permanent sequela of acute immune response diseases, (b) diseases associated with live viral infections, or (c) sequela caused by chronic infections |

3. Agreed Terms with Remaining Issues

Although the parties agreed on the constructions of a number of terms, Classen seeks to change three. *See* ECF No. 220 at 2-4, 6-8. Classen asserts that the requested changes are mere "clarification[s]" or fix "grammatical typo[s]." *Id.* at 2-3. The defendants dispute these characterizations and seek to hold Classen to their agreements. *See id.* at 8.

Because claim construction is a matter of law, the Court is not obligated to follow the parties' agreements. *See Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995) ("[T]he trial judge has an independent obligation to determine the meaning of the claims, notwithstanding the views asserted by the adversary parties."). "In exercising this obligation, district courts are not bound by the stipulation of parties concerning claim terms." *Cross Atl. Capital Partners, Inc. v. Facebook, Inc.*, Civ. No. 07-2768, 2011 WL 941870, at *9

(E.D. Pa. Mar. 17, 2011) (collecting cases).[42] Accordingly, Classen's agreement does not remove this Court's obligation to construe the claims.

a. Term 16

| Claim Language | Agreed Construction | Classen's Proposed Construction[43] |
|---|---|---|
| "*infectious disease-causing organism associated immunogens*"[44] | any substance, derived from infectious disease-causing organisms, capable of inducing an immune response | any substance, derived from *an organism known to induce an infectious disease in said subject's species* ~~disease-causing organisms~~, capable of inducing an immune response |

The defendants assert that the specification supports the previously-agreed construction, and Classen should be held to its agreement. *See* ECF Nos. 220 at 6-7, 221 at 36. Classen asserts that "[i]t would be immaterial if the disease developed in spiders or birds, but not in mammals and humans. Since the claims are directed toward immunizing mammals and human beings,

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[42] *See also Semiconductor Energy Lab. Co., Ltd. v. Chi Mei Optoelectronics Corp.*, No. C 04-04675, 2006 WL 6130994, at *6 (N.D. Cal. Mar. 27, 2006) ("Defendants' second argument—that plaintiff has 'waived' its right to offer alternate constructions--has no bearing on the court's ability to determine the proper construction as a matter of law. A court is free to accept either party's proposed construction, or to reject both if both are flawed.").

[43] Additions are shown by italics and deletions by strikethrough.

[44] '139 patent, Claims 1, 63, 65; '739 patent, Claims 1, 71, 96, 110.

then the disease that is being immunized against must be present in mammals and human beings, not some foreign species," but does not provide any evidence to support this conclusion. *See* ECF No. 232 at 42.

The defendants are correct that the specification references cross-species immunization. In the examples, mice were given "commonly available human vaccines." '139 patent, col. 36, ll.12; col. 38-41. However, there is no indication whether the mice could actually contract the human diseases against which they were being vaccinated. Classen's concern about "spiders or birds" is overblown, as the inventions all speak solely to mammals. Viewed in this context, the agreed construction is appropriate, as there is no evidence justifying limiting the term to a single species.

| **Claim Language** | **Court's Construction** |
|---|---|
| "*infectious disease-causing organism associated immunogens*" | any substance, derived from infectious disease-causing organisms, capable of inducing an immune response |

b. Term 18

| **Claim Language** | **Agreed Construction** | **Classen's Proposed Construction**[45] |
|---|---|---|
| "*considering the incidence, prevalence or* | considering the incidence, prevalence or | considering the incidence, prevalence or frequency of ~~all~~ |

[45] Additions are shown by italics and deletions by strikethrough.

| | | |
|---|---|---|
| *frequency of a chronic immune mediated disorder in a first group . . . relative to that in at least one other group*"[46] | frequency of all the chronic immune mediated disorders in one group relative to the incidence, prevalence or frequency of the same one or more chronic immune-mediated disorders in at least one other group | *one or more of* the chronic immune mediated disorders in one group relative to the incidence, prevalence or frequency of the same one or more chronic immune-mediated disorders in at least one other group |

Classen asserts that its proposed change is merely typographical, which the defendants dispute. *See* ECF No. 220 at 3,7-8. This term--and the dispute over the construction--is very similar to the disputed Term 4. Although the defendants are correct that this is a substantive issue, the Court must resolve the dispute as a matter of law. *See Exxon Chem. Patents*, 64 F.3d at 1555; *Cross Alt. Capital Partners*, 2011 WL 941870, at *9.

Much like the Claim in Term 4, this term is a substep of the claim. Although the term limitation states "a chronic immune mediated disorder," earlier in the step the limitation has "one or more chronic immune mediated disorders." '790 patent, col. 51, ll.29-31. As with Term 4, the logical reading is carrying forward the "one or more"; the Court will construe the term accordingly.

