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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

MEDIMMUNE, LLC,

Plaintiff,

v.

PDL BIOPHARMA, INC.,

Defendant.

Case Number C 08-5590 JF (HRL)

ORDER[1] GRANTING MEDIMMUNE'S MOTION FOR SUMMARY JUDGMENT ON INVALIDITY; GRANTING IN PART AND DENYING IN PART MEDIMMUNE'S MOTION FOR SUMMARY JUDGMENT ON PDL'S 6TH, 7TH, 9TH, AND 10TH COUNTERCLAIMS; GRANTING MEDIMMUNE'S MOTION FOR SUMMARY JUDGMENT ON PDL'S 8TH COUNTERCLAIM; GRANTING PDL'S MOTION FOR SUMMARY JUDGMENT ON MEDIMMUNE'S COUNT VII; AND TERMINATING AS MOOT PDL'S MOTION FOR SUMMARY JUDGMENT ON MEDIMMUNE'S PRIOR INVENTION DEFENSE.

[re: document nos. 761, 770, 775, 776, 777]

Before the Court are three motions for summary judgment brought by Plaintiff MedImmune, LLC ("MedImmune") and two motions for summary judgment brought by Defendant PDL BioPharma, Inc. ("PDL"). The Court has considered the moving and responding

[1] This disposition is not designated for publication in the official reports.

papers and the oral arguments of counsel presented at the hearing on December 2, 2010. For the reasons discussed below, MedImmune's motion for summary judgment will be granted with respect to invalidity and PDL's 6th, 8th, 9th, and 10th counterclaims; MedImmune's motion for summary judgment on PDL's 7th counterclaim will be denied. PDL's motion for summary judgment on MedImmune's Count VII will be granted, and PDL's motion for summary judgment on MedImmune's prior invention defense will be terminated as moot.

I. MedImmune's Motion for Summary Judgment of Invalidity

MedImmune first moves for summary judgment of invalidity with respect to Claim 28 of United States Patent No. 6,180,370 ("the '370 patent") on the ground that the claim was anticipated by prior art. PDL moves to strike the motion in its entirety, asserting that the theory upon which the motion is based was not disclosed in MedImmune's Invalidity Contentions as required by this Court's Patent Local Rules. Because MedImmune's Invalidity Contentions meet the minimum requirements of the Rules and PDL has not been prejudiced by any lack of specificity in MedImmune's anticipation claim, the motion to strike will be denied.

MedImmune contends that Claim 28 is invalid because the genus of immunoglobulins it discloses includes at least one that was anticipated by United States Patent No. 6,548,640 B1 ("the Winter '640 patent"). The parties agree that five of the six limitations established in Claim 28 are found in the Winter '640 patent. Their dispute is limited to whether the requirement in Claim 28 that there be seventy percent homology between the *donor* immunoglobulin framework and the *acceptor* immunoglobulin framework necessarily implies the same degree of homology between the *donor* framework and the *final humanized* immunoglobulin framework. Because Claim 28, unlike other claims in the '370 patent, does not limit substitutions between the acceptor immunoglobulin framework and final humanized immunoglobulin framework, the Court concludes that the homology requirement does not carry through, and accordingly, that the Winter '640 patent meets all the requirements of Claim 28.

A. Background

The '370 patent is concerned with the engineering of immunoglobulins, also known as antibodies, that are capable of binding to particular antigens within the human body. These

engineered (or humanized) immunoglobulins combine elements of donor immunoglobulins developed in mice or rats to bind particular antigens with acceptor human immunoglobulins that prevent the human immune system from recognizing the immunoglobulin itself as an antigen. Each immunoglobulin is comprised of four amino acid chains–two identical light chains and two identical heavy chains. Each chain has a constant and a variable region. The variable region, which determines an immunoglobulin's ability to recognize and bind to particular antigens, is comprised of three complementary determining regions ("CDRs") and four framework regions. While the three CDRs are primarily responsible for binding to the antigen, the framework positions and aligns them so that they have the correct orientation to interact with the other chains' CDRs, thereby forming the antigen binding site.

A number of different means have been used to create humanized antibodies. Originally, scientists combined the murine antibody's variable region (the six CDRs and the framework regions) with the constant region of a human antibody. This combination, referred to as a "chimeric" antibody, often triggered an immunogenic response in which the human immune system attacked the antibody as it would an antigen. Scientists therefore tried to humanize the antibody further by substituting only the CDRs in a human immunoglobulin while retaining the human framework. This technique, known as CDR grafting, produced a result superior to that associated with chimeric antibodies, but the antibodies still did not bind to the target antigens as well as desired. Several humanized immunoglobulins created using the CDR grafting approach were disclosed in a patents awarded to Sir Gregory Winter. One of these is the Winter '640 patent, which was issued on April 15, 2003.

Working to improve upon this technique, Dr. Cary Queen determined that while the CDRs are primary in the binding process, the framework of the variable region also affects the ability of a CDR to bind to the antigen. One of the approaches that Dr. Queen developed to improve binding affinity while avoiding an immunogenic reaction was the use of a human variable region framework that has a high degree of similarity or homology[2] to the murine

[2] Homology or sequence identity is the measure of the similarity between two amino acid sequences. To determine homology, the amino acid at each position in one sequence is

antibody.

Dr. Queen sought and was awarded the '370 patent, which includes claims pertaining to the refined process of creating humanized immunoglobulins as well as claims pertaining to the composition of certain humanized immunoglobulins. Claim 28, the only claim at issue here, is a composition claim that recites a class, or genus, of humanized immunoglobulins.[3] The claim reads, in its entirety:

> A humanized immunoglobulin having complementarity determining regions (CDRs) from a donor immunoglobulin, and heavy and light chain variable region frameworks from human acceptor immunoglobulin heavy and light chain frameworks which humanized immunoglobulin specifically binds to an antigen, wherein the sequence of the acceptor immunoglobulin heavy chain variable region framework is at least 70% identical to the sequence of the donor immunoglobulin heavy chain variable region framework, and the humanized immunoglobulin heavy chain variable region framework comprises at least 70 amino acids identical to those in the acceptor human immunoglobulin heavy chain variable region framework, wherein percentage sequence identity is determined by aligning amino acids in said frameworks by Kabat numbering.

'370 Patent Col. 171:27-172:4.

The parties agree that Claim 28, as construed previously by the Court, contains the following six limitations:

(1) The claimed composition must be a "humanized immunoglobulin."

(2) The final "humanized immunoglobulin" must have "CDRs from a donor immunoglobulin."

(3) The final "humanized immunoglobulin" must have "heavy and light chain variable region frameworks from human acceptor immunoglobulin heavy and light chain frameworks."

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compared to the amino acid found at the corresponding position in a second sequence. The total number of matches divided by the total length of the sequences being compared is deemed the percent identity. To determine which amino acids correspond, the sequence of the amino acids must be aligned by a system developed by Elvin A. Kabat. Kabat assigns a number to each amino acid position in an antibody sequence.

[3] *See* Claim Construction Order at 12:1-11 ("Claim 28 describes the invention of a humanized immunoglobulin and defines its characteristics, including the requisite degree of homology. Claim 28 does not define how that humanized immunoglobulin with those specified characteristics must be created.").

(4) The final "humanized immunoglobulin" must "specifically bind to an antigen."

(5) The "sequence of the acceptor immunoglobulin heavy chain variable region framework" must be "at least 70% identical to the sequence of the donor immunoglobulin heavy chain variable region framework."

(6) the "humanized immunoglobulin heavy chain variable region framework" must comprise "at least 70 amino acids identical to those in the acceptor human immunoglobulin heavy chain variable region framework."

Pl.'s Motion at 4:25-5:12; *see* Berl Decl, Ex. B ("Bluestone Infringement Report") at 12-49.