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[46] '790 patent, Claim 1(I(a)).

| Claim Language | Court's Construction |
|---|---|
| "*considering the incidence, prevalence or frequency of a chronic immune mediated disorder in a first group . . . relative to that in at least one other group*" | considering the incidence, prevalence or frequency of the one or more of the chronic immune mediated disorders in one group relative to the incidence, prevalence or frequency of the same one or more chronic immune-mediated disorders in at least one other group |

c. Term 19

| Claim Language | Agreed Construction | Classen's Proposed Construction[47] |
|---|---|---|
| "*immunogenic agent(s)*"[48] | vaccine(s) which comprise(s) a pharmaceutically-acceptable composition comprising at least one immunogen in an amount such that, when administered according to an immunization schedule, it contributes to a desired effect against a chronic immune-mediated disorder | vaccine(s) which comprise(s) a pharmaceutically-acceptable composition comprising at least one immunogen in an amount such that, when administered according to an immunization schedule, it contributes to a desired effect ~~against a chronic immune-mediated disorder~~ |

Classen asserts that the "against a chronic immune-mediated disorder" language is erroneously part of the agreed

[47] Additions are shown by italics and deletions by strikethrough.

[48] '739 patent, Claims 21, 109.

construction, stating "[a]lthough Dr. Classen has recognized the interrelation between vaccines and chronic immune mediated disorders, this interrelation is not properly part of the definition of vaccine." ECF No. 220 at 4. The defendants assert no argument other than seeking to hold Classen to the agreement. *See id.* at 8.

Neither party has submitted any evidence for construction of this term. *Stedman's Medical Dictionary* gives "immunogenic" as a synonym for "antigenic," which it defines as "[h]aving the properties of an antigen." *Stedman's Medical Dictionary*, 108, 954 (28th ed. 2006). Antigen--a synonym of immunogen--is defined as:

> Any substance that, as a result of coming in contact with appropriate cells, induces a state of sensitivity or immune responsiveness and that reacts in a demonstrable way with antibodies or immune cells of the sensitive subject in vivo or in vitro. Modern usage tends to retain the broad meaning of [antigen], employing the terms 'antigenic determinant' or 'determinant group' for the particular chemical group of a molecule that confers antigenic specificity."

*Id.* at 105; *see id.* at 954 ("immunogen"). *Stedman's* defines vaccine as:

> Originally the live v. (vaccinia, cowpox) virus inoculated in the skin as prophylaxis against smallpox and obtained from the skin of calves inoculated with seed virus. Usage has extend the meaning to include essentially any preparation intended for active immunologic prophylaxis; e.g., preparations of killed microbes of virulent strains or living microbes of attenuated (variant or mutant) strains; or microbial, fungal, plant, protozoal, or metazoan derivatives or products.

*Id.* at 2081.

From these definitions, it is clear that the immunogens are generally administered through vaccines for the purposes of preventing diseases caused by virus or other microbes. Although preventing a chronic immune mediated disorder may also be a desired effect, it is clear that is not its only purpose.[49] The formerly agreed construction incorrectly implies that the only desired effect is the prevention of chronic immune mediated disorders. Accordingly, the Court will adopt Classen's proposed construction.

| **Claim Language** | **Court's Construction** |
|---|---|
| "*immunogenic agent(s)*" | vaccine(s) which comprise(s) a pharmaceutically-acceptable composition comprising at least one immunogen in an amount such that, when administered according to an immunization schedule, it contributes to a desired effect |

[49] *See also* '139 patent, col. 1, ll.16-21 ("The present invention involves the fields of immunology and medicine, and more particularly relates to immunization methods, and compositions used therewith, for immunizing young mammals, such as human infants and children, against at least one chronic immune mediated disorders, and, preferably, also against at least one infectious disease.").

4. Agreed Terms

The parties have agreed on constructions for several terms. ECF No. 220 at 50-51. The Court has reviewed these proposals and will adopt them with one exception.

The parties generally construe Term 21 "pediatric immunogen" and Term 22 "non-pediatric immunogen" in parallel, with the exception italicized:

| Term 21: "*pediatric immunogen*"[50] | Term 22: "*non-pediatric immunogen*"[51] |
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| immunogen that was routinely administered after birth to children less than 16 weeks old in *moderate* developed nations of moderate latitude in 1992 | immunogen not routinely administered to children prior to 16 weeks in *modern* developed nations of moderate latitude in 1992 |

The discrepancy between these constructions is "*moderate* developed nations" in Term 21 and "*modern* developed nations" in Term 22. "*Moderate* developed nations" is ungrammatical and does not appear to be what the parties intended. A Google search of that phrase returned four results, all from the same blog. *See* https://www.google.com/search?q=%22moderate+developed+nations%22 (last accessed August 22, 2013). The specification states that "[d]eveloped countries have expensive water purification and sewer systems that reduce an infant's exposure to the pathogens" and "may include the United States, Canada and the European

[50] '739 patent, Claims 21, 30, 45.