B. Legal Standard

1. Summary Judgment

A motion for summary judgment should be granted if there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48, 106 S.Ct. 2505, 2509-10, 91 L.Ed.2d 202 (1986). Material facts are those that might affect the outcome of the case under the governing law. *Id.* at 248. There is a genuine dispute about a material fact if there is sufficient evidence for a reasonable jury to return a verdict for the nonmoving party. *Id.* The moving party bears the initial burden of informing the Court of the basis for the motion and identifying portions of the pleadings, depositions, admissions, or affidavits that demonstrate the absence of a triable issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S.Ct. 2548, 2552, 91 L.Ed.2d 265 (1986). Where the party moving for summary judgment would not bear the ultimate burden of persuasion at trial, it must either produce evidence negating an essential element of the nonmoving party's claim or defense or show that the nonmoving party does not have enough evidence of an essential element to carry its ultimate burden of persuasion at trial. *Nissan Fire & Marine Ins. Co. v. Fritz Cos.*, 210 F.3d 1099, 1102 (9th Cir. 2000). If the moving party meets its initial burden, the burden shifts to the nonmoving party to present specific facts showing that there is a genuine issue of material fact for trial. Fed. R. Civ. P. 56(e); *Celotex*, 477 U.S. at 324, 106 S.Ct. at 2553.

The evidence and all reasonable inferences must be viewed in the light most favorable to

the nonmoving party. *T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626, 630-31 (9th Cir. 1987). Summary judgment thus is not appropriate if the nonmoving party presents evidence from which a reasonable jury could resolve the material issue in its favor. *Liberty Lobby*, 477 U.S. at 248-49, 106 S.Ct. at 2510; *Barlow v. Ground*, 943 F.2d 1132, 1134-36 (9th Cir. 1991).

2. Patent Invalidity

Inventions must be novel. 35 U.S.C. § 102. "Invalidity based upon lack of novelty (often called 'anticipation') requires that the same invention, including each element and limitation of the claims, was known or used by others before it was invented by the patentee." *Oney v. Ratliff*, 182 F.3d 893, 895 (Fed. Cir. 1999). Claims that cover a genus of compositions are invalid if even one of the claimed compositions is not new. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985).

Determining whether a patent has been anticipated is a two-step process. The first step is to construe the claim to determine its meaning, which is a question of law. *Elmer v. ICC Fabricating, Inc.*, 67 F.3d 1571, 1574 (Fed. Cir. 1995). The second step is to compare the properly construed claim to the disclosure of the reference to prior art to assess whether that disclosure meets all the limitations of the claim. *Id.* This step is a question of fact and involves three parts. First, the trier of fact must determine whether the challenging reference is prior art. *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576-78 (Fed. Cir. 1996). Second, the finder of fact must ascertain that the prior art is enabled so as to put the invention in the public's possession. *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1479 (Fed. Cir. 1986). Prior art patent references are presumed enabled. *In re Sasse*, 629 F.2d 675, 681 (C.C.P.A. 1980). Third, the trier of fact must determine if "each limitation of the claim is found in a single reference, either expressly or inherently." *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006). In order to overcome the presumption of validity under 35 U.S.C. § 282, the party seeking to invalidate the patent must present clear and convincing evidence that the claim was anticipated. *Atlas Powder*, 190 F.3d at 1347.

C. Discussion

1. Motion to Strike Pursuant to Patent Local Rule 3-3

PDL first moves to strike MedImmune's motion for failure to comply with Patent Local Rule 3-3. The Rule provides that a party accused of infringement must assert formal Invalidity Contentions that identify "each item of prior art that allegedly anticipates each asserted claim or renders it obvious," P.L.R. 3-3(a), state "[w]hether each item of prior art anticipates each asserted claim or renders it obvious," P.L.R. 3-3(b), and provide a chart "identifying where specifically in each alleged item of prior art each limitation of each asserted claim is found," P.L.R. 3-3(c). In addition, "[i]f obviousness is alleged," the party must provide "an explanation of why the prior art renders the asserted claim obvious." P.L.R. 3-3(b).

PDL asserts that prior to filing the instant motion, MedImmune never suggested that Claim 28 of the '370 patent was anticipated by the Winter '640 patent because the '370 patent requires a lesser degree of homology between the humanized immunoglobulin and the donor immunoglobulin than between the donor and acceptor immunoglobulins. Specifically, PDL contends that MedImmune failed to include such an assertion in its Invalidity Contentions as required by Rule 3-3, noting that all of the references to the Winter '640 patent in MedImmune's Invalidity Contentions and accompanying chart are directed to obviousness rather than anticipation. PDL also argues that MedImmune's proffered validity experts did not opine that the Winter '640 patent anticipates Claim 28 of the '370 patent.

However, MedImmune's Invalidity Contentions state expressly that "[a]sserted claim 28 of the '370 patent is *anticipated* and/or rendered obvious by the following references . . . ." Fletcher Decl., Ex. 12 ("Invalidity Contentions") at 2 (emphasis added). The subsequent list of references includes more than a hundred pieces of prior art, including the Winter '640 patent. *Id.* at 7. Referring to what the parties have called Limitation 5 and Limitation 6, the Invalidity Contentions note that Limitation 6 has been "used, disclosed, and suggested by prior art including [the Winter '640 patent]," while Limitation 5 "is neither necessary, critical, nor relevant to achieving the desired goals of the '370 patent, and cannot distinguish the claimed invention from prior art." *Id.* at 8. The Invalidity Contentions also contain an assertion that on

the basis of disclosures including the Winter '640 patent, "[p]ersons skilled in the art would have had reason to modify the humanized antibodies" to reach a seventy-percent identity between the donor and acceptor frameworks. *Id.* Finally, the chart accompanying the Invalidity Contentions lists citations to the Winter '640 patent under each limitation in the patent. The language under Limitation 5 states that "a person of ordinary skill in the art would have had reason to use an [acceptor framework] that retains the structural features of the [donor framework]." *Id.* Ex. A.

Courts in this district have held that the requrement of Rule 3-3(b) can be satisfied even where anticipation and obviousness are described using an "and/or" clause, because the court "assumes that a prior art reference that does not anticipate by going to all the elements of a claim will be used for . . . obviousness contentions." *Avago Tech. Gen. IP Pte Ltd. v. Elan Microelectronics Corp.*, No. C04-05385 JW (HRL), 2007 WL 951818 (N.D. Cal. Mar. 8, 2007); *see also Keithley v. The Homestore.Com*, 553 F. Supp. 2d 1148, 1150 (N.D. Cal. 2008). In *Keithley*, the court accepted a list of seventy-two prior art references "which did not specify whether each reference art anticipated the patent, rendered it obvious, or both" as satisfying Rule 3-3(b). 553 F. Supp. 2d at 1150.

At the least, MedImmune's grouping of more than a hundred references as prior art that "anticipated and/or made obvious" PDL's '370 patent approaches the minimum disclosure permitted under Rule 3-3(b). Had PDL demanded greater specificity with respect to MedImmune's assertion of anticipation or obviousness, it well may have obtained relief.[4] However, where the accompanying chart includes references showing where each of the claimed terms is found, anticipation is at issue. PDL's mistaken assumption that MedImmune was asserting only obviousness does not justify striking or disregarding the merits of MedImmune's motion.

It is true that MedImmune's statement with respect to Limitation 5 that "a person of ordinary skill in the art would have had reason to use an [acceptor framework] that retains the structural features of the [donor framework]" articulates an obviousness argument. However,

[4] PDL raised numerous other complaints as to the sufficiency of MedImmune's Invalidity Contentions. *See* Fletcher Decl., Ex. 13-14.

while Rule 3-3(b) requires that "[i]f obviousness is alleged," the party must provide "an explanation of why the prior art renders the asserted claim obvious," no such explanation is required with respect to anticipation. The additional requirements for obviousness reflect the different standards by which anticipation and obviousness are measured. While anticipation requires that a single source contain all the elements of a claim, a claim may be demonstrated to be obvious to one with ordinary skill in the art by a showing of suggestion or motivation to modify or combine the teachings of prior art to the claimed invention. *Avago*, 2007 WL 951818, at *3.

Keeping in mind the reasoning behind the rule, the Court concludes that a party's formal Invalidity Contentions need not supply a theory of anticipation as long as anticipation is asserted and the accompanying chart meets the Rule's requirement of indicating "where specifically in each alleged item of prior art each limitation of each asserted claim is found." PDL pointed out at oral argument that MedImmune's references to the Winter '640 patent do not discuss the homology of the Winter '640 patent. *See* Invalidity Contentions, Ex. A at 3, ("[Winter patent] at Cols. 1-6, 9-21, 23-27 and Figs discussed their in."). However, while this is literally true, the references do describe the basic structure of the donor and humanized antibodies from which the homology may be determined. *See* Rees Decl., Ex. A at ¶¶ 23-24.

PDL also contended at oral argument that had MedImmune properly raised its anticipation argument in its Invalidity Contentions, the Court could have addressed during claim construction the issue of how and to what extent Limitation 5 determines the makeup of the final humanized immunoglobulin framework. However, the precise scope of Limitation 5 is an issue in the obviousness analysis as well. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966) (announcing the test for obviousness, including an examination of "differences between the prior art and the claims at issue"). PDL thus cannot show that its proffered construction of Limitation 5 was compromised by the lack of specificity in MedImmune's anticipation contention.

PDL's Rule 4-2 disclosure argued that Limitation 5 should be construed to require a seventy percent identity between the donor and acceptor frameworks, but it did not address the degree of identity between the donor and final humanized immunoglobulin frameworks. *See*

PDL's Patent Local Rule 4-2 Statement (June 15, 2009) at 15. MedImmune similarly failed to specify how the limitation operates as a limitation on the final humanized immunoglobulin. *See* MedImmune's Patent Local Rule 4-2 Disclosure (June 15, 2009). Indeed, prior to and during claim construction, both parties appeared to treat Limitation 5 as a process limitation rather than product limitation. In its Invalidity Contention chart, MedImmune states with respect to Limitation 5 that "a person skilled in the art would have had reason to *use* [an acceptor framework] that retains the structural features of the [donor framework]." Invalidity Contention, Ex. A (emphasis added). PDL uses similar process language to distinguish the Winter '640 patent, claiming that the patent "does not describe or otherwise disclose the *use* of an acceptor framework region that is at least 70% identical to the donor framework region." Berl. Decl., Ex. C ("Bluestone Invalidity Report") at 36 (emphasis added). However, because Claim 28 subsequently has been construed as a product claim, the parties agree that the process by which Winter made his humanized immunoglobulin–i.e., whether or not a homologous acceptor framework is *used*--is "irrelevant." *See* Def.'s Op. at 18 n.4; *cf. G.E. Co. v. Wabash Appliance Corp.*, 304, U.S, 364, 373 (1938) ("Although in some instances a claim may validly describe a new product with some reference to the method of production, a patentee who does not distinguish his product from what is old except by reference, express or constructive, to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced.").

The parties' joint failure to address the present issue during claim construction thus stems from their mutual mistake about the purpose of Limitation 5, not MedImmune's lack of specificity in its Invalidity Contentions. Indeed, MedImmune's statement that the donor/acceptor homology is not "relevant to achieving the desired goals of the '370 patent, and cannot distinguish the claimed invention from prior art" is essentially the same argument that it makes in the instant motion. Invalidity Contentions at 8.

PDL also argues that it received no notice of MedImmune's anticipation argument from MedImmune's experts. However, the record suggests otherwise. Dr. Ravetch opines that the Winter '640 patent "satisfies every limitation of Claim 28 . . . with the possible exception of the

language directed to 70% heavy chain framework identity between the donor and acceptor immunoglobulin." Fletcher Decl. Ex. 4 (Ravetch Expert Report) ¶ 150. In a separate subsection of the "Anticipation and Obviousness" section of his report entitled "The Relationship Between the Framework Identity Language and the Final Humanized Immunoglobulin," Dr. Ravetch dedicates several paragraphs to MedImmune's argument concerning the relationship between the framework identity language and the final humanized immunoglobulin. *Id.* ¶¶ 194-196. The report states specifically that "[i]f the claim requires at least about 56% or at least about 59% identity between the donor and final heavy chain frameworks, then the antibodies disclosed in Verhoeyen, the Winter patent, and potentially Jones would all meet the homology requirement." *Id.* ¶ 195.

PDL also claims that MedImmune's alleged noncompliance with Rule 3-3(b) led to an "ambush" of PDL's expert, Dr. Bluestone, at his deposition. During that deposition, MedImmune's counsel walked Dr. Bluestone through a series of exhibits describing a hypothetical immunoglobulin he called "Humanized 922." Bluestone Dep. at 299:13-309:17. The composition of "Humanized 922" was identical to the immunoglobin described in the Winter '640 patent, although the process of creation was not. Mot. at 14. The exhibits included the sequence homology between the donor and acceptor frameworks as well as framework changes between the acceptor immunoglobulin and the final humanized immunoglobulin of the hypothetical antibody. *Id.* Dr. Bluestone tentatively agreed that the framework changes between the acceptor immunoglobulin and the humanized immunoglobulin were permitted and that this final humanized immunoglobulin met the requirements of Claim 28. See Bluestone Dep. 309:13 ("All right. I'll bite."). While he compared the homology of the donor and acceptor immunoglobulins (71.3%), mot. at 14; Bluestone Dep. 301:11-13, Dr. Bluestone was not given–and did not state that he required–the homology between the donor and final immunoglobin (less than seventy percent). Mot. at 14. PDL argues that this exercise was intended to mislead Dr. Bluestone into an admission that the Winter '640 patent comes within the scope of Claim 28.

If in fact MedImmune chose not to disclose its anticipation argument in order "ambush"

Dr. Bluestone with the "Humanized 922/Winter '640 immunoglobulin thought experiment, its strategy was ill-advised. The value of an expert witness's testimony is correlated to the expert's confidence in the application his or her learning and experience in the discipline. A "gotcha" moment is of much less use than an expert's reasoned analysis. Whether or not Dr. Bluestone would have answered MedImmune's questions differently had he known of MedImmune's anticipation claim is of less importance than his obvious uncertainty in analyzing the exhibits put before him on the spot. *See* Bluestone Dep. 303:3-4 ("[I]t's hard to tell with all the framework changes."); *see also id.* 308:9-309:4 (Dr. Bluestone request for assistance sorting through the exhibits). Accordingly, the Court gives such testimony little weight.[5]

2. Construction of Claim Limitations

The first step in determining whether a claim is anticipated is to construe the claim to determine its meaning, which is a question of law. *Elmer v. ICC Fabricating, Inc.*, 67 F.3d 1571, 1574 (Fed. Cir. 1995). After an extensive hearing and detailed briefing by the parties, the Court issued a claim construction order construing the disputed terms of Claim 28. *See* Claim Construction Order (Feb. 22, 2010). Following claim construction, the parties agreed on the six limitations described above. The parties now dispute how Limitation 5 (which states that the "sequence of the acceptor immunoglobulin heavy chain variable region framework [must be] at least 70% identical to the sequence of the donor immunoglobulin heavy chain variable region framework") acts to restrict the composition of the final humanized immunoglobulin. Whether the seventy percent homology requirement between the donor and acceptor frameworks is carried through to the final humanized immunoglobulin framework determines whether the Winter '640 patent meets all the limitations of Claim 28 of the '370 patent.