[51] '739 patent, Claims 21, 30, 45.

nations listed in the table pertaining to Example 101." '139 patent, col. 30, ll.10-12, 17-19. This indicates that "modern," not "moderate" is the appropriate word. Accordingly, the Court will use "modern developed nations" for both terms.

III. Constructions

The 26 terms as construed by the Court--including those agreed by the parties--are as follows:

| Claim Language | Patent Claims | Court's Construction |
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| 1. "*may be identified as a lower risk screened immunization schedule . . . with regard to the risk of developing said chronic immune mediated disorder(s)*" | '139 patent, Claims 1(I(b)), 63(I(b)), 65(I(b)); '739 patent, Claims 1(I(b)), 71(I(b)), 96(I(b)). | may be identified, whether or not that identification is actually made, as a screened immunization schedule which possibly causes a decreased risk of acquiring the chronic immune mediated disorder(s) being compared, such conclusion based upon the application of statistical principles |
| 2. "*may be identified . . . as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s)*" | '139 patent, Claims 1(I(b)), 63(I(b)), 65(I(b)); '739 patent, Claims 1(I(b)), 71(I(b)), 96(I(b)). | may be identified, whether or not that identification is actually made, as a screened immunization schedule that possibly causes an increased risk of acquiring the chronic immune mediated disorder(s) being compared, such conclusion based upon the application |

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| | | of statistical principles |
| 3. *"evaluating the association between said immunization schedule and one or more chronic immune mediated disorders"* | '739 patent, Claim 109(I). | evaluating the possible causal relationship, which is based upon the application of statistical principles, between said immunization schedule and one or more chronic immune-mediated disorders |
| 4. *"comparing the incidence, prevalence or frequency of a chronic immune mediated disorder in a group . . . to that in a control group"* | '739 patent, Claim 109(I(a)). | comparing the incidence, prevalence or frequency of the chronic immune-mediated disorder(s) being evaluated in a first group relative to the incidence, prevalence or frequency of the same chronic immune-mediated disorder(s) in a control group |
| 5. *"comparing the risk of said chronic immune mediated disorder associated between two or more immunization schedules"* | '739 patent, Claim 109 (I(b)). | comparing the risk of acquiring the same chronic immune-mediated disorder(s) being evaluated which are possibly caused by immunizations schedules, such conclusion based upon the application of statistical principles |
| 6. *"safe immunization . . . reflective of the analysis from I"* | '739 patent, Claim 109(II). | immunization which possibly causes a decreased risk of acquiring the chronic immune-mediated disorders evaluated in (I), |

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| | | such conclusion based upon the application of statistical principles |
| 7. "*comparing the incidence, prevalence or frequency of at least one chronic immune-mediated disorder in said first and second groups*" | '739 patent, Claim 110(I(b)). | comparing the incidence, prevalence or frequency of one or more chronic immune-mediated disorders in a first group relative to the incidence, prevalence or frequency of the same one or more chronic immune-mediated disorders in a second group |
| 8. "*lower risk screened immunization schedule . . . with regard to the incidence or severity of said chronic immune mediated disorder(s)*" | '739 patent, Claim 110(I(b)). | a screened immunization schedule which possibly causes a decreased risk of incidence or severity of the chronic immune-mediated disorder(s) being compared, such conclusion based upon the application of statistical principles |
| 9. "*higher risk screened immunization schedule with regard to the incidence or severity of said chronic immune mediated disorder(s)*" | '739 patent, Claim 110(I(b)). | schedule which possibly causes an increased risk of incidence or severity of the chronic immune-mediated disorder(s) being compared, such conclusion based upon the application of statistical principles |

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| 10. "*considering the association between said immunization schedule and one or more chronic immune mediated disorders*" | '790 patent, Claim 1(I). | considering the possible causal relationship, which is based upon the application of statistical principles, between said immunization schedule and one or more chronic immune-mediated disorders |
| 11. "*considering the risk of said chronic immune mediated disorder associated with said immunization schedule relative to at least one other immunization schedule*" | '790 patent, Claim 1(I(b). | considering the risk of the chronic immune-mediated disorder(s) possibly caused by the immunizations schedule, such conclusion being based upon the application of statistical principles, relative to the risk of the same one or more chronic immune-mediated disorders possibly caused by at least one other immunization, such conclusion being based upon the application of statistical principles |
| 12. "*identifying at least one human subject who would be expected to be immunized safely with said one or more immunogens according to said immunization schedule reflective of the analysis from (I)*" | '790 patent, Claim 1 (II). | identifying at least one human subject whom a practitioner would reasonably expect, based on the possible causal relationship concluded in (I), to have a decreased risk of acquiring the chronic immune mediated disorder(s) |