According to PDL, the humanized immunoglobulin described in the Winter '640 is distinguished from those covered by the PDL's '370 patent because the latter requires seventy percent (or sixty-one of eighty-seven) of the amino acids in the heavy chain variable region

[5] In contrast, as detailed below, Dr. Bluestone's admission that Claim 28 allows any framework substitutions between the acceptor immunoglobulin and final humanized immoglobulin–made in reference to an examination of his own infringement report–serves MedImmune's purposes much more persuasively and less theatrically.

framework of the final humanized immunoglobulin be identical to those in framework of the donor immunoglobulin, while only fifty-seven out of eighty-seven amino acids (65.5%) in the humanized immunoglobulin framework described in the Winter '640 patent are identical to those in the donor framework. MedImmune contends that Claim 28 thus requires a lesser degree of homology met by the immunoglobulin described by the Winter '640 patent.

Claim 28 involves the relationship among three different immunoglobulins: a donor immunoglobulin, an acceptor immunoglobulin, and the humanized immunoglobulin. The plain language of Limitation 5 requires that *acceptor* immunoglobulin framework be at least seventy percent identical to the *donor* immunoglobulin framework, which means that sixty-one of eighty-seven amino acids must be identical. Limitation 6 requires that the *humanized immunoglobulin* framework comprise at least seventy amino acids identical to those in the *acceptor* human immunoglobulin framework. Because Claim 28 is a composition claim rather than a process claim, *see supra* note 3, both parties read the two limitations together such that Limitation 5 applies to the composition of the final humanized immunoglobulin.

MedImmune contends that while Limitation 5 requires that sixty-one of eighty-seven amino acids in the acceptor immunoglobulin be identical to those in the donor immunoglobulin, it does not require that all of these identical amino acids be included in the final humanized immunoglobulin. It argues that because it requires that only seventy amino acids in the acceptor immunoglobulin framework be identical to those in the final humanized immunoglobulin framework, Limitation 6 allows for the substitution of *any* of the seventeen (87 - 70 = 17) remaining amino acids, even if the result is that the humanized immunoglobulin has less than seventy percent identity with the donor. Reading the two clauses in this way, MedImmune asserts that Claim 28 requires identity of as few as forty-four of eighty-seven amino acids between the *donor* immunoglobulin and the *final humanized immoglobulin*.

PDL takes the position that Limitations 5 and 6 should be read as mutually reinforcing: "[t]o be covered by claim 28 the amino acid sequence of the framework of a final humanized immunoglobulin must have at least 70 amino acids identical to the framework of the acceptor immunoglobulin (Limitation 6), and at least 61 *of those* amino acids must be identical to the

donor sequence (Limitation 5)." Op. at 15. In other words, the identity between the acceptor framework and the donor framework must be carried through to the humanized immunoglobulin. PDL supports its reading by explaining the different purposes served by the two limitations. According to PDL, there are two key aspects to the '370 patent: (1) retaining substantially the same affinity as the donor antibody to the target antigen; and (2) avoiding immunogenicity in humans. "The donor/humanized immonglobulin homology requirement of Limitation 5 is directed to the objective of retaining binding affinity, the acceptor/humanized immunoglobulin homology requirement of Limitation 6 is directed to reducing immunogenicity." *Id.*

PDL argues that the Court determined this issue in its Claim Construction Order when it indicated that "Claim 28 describes the invention of a humanized immunoglobulin and defines its characteristics, *including the requisite degree of homology*." Claim Construction Order at 12:5-7 (emphasis added); *see also id.* at 12:8-11 ("The language of the claim requires *substantial homology*, but it does not specify how that percent of identity must be achieved . . . .") (emphasis added). PDL also claims that MedImmune has conceded that "Limitation 5 is a limitation on the final humanized immunoglobulin." Mot. at 8:3. However, PDL ignores MedImmune's basic contention that while Limitation 5 *does* require a degree of homology in the final humanized immunoglobulin, the homology required is less than that claimed by PDL. Because the Claim Construction Order did not address the degree of homology required between the donor immunoglobulin and the humanized immunoglobulin, the Court must undertake that analysis here.

The starting point for ascertaining a claim's meaning is the claim language itself. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). While PDL emphasizes that a high degree of homology between the donor immunoglobulin and the final humanized immunoglobulin is consistent with the purposes of the patent, it cannot escape the fact that the actual language of Limitation 5 describes the relationship between the donor and acceptor immunoglobulins, not the donor and humanized immunoglobulins. The patentee easily could have described the latter relationship simply by using "humanized immunoglobulin" instead of "acceptor immunoglobulin" in the clause in question. As MedImmune points out, in a different

Queen patent issued prior to the '370 patent, the patentee did just that.[6] For whatever reason, the patentee chose not to make that comparison in Claim 28 of the '370 patent. A fundamental tenet of patent law is that courts are not permitted to redraft claims. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357 (Fed. Cir. 1999); *see also Quantum Corp. v. Rodime/ Plc*, 65 F.3d 1577, 1584 (Fed. Cir. 1995) ("Although we construe claims, if possible, so as to sustain their validity, it is well settled that no matter how great the temptations of fairness or policy making, courts do not redraft claims.") (internal citation omitted).

Because Limitation 5 does not relate the donor immunoglobulin framework directly to the final humanized immunoglobulin framework, the question is whether Limitation 6, which describes the homology required between the acceptor and the final humanized immunoglobulin, necessarily requires that the homology between the donor and acceptor immunoglobulins be carried through to the humanized immunoglobulin. Limitation 6 requires that the "humanized immunoglobulin heavy chain variable region framework" comprise "at least 70 amino acids identical to those in the acceptor human immunoglobulin heavy chain variable region framework." Nothing in this language indicates that the homology requirement between the donor and acceptor of Limitation 5 is carried through to the final immunoglobulin.

The Court next turns to the specification, *see Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc) ("claims must be read in view of the specification of which they are a part"), as well as the other claims in the patent, *see Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 ("Other claims of the patent in question, both asserted and unasserted, can also

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[6] Claim 1 of United States Patent No. 5,693,763 ("the '763 patent") reads in full:

> A humanized immunoglobulin having complementary determining regions (CDRs) from a donor immunoglobulin and heavy and light chain variable region frameworks from human acceptor immunoglobulin heavy and light chain frameworks, which humanized immunoglobulin specifically binds to an antigen with an affinity constant of at least 107M-1 and no greater than about four-fold that of the donor immunoglobulin, wherein the sequence of *the humanized immunoglobulin* heavy chain variable region framework is at least 65% identical to the sequence of the *donor immunoglobulin* heavy chain variable region framework and comprises at least 70 amino acid residues identical to an acceptor human immunoglobulin heavy chain variable region amino acid sequence.

Berl. Decl., Ex. G (claim 1); *see also id.* (Claim 11).

be valuable sources of enlightenment as to the meaning of a claim term") . In the case of the '370 patent, there are indications in the specification that the patent generally contemplated that with one exception the only substitutions between the acceptor immunoglobulin framework and the humanized immunoglobulin framework would be the replacement of amino acids in the acceptor framework with amino acids from the donor framework.[7] *See* '370 patent at '3:1-2 ("amino acids from the acceptor immunoglobulin chain may be replaced with amino acids from the CDR-donor immunoglobulin chain"); *id.* at 11:29-42 ("Most humanized immunoglobulins that have been previously described have comprised a framework that is identical to the framework of a particular human immunoglobulin chain . . . . The present invention includes criteria by which a limited number of amino acids in the framework of a humanized immunoglobulin chain are chosen to be the same as the amino acids at those positions *in the donor rather than in the acceptor* . . . ."). If these restrictions always were operative in Claim 28, then the homology between the final humanized immunoglobulin and the donor necessarily would be higher than that of the donor and the acceptor.[8]

However, the specification also includes a category of substitutions (Category 5) in which the amino acid in a given position in both the acceptor and donor sequences is rare for

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[7]The specification describes five instances in which amino acids from the acceptor immunoglobulin should be replaced. In Category 1, the amino acid is in a CDR (as opposed to the framework). *See* '370 patent 13:64-65. In Categories 2 through 4, the amino acids from the acceptor immunoglobulin should be replaced with those from the donor framework: Category 2 allows replacement if the acceptor immunoglobulin is rare in that position for human sequences while the donor amino acid is common; Category 3 allows replacement of amino acids in the positions immediately adjacent to one of the CDRs; and Category 4 allows replacement of amino acids in positions that are close to the CDRs and have a good probability of interacting with the amino acids in the CDRs. *See id.* 13:66-15:55. Category 5 provides that where the amino acids in a particular position in both the donor and acceptor sequences are rare in that position for human sequences, an amino acid that is in neither the donor nor the acceptor framework may be substituted. *See id.* 15:56-16:3.