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| | | considered in (I) if said human subject is immunized with said one or more immunogens |
| 13. *"immunizing said subject"* | '139 patent, Claims 1(II), 63(II), 65(II); '739 patent, Claims 1(II), 71(II), 96(II). | immunizing said subject after said screening |
| 14. *"immunizing said humans . . . by a method identified in (I)"* | '790 patent, Claim 1(III). | Plain and ordinary meaning |
| 15. *"chronic immune-mediated disorder"* | '139 patent, Claims 1, 36, 37, 63, 65; '739 patent, Claims 1, 2, 3, 35, 42, 53, 66, 71, 72, 73, 96, 97, 109, 110; '790 patent, Claims 1, 2, 7, 10-19, 136-64, 191, 192, 196, 199, 200, 205, 206. | disorder(s) which result from the abnormal function of the immune system and do(es) not include (a) permanent sequela of acute immune response diseases, (b) diseases associated with live viral infections, or (c) sequela caused by chronic infections |
| 16. *"infectious disease-causing organism associated immunogens"* | '139 patent, Claims 1, 63, 65; '739 patent, Claims 1, 71, 96, 110. | any substance, derived from infectious disease-causing organisms, capable of inducing an immune response |
| 17. *"protecting against or inducing a chronic immune-mediated disorder in said first and said second groups"* | '139 patent, Claims 1(I(b)), 63(I(b)), 65(I(b)); '739 patent, Claims 1(I(b)), 71(I(b)), 96(I(b)). | Protecting against or inducing the same one or more chronic immune-mediated disorders in said first group and said second group |
| 18. *"considering the incidence, prevalence or frequency of a chronic immune* | '790 patent, Claim 1(I(a)). | considering the incidence, prevalence or frequency of the one or more of the |

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| *mediated disorder in a first group . . . relative to that in at least one other group"* | | chronic immune mediated disorders in one group relative to the incidence, prevalence or frequency of the same one or more chronic immune-mediated disorders in at least one other group |
| 19. "*immunogenic agent(s)"* | '739 patent, Claims 21, 109. | vaccine(s) which comprise(s) a pharmaceutically-acceptable composition comprising at least one immunogen in an amount such that, when administered according to an immunization schedule, it contributes to a desired effect |
| 20. "*immunogen(s)"* | '139 patent, Claims 26, 28; '739 patent, Claims 4-6, 8-12, 21, 25-27, 30, 34, 42, 45, 46, 55-58, 89-91, 97, 109, 110, 113; '790 patent, Claims 1, 5, 6, 8, 20-29, 40-116, 165-169, 191, 192, 196, 199, 200, 205 | Any substance(s) capable of inducing an immune response |
| 21. "*pediatric immunogen"* | '739 patent, Claims 21, 30, 45 | immunogen that was routinely administered after birth to children less than 16 weeks old in modern developed nations of moderate latitude in 1992 |

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| 22. "*non-pediatric immunogen*" | '739 patent, Claims 21, 30, 45 | immunogen not routinely administered to children prior to 16 weeks in modern developed nations of moderate latitude in 1992 |
| 23. "*early immunogen*" ('139 patent) | '139 patent, Claims 1, 3, 4, 63, 64, 65 | first dose of at least one infectious disease-causing organism associated immunogen, which is given to both groups and is given sooner after birth according to one or more of the screened immunization schedules than according to one or more of the other screened immunization schedules, regardless of its time of administration in the latter schedule(s) |
| 24. "*early infectious disease-causing organism associated immunogen*" ('139 patent) | '139 patent, Claims 1, 63, 65 | first dose of at least one infectious disease-causing organism associated immunogen, which is given to both groups and is given sooner after birth according to one or more of the screened immunization schedules than according to one or more of the other screened immunization schedules, |

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| | | regardless of its time of administration in the latter schedule(s) |
| 25. "*early immunogen*" ('739 patent) | '739 patent, Claims 71, 75, 78, 81, 82, 96 | first dose of at least one infectious disease-causing organism associated immunogen, which is given to both groups and is given sooner after birth according to the first screened immunization schedule than according to the second schedule, regardless of its time of administration in the second group |
| 26. "*early infectious disease-causing organism-associated immunogens*" ('739 patent) | '739 patent, Claims 71, 96 | first dose of at least one infectious disease-causing organism associated immunogen, which is given to both groups and is given sooner after birth according to the first screened immunization schedule than according to the second schedule, regardless of its time of administration in the second group |

8/27/13
Date

William D. Quarles, Jr.
United States District Judge