[8] MedImmune notes that if Claim 28 did limit framework substitutions to the rules defined in the patent, PDL documents indicate that Synagis would not have infringed. MedImmune references an exchange between Dr. Queen and Dr. Maximiliano Vasquez which appears to indicate that the subsitutions were made in Synagis that fell outside of categories described above. *See* Fletcher Decl. Ex. 1 (Vasquez Dep.) 313:9-11; Fletcher Decl. Ex. 3 (email exchange between Dr. Vasquez and Dr. Queen).

human sequences, in which case it may be replaced with an amino acid that is typical for human sequences. '370 patent 15:62-67. MedImmune overstates this point somewhat by arguing that this type of substitution "intentionally *reduces* the final humanized immunoglobulin's identity with the donor." Reply at 6. In fact, a reduction in identity would occur only if the amino acids in both sequences *both* were rare in human sequences *and* identical to each other. The specification does not address such a circumstance directly.

A much more significant problem for PDL is that Claim 28 makes no reference to any restriction on substitutions. Other claims in the '370 patent explain in detail how substitutions between acceptor and humanized immunoglobulin frameworks are to be made. For example, Claim 29 contains language identical to that of Claim 28 except that it only requires a homology of sixty-five percent between the donor and acceptor frameworks. However, while Claim 28 requires that "the humanized immunoglobulin heavy chain variable region framework comprises at least 70 amino acids identical to those in the acceptor human immunoglobulin heavy chain variable region framework," Claim 29 states that

> "the humanized immonoglobulin heavy chain variable region framework comprises at least 70 amino acids identical to those in the acceptor immunoglobulin heavy chain variable region framework . . . wherein said humanized immunoglobulin comprises amino acids from the donor immunoglobulin heavy chain framework outside the Kabat CDRs that replace the corresponding amino acids in the acceptor immunoglobulin heavy chain framework, and each of these said donor amino acids:
> (I) is adjacent to a CDR in the donor immunoglobulin sequence, or
> (II) is capable of interacting with the CDRs."

'370 patent Claim 29. The patentee's decision not to include such restrictions in Claim 28 must be afforded considerable weight. *See Helmsderfer v. Bobrick Washroom Equipment, Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008) ("It is often the case that different claims are directed to and cover different disclosed embodiments. *The patentee chooses the language and accordingly the scope of his claim*." (emphasis added)).

The prosecution history also supports MedImmune's construction. In a draft of what later issued as Claim 28, Limitation 5 read: "wherein the sequence of the *humanized* immunoglobulin heavy chain variable region framework is at least 70% identical to the sequence of the *donor* immunoglobulin heavy chain variable framework." Fletcher Decl., Ex. 10 (portion

of the prosecution history of the Queen patents filed in response to Official Action dated Nov. 18, 1997) at 14 . Following a rejection by the examiner, the patentee amended Limitation 5 to its present form, which compares the acceptor and the donor immunoglobulins. *See* Weiswasser Decl. Ex. 10 (portion of the prosecution history of the Queen patents filed in response to Official Action dated April 29, 1999) at 12. MedImmune contends that PDL's interpretation impermissibly would undo this amendment *sub silentio*. *See Bd. Of Regents of the Univ. Of Texas Sys. v. BENQ Am. Corp.*, 533 F.3d 1362, 1370 (Fed. Cir. 2008) (refusing to construe "syllabic element" to mean "word" where patentee had amended claims in prosecution to replace "word" with "syllabic element").

PDL points out that new claims were added during prosecution that distinguished prior art based on the requirement of homology between the final immunoglobulin and donor immunoglobulin frameworks. *See* Weiswasser Decl. Ex. 10 at 21 (Amendment G (August 9, 1999). However, the language in these new claims contained the substitution restrictions included in Claim 29 but not in Claim 28. *See id.* at 12-13.

While extrinsic evidence may not be used to vary or contradict the claim language or the import of other parts of the specification, it may be used to help the Court come to the proper understanding of the claims. *Vitronics Corp. v. Conceptronics*, 90 F.3d 1576, 1584 (Fed. Cir. 1996). Here, MedImmune suggests that PDL's own experts did not read the patent as including any limitations on the substitutions that can be made between the acceptor framework and the final immunoglobulin framework. MedImmune points to Dr. Bluestone's agreement in his deposition testimony that "any framework substitutions" are permitted in Claim 28.[9] The deposition testimony of Dr. Queen also indicates that Claim 28 allows substitutions of amino acids beyond the rules described in the specifications; indeed, Dr. Queen expressly distinguishes Claim 28 from other claims that require that acceptor amino acids be replaced by donor amino

[9] Q: [W]ith respect to the claim [Claim 28], any framework substitutions are permitted not just those in categories 2 through 5; correct?
[Bluestone]: Correct.
Bluestone Dep. At 287:19-22.

acids.[10]

MedImmune also notes that in his invalidity analysis of Synagis and motavizumab, Dr. Bluestone carefully describes the homology between the donor and acceptor immunoglobulin frameworks but undertakes no analysis of whether that homology "carries over" to the final humanized immunoglobulin framework. Bluestone Infringement Report at 31-32. Similarly, MedImmune cites Dr. Queen's interrogatory response indicating that PDL's first humanized antibody–humanized anti-Tac–which was made during the fall of 1988, falls outside of the scope of Claim 28 because the donor and acceptor frameworks were only sixty-seven percent rather than seventy percent identical. Fletcher Decl., Ex. 2 at 262:7-265:14; Ex. 8 at 3:12-17. However, following the framework changes, the final sequence of humanized anti-Tac is eighty percent identical to the donor sequence. '370 patent 3:63-4:4. If the donor to final immunoglobulin analysis had been undertaken, the immunoglobulin would come within Claim 28.

Because Claim 28 is a product claim, the limitations described in the claim are operative only to the degree that they restrict the composition of the final product, in this case the final humanized immunoglobulin. *See In re Brown*, 459 F.2d 531, 535 (Fed. Cir.) ("[I]t is the patentability of the product claimed and not of the recited process steps which must be established."). Limitation 5 calls out the required homology between the donor and acceptor immunoglobulin frameworks, not between the donor and final humanized immunoglobulin. In this respect, the prosecution history, the language used in other PDL patents, and Dr. Bluestone's infringement analysis all are consistent with the plain language of the patent. Accordingly, Limitation 5 limits the composition of the final humanized immunoglobulin only to the degree that the homology between the donor and acceptor immunoglobulin frameworks is carried

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[10] Q: [I]t's your testimony that it's also within the scope of your invention to change that adjacent residue to a different amino acid that's not in the murine sequence?
[Queen]: "That would be in the scope, but I don't think that's what the rules said. In other words, it would necessarily bring it under the claims. Most of our claims, *not the ones at issue in this infringement case but in others*, are – say make a substitution of the donor amino acid. So if it was something other than the donor amino acid, it wouldn't bring it under the coverage of the claim.
Queen Dep. at 238:9-20 (emphasis added).

through to the final humanized immunoglobulin framework. Limitation 6, which describes the homology between the acceptor and final humanized frameworks, places no restrictions on framework changes as long as seventy amino acids are identical. This is clear not only from the language of the claim but also from the fact that the specification and other claims in the patent include such restrictions while Claim 28 does not. Both Dr. Bluestone and Dr. Queen understood Claim 28 in this way. Without any language in the claim restricting substitutions between the acceptor and the final humanized immunoglobulin beyond the requirement that seventy amino acids remain identical, Limitation 5 must be read only to require an identity of forty-four of the eighty-seven amino acids in the heavy chain variable region framework, or 50.6% homology.

While the teaching of the '370 patent as a whole is the use of acceptor immunoglobulin frameworks with a high degree of homology to the donor immunoglobulin frameworks in order to improve the binding affinity of the final humanized immunoglobulin to the target antigen, Claim 28 does not contain the restrictions present in other claims in the '370 patent or other patents of the same family. Without such restrictions, there is no justification for a narrower interpretation, even if such an interpretation would be more consistent with the ultimate purposes of the patent. PDL is bound by the language chosen by the patentee.

3. Anticipation

The second step of anticipation analysis–whether the prior art discloses all of the elements of the patent claim–is a question of fact. *Elmer v. ICC Fabricating, Inc.*, 67 F.3d 1571, 1574 (Fed. Cir. 1995). Summary judgment is appropriate only if there is no question of material fact as to whether the patent in fact is anticipated by prior art. *EnzoBiochem, Inc. v. Applera Corp.*, 559 F.3d 1325, 1332 (Fed. Cir. 2010).

Under § 102(a), a document is prior art only if it is published before the invention date. The Winter '640 patent was issued on April 15, 2003, resulting from a patent application filed on May 3, 1988. Winter '640 patent. According to PDL, the subject matter covered by Claim 28 was conceived in July 1988. Berl Decl., Ex. A at 3:10-11. Thus, there is no question of fact as to whether the Winter '640 patent is prior art.

The Court next must determine whether the prior art is enabled. However, prior art patent references are presumed enabled. *In re Sasse*, 629 F.2d 675, 681 (C.C.P.A. 1980). PDL has not attempted to rebut that presumption.

Finally, the trier of fact must determine if "each limitation of the claim is found in a single reference, either expressly or inherently." *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006). MedImmune has presented uncontested evidence that:

- (Limitation 1) The Winter '640 patent discloses "a fully 'humanized' anti-lysozyme antibody." Rees Expert Report at 72; Winter '640 patent 23:34-36.
- (Limitation 2) The final humanized antibody "contains the full sequences of all the CDRs found in the donor immunoglobulin." Rees Expert Report at 72; Winter '640 patent 12:32-14:49.
- (Limitation 3) The final humanized antibody contains heavy and light chain variable region frameworks from human acceptor antibody frameworks. Rees Expert Report at 72; Winter '640 patent 12:32-14:49.
- (Limitation 4) The final humanized antibody "specifically binds the target lysozyme antigen, with an affinity in the range of 5-50 nM." Rees Expert Report at 72; Winter '640 patent 24:29-50.
- (Limitation 6) The final humanized antibody's heavy chain framework has 87 of 87 amino acids identical to the human acceptor immunoglobulin (because the acceptor and final immunoglobulin frameworks are identical). Rees Expert Report at 72.

Accordingly, the Court finds and concludes that Limitations 1-4 and Limitation 6 of Claim 28 of the '370 patent are found in the Winter '640 patent.

It also is undisputed that the humanized immunoglobulins described in the Winter '640 have 65.5% homology between the donor and acceptor immunoglobulins. *See* Bluestone Decl. ¶ 6; Rees Expert Report at 73. Because the Winter '640 patent retains the heavy chain variable region framework from the human acceptor antibody, eighty-seven of eighty-seven amino acids between the acceptor immunoglobulin framework and final humanized immunoglobulin framework are identical. *See* Ravetch Expert Report at ¶ 148 ("[T]he heavy chain of the

humanized anti-lysozyme antibody used the framework region sequences of the NEW human antibody (also referred to as NEWM)."); Mot. fn. 3. Thus, the required degree of homology between donor immunoglobulin framework and the final humanized immunoglobulin framework is 65.5%, *see id.*, or fifty-six of eighty-seven amino acids. *See* Rees Expert Report at 73.

PDL consistently has contended that Limitation 5 is not disclosed by the Winter '640 patent. In his declaration in opposition to the instant motion, Dr. Bluestone restates the position take in his invalidity report that "Limitation 5 is not met in the humanized immunoglobulin disclosed in [the Winter '640 patent] because the identity between the donor and acceptor immunoglobulins used to create the humanized heavy chain is 65.5% (the '370 Patent requires 70%)." Bluestone Decl. ¶ 6 (internal quotation marks omitted). PDL argues that Dr. Bluestone's declaration creates a factual question as to whether Limitation 5 is met by the Winter '640 patent. *See Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1364-1365 (Fed. Cir. 1998) (holding that summary judgment should be denied where there are "differences in expert opinion" as to what a reference discloses).

However, Dr. Bluestone's opinion does not create a contested issue of fact. Both Dr. Bluestone and MedImmune's experts agree that the identity between the donor and acceptor immunoglobulin frameworks is 65.5%. *See* Bluestone Decl. ¶ 6; Rees Expert Report at 73. The issue actually in dispute is not the factual question of the degree of homology between the donor and acceptor immunoglobulin frameworks or between the donor and final immunoglobulin frameworks described in the Winter '640 patent, but the legal question of whether Claim 28 as written requires seventy percent homology between the donor and final frameworks. As discussed above, Claim 28 cannot be read to contain such a requirement. Limitation 5 requires only that forty-four of the eighty-seven amino acids, or 50.6%, be homologous. The Winter '640 patent, which demonstrates homology of 65.5% thus meets Limitation 5.

The Winter '640 patent thus meets all of the limitations of Claim 28. A patent that would exclude the public from practicing prior art is invalid, even if it also covers subject matter that is not in the prior art. *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999). Accordingly, the Court finds and concludes that Claim 28 of the '370 patent is anticipated and

therefore invalid.[11]

II. MedImmune's Motion for Summary Judgment on PDL's Contract Counterclaims.

PDL alleges that MedImmune violated its obligations under the parties' License Agreement by calculating the royalties owed to PDL for international sales of Synagis based on MedImmune's sales to Abbott rather than Abbott's sales to end-users. PDL contends that Abbott is a "sublicensee" of MedImmune under the terms of the License Agreement, and that MedImmune's failure to calculate its royalties based on Abbott's sales constitutes a breach of contract, breach of the implied covenant of good faith and fair dealing, and fraud. PDL also claims that MedImmune breached its contractual obligation to comply with PDL's request for an independent inspection of MedImmune's books and records. MedImmune moves for summary judgment on the grounds that Abbott is not a "sublicensee" under the terms of the License Agreement and that it complied with the agreement's inspection requirements.

A. Background

In July 1997, PDL and MedImmune entered into an agreement granting MedImmune a nonexclusive license to "make, import, have made, use or sell" antibody products that would otherwise infringe PDL's Patents. Fletcher Decl., Ex. 1 (License Agreement § 2.01). The agreement provides that MedImmune will pay PDL a quarterly royalty of "Three Percent (3%) of the Net Sales of all Licensed Products sold by MedImmune or its Affiliates or sublicensees to non-Affiliated third parties." *Id.* § 3.03. Transfers or sales between MedImmune and its "sublicensees and Affiliates" are not subject to royalty; instead, the royalty is to be calculated on the "subsequent sale . . . to a non-affiliated third party." *Id.*§ 3.04.

In December 1997, MedImmune executed an agreement making Abbott International, Ltd. ("Abbott") the exclusive distributor of Synagis, a pharmaceutical covered by the License Agreement, outside the United States ("the Distribution Agreement"). Fletcher Decl., Ex. 2. Abbott agreed to purchase Synagis from MedImmune at a transfer price equal to forty-five

[11] Because Claim 28 of the '370 patent is the sole basis of PDL's claim of infringement, MedImmune's motion for summary judgment on PDL's 8th counterclaim also will be granted. PDL's motion for summary judgment on MedImmune's prior invention defense will be terminated as moot.

percent of all of its net sales of Synagis below $200 million, and fifty percent of all of its net sales above $200 million. *Id.* The Distribution Agreement contains no express grant of a license to MedImmune's Synagis patents or a sublicense of any of other patents, including PDL's Queen Patents. *Id.* MedImmune also hired a German contract manufacturer, Dr. Karl Thomae GmbH ("Thomae"), to make Synagis for MedImmune to sell within the United States and for Abbott to resell internationally. Fletcher Decl., Ex 3.[12]

In 1998, when sales of Synagis commenced, MedImmune began submitting quarterly royalty reports to PDL showing both domestic and international sales of the product and the calculation of MedImmune's royalties. Fletcher Decl., Ex. 12. MedImmune paid royalties based on its revenue from its sale of Synagis to Abbott, rather than Abbott's subsequent sales to third-parties. *Id.*

In December 2008, MedImmune brought the instant action, seeking a declaratory judgment of patent non-infringment and invalidity of PDL's patents. It later added a claim that PDL had violated the "most favored licensee" clause of the License Agreement. In June 2009, seven months after MedImmune filed its complaint, PDL sought to exercise its right to inspect MedImmune's books and records pursuant to § 3.09 of the License Agreement. KPMG, the accounting firm selected by PDL, contacted MedImmune and stated that it intended as a part of the inspection to conduct interviews with MedImmune employees in a variety of fields. Fletcher Decl., Ex. 27 at 8. In light of the pending litigation, MedImmune requested that all communications relating to the inspection be submitted in writing and directed to its outside counsel, who would respond in writing. *Id.*, Ex. 28. KPMG complained that such an arrangment was "atypical," *id.*, Ex. 29, but it was instructed by PDL to proceed, *id.*, Ex 30. KPMG then proposed a nondisclosure agreement, which permitted it to release MedImmune's confidential information after three years. *Id.*, Ex. 33. MedImmune requested an indefinite term of confidentiality. *Id.* KPMG raised concerns with PDL about MedImmune's request for

[12] In February 2005, MedImmune and Abbott replaced the Distribution Agreement with an amended agreement reflecting the development of motavizumab, another licensed product. Fletcher Decl., Ex. 5. The Amended Distribution Agreement preserved the fundamentals of the parties' previous arrangement but increased MedImmune's share of sales. *Id.*

permanent nondisclosure and return of all confidential information subsequent to the review, as well as MedImmune's request that PDL sign the non-disclosure agreement. *Id.*, Ex 34. On November 16, 2009, KPMG informed MedImmune that it could not remove the sentence regarding confidentiality termination completely, but would increase the period of confidentiality to four years. *Id.*, Ex. 35. On November 19, MedImmune responded that KPMG's changes were "not acceptable," and on December 3, provided KPMG with a draft that included the same provisions to which KPMG had objected. *Id.*, Ex. 39. The parties then exchanged emails to arrange further negotiations. *Id.*

On December 10, 2009, PDL notified MedImmune that it was terminating the License Agreement. *Id.*, Ex. 40. Two business days later, PDL filed an amended answer in the instant case adding a claim for patent infringement and breach of contract claims for underpayment of royalties and failure to permit inspection. *See* Dkt. 244. In July 2010, PDL again amended its answer to add claims for fraud and breach of the implied covenant of good faith and fair dealing. *See* Dkt. 676.

B. Legal Standard

The interpretation of private contracts, including patent licenses, ordinarily is a question of state law. *Texas Instruments, Inv. v. Tessera, Inc.*, 231 F.3d 1325, 1329 (Fed. Cir. 2000) (citing *Volt Info. Sci., Inc. v. Bd. of Tr. Of Leland Stanford Junior Univ.*, 489 U.S. 468, 474 (1989)). Under California law, "interpretation of a written instrument becomes solely a judicial function only when it is based on the words of the instrument alone, when there is no conflict in the extrinsic evidence, or when a determination was made based on incompetent evidence."*City of Hope National Medical Center v. Genentech, Inc.*, 43 Cal. 4th 375 (2008).

Contracts are interpreted so as to effectuate the mutual intention of the parties at the time the contract is formed. Cal Civ. Code, § 1636. Such intent is to be inferred, if possible, solely from the written provisions of the contract. *AIU Ins. Co. v. Superior Court*, 51 Cal. 3d 807, 821 (1990). When the meaning of the words used in a contract is disputed, the court must "provisionally receive any proffered extrinsic evidence that is relevant to prove a meaning to which the language of the instrument is reasonably susceptible," determine if the language is

reasonably susceptible to the interpretation urged, and if so admit the evidence to aid its interpretation. *Wolf v. Walt Disney Pictures & Television*, 162 Cal. App. 4th 1107, 1126 (Cal. Ct. App. 2008). "[A] court gives the contract terms their ordinary and popular meaning unless the contracting parties use them in a technical or a special sense." *Id.* Where the contract is between sophisticated parties who regularly apply the basic tenets of patent law, the court assumes the "parties would have negotiated the clauses of the patent license agreement with knowledge of patent law." *Texas Instruments*, 231 F.3d at 1330.

C. Discussion

1. Abbott is not a licensee

The parties dispute the meaning of the terms "sublicense" and "sublicensee" in the License Agreement. While the agreement itself does not define these terms, § 2.01 grants MedImmune "a nonexclusive license under PDL's patent rights, . . . including the right to sublicense (subject to section 2.02), to make, import, have made, use or sell" licensed products. Section 2.02 sets forth the conditions on which MedImmune may exercise its right to sublicense, providing that MedImmune

> shall have the right to grant sublicenses of its rights under Section 2.01 only in connection with the assignment or license by it of a Licensed Product to a third party and only with respect to that Licensed Product. The right to grant sublicenses under Section 2.01 shall be on terms and conditions which are subject to and subordinate to the terms of this Agreement.

Sections 3.03 and 3.04 govern the payment of royalties where MedImmune has granted such a sublicense. Section 3.03 provides that MedImmune will pay PDL a three-percent royalty of the net sales of all licensed products sold "by MedImmune or its Affiliates or sublicensees to non-Affiliated third parties," while § 3.04 provides that

> [s]ales between and among MedImmune, its sublicensees and its Affiliates of Licensed Products which are subsequently resold to or to be resold by such sublicensees or Affiliates shall be subject to a royalty, but in such cases royalties shall accrue and be calculated on any subsequent sale of such Licensed Product to a non-affiliated third party.

PDL contends that any entity that contracts with MedImmune to sell licensed products for resale may be considered a sublicensee. Because the License Agreement contemplates that MedImmune will sell products to "sublicensees" who then resell them to "a non-affiliated third

party," PDL contends that "sublicensee" encompasses distribution agreements in which licensed products are sold by MedImmune for resale. PDL points to the exclusive nature of MedImmune's distribution agreement with Abbott, the fact that MedImmune's revenues are fixed to a percentage of Abbott's end-user sales, and Abbott's role in obtaining foreign regulatory approval of the product. However, this interpretation cannot be squared with the ordinary understanding of a patent license or the language of the License Agreement.

The License Agreement identifies the right to grant sublicenses as one arising "under PDL's patent rights" and specifies that MedImmune has the "right to grant sublicenses *of its rights*." Thus the License Agreement is clear that a sublicense must be a conveyance of some portion of the rights that *MedImmune* has been granted by PDL pursuant to the patent, not merely the sale of patented products. Nothing in the MedImmune-Abbott Distribution Agreement purports to convey any rights under PDL's patents to Abbott. Instead, the agreement provides for the sale of patented products, a right expressly granted to MedImmune by the License Agreement.

The right to practice a patent normally is conveyed expressly. *McCoy v. Mitsuboshi Cutlery Inc.*, 67 F.3d 917, 920 at *6 (Fed. Cir. 1995); *see Nano-Proprietary, Inc. v. Canon, Inc.*, No. A-05CA-258-SS, 2007 WL 628792 (W.D. Tex. Feb. 22, 2007) (finding that a sublicense existed because of express contractual grant of "intellectual property" to third party). While in some circumstances a license may be implied by the course of conduct between the parties, *McCoy*, 67 F.3d at 920, in this case, although the Distribution Agreement provides an exclusive geographic area in which Abbott may resell the product, nothing in the agreement suggests that MedImmune has conveyed any of PDL's patent rights to Abbott. Under controlling law, the mere sale of the product to a distributor for resale "does not create a sublicense." *Lisle Corp. v. Edwards*, 777 F.2d 693, 695 (Fed Cir. 1985) (sale to distributor for resale under its trademark did not constitute a sublicense), and this is true even where the distribution agreement is exclusive, *Unidisco, Inc. v. Schattner*, 824 F.2d 965 (Fed. Cir. 1987).[13] Because the License Agreement

[13] PDL notes that its United States patent rights are not exhausted when a patented product is manufactured and sold outside the United States. Def.'s Op. at 8 (citing *Jazz Photo*

makes no distinction between the scope of foreign and domestic sales, it would be unreasonable to infer that the parties intended that foreign distribution agreements would be considered sublicenses while domestic distribution agreements would not. Moreover, PDL has not directed the Court's attention to any way in which its foreign patents would be implicated by Abbott's resale of Synagis.

To be sure, MedImmune and Abbott *could* have contracted to extend to Abbott the same protection from infringement actions that the License Agreement affords to MedImmune. Had Abbott sought the right to import Synagis into the United States, or to manufacture it for itself, the royalty provision regarding sales by sublicensees clearly would apply to Abbott's sales. However, MedImmune and Abbott did not make such a contract.

Likewise, PDL could have contracted to create a royalty scheme under which MedImmune would pay royalties based on sales to end-users if MedImmune entered into any distribution agreements. However, by using the term "sublicensee" without any indication that the term would be understood in any way other than its normal sense, and by delineating explicitly the right to grant sublicenses as one arising under PDL's patent rights, the parties restricted the meaning of "sublicensee" to a conveyence of rights under PDL's patents.

PDL nonetheless argues that extrinsic evidence supports its construction. It notes that Abbott has referred to itself as a licensee and that PDL wrote to both Abbott and MedImmune referring to Abbott as sublicensee and was not corrected by MedImmune. LaMagna Decl. Ex. 2, 3. PDL also highlights a presentation in which MedImmune refers to its share of Synagis sales as a "royalty," *id.*, Ex. 4. It asserts that in the use of other licenses involving the Queen patents, the "international commercialization partners" of licensees have been treated as sublicensees. *Id.* Ex 9. Finally, PDL cites an industry practice of license agreements involving only the sale of

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Corp. v. ITC, 264 F.3d 1094, 1105 (Fed. Cir. 2001)). This is true, but these rights are not exhausted precisely because they are not implicated by such sale. *Fujifim Corp. v Benum*, 605 F.3d 1366 (Fed. Cir. 2010) ("[A]n infringing use must occur in the country where the patent is enforceable."). If Abbott were to buy Synagis overseas and import it into the United States, the foreign sale would not act as a license but instead would afford no protection at all from charges of infringement.

products.

None of this extrinsic evidence is sufficient to show that the disputed terms are reasonably susceptible to PDL's interpretation. Abbott's Rule 30(b)(6) witness confirmed that Abbott's understanding that Abbott does not have a license to Synagis. Gaffney Decl., Ex. 1. Indeed, an Abbott representative indicated that it sought but did not receive a license and instead settled for a distribution agreement. Fletcher Decl., Ex. 4 at 19. MedImmune was not obligated to correct PDL's characterization of Abbott as a sublicensee because the contract itself sets forth the means for designating sublicensees. *See* License Agreement § 2.02 (requiring MedImmune to promptly inform PDL following the execution of a sublicense). PDL's evidence regarding the "international commercialization partners" of its other licensees does not provide any details about the relevant agreements. In particular, the contracts between the licensees and their partners, which conceivably could show that the relationships are analogous, are not in the record. Finally, the testimony of PDL's expert that "an entity need not manufacture a licensed product to be considered a 'sublicensee' as that term is used in the industry," Lentz Decl. ¶ 7, provides no support for the proposition that a distribution agreement that expressly does *not* purport to convey patent rights nonetheless is a sublicense.

2. Abbott is not a *de facto* licensee

PDL argues alternatively that even though the MedImmune-Abbott agreement does not expressly convey a license to practice a patent, the terms of the agreement constitute a *de facto* sublicense. However, courts have found *de facto* sublicenses only where a licensee exercised its right to "have made" and to "sell" licensed products so as to grant a third-party an unlimited right to make and use the patented product. *See EI du Pont de Nemours v. Shell Oil Co.*, 498 A. 2d 1108 (Del. S. Ct. 1985). The theory never has been applied where the licensee has separate contracts with a manufacturer and distributor. *Cyrix v. Intel Corp.*, 77 F.3d 1381 (Fed. Cir. 1996) (distinguishing *du Pont* on the grounds that the licensee had separate agreements with a manufacturer and distributor).

In *EI du Pont de Nemours v. Shell Oil Co*, du Pont refused to grant Carbide a license to produce a patented product. Carbide then contracted with Shell, which held a license to make,

have made, use, and sell product covered under du Pont's patent but was precluded from entering into sublicenses. Shell agreed to sell Carbide as much of the product as Carbide required, while simultaneously contracting to have Carbide manufacture exactly that amount of product. The Supreme Court of Delaware held that Shell had exercised its right to "have made" and to "sell" so as give Carbide full rights to make and use the product–rights that amounted to a full sublicense. *See Cyrix Corp. v. Intel Corp.*, 77 F.3d 1381, 1387 (Fed. Cir. 1996) (explaining and distinguishing *du Pont*). Here, however, the Distribution Agreement involved only the sale of licensed products. There is no allegation, let alone evidence, that Abbott was authorized to make any licensed products.

PDL also contends that MedImmune's separate contracts with Abbott and Thomae taken together amount to a *de facto* sublicense. It proffers evidence that MedImmune contemplated an agreement with Boehringer, a European pharmaceutical company of which Thomae is a subsidiary, under which Thomae would manufacture and Boehringer would distribute Synagis. If such an agreement in fact had materialized, it is conceivable that it could have constituted a *de facto* license. However, PDL does not allege, nor is there any evidence, that Thomae and Abbott are affiliated or that MedImmune's contracts with them are anything other than separate arms-length business agreements.

At oral argument, PDL attempted to distinguish *Cyrix* on the basis that in that case both the licensee and the sublicensee manufactured products for the buyer, while in this case, Thomae produces all of the Synagis intended for Abbott and delivers it directly to Abbott. PDL argues that this circumstance means that Thomae is producing Synagis for *Abbott* rather than for MedImmune. However, because MedImmune's contracts with Abbott and Thomae are separate arms-length contracts and there is no evidence that Abbott and Thomae are affliated, PDL does not explain why Thomae's production capacity or delivery arrangements are relevant.

MedImmune's failure to pay royalties based on Abbott's sales to third parties is a necessary element of both PDL's sixth counterclaim for breach of contract and PDL's tenth

counterclaim for breach of the implied covenant of good faith and fair dealing.[14] Because Abbott is not a sublicensee under the contract, neither claim can survive summary judgment. PDL's ninth counterclaim for fraud alleges that MedImmune did not intend to keep its promise to pay royalties on the sales of its sublicensees. Because MedImmune was not required by the contract to make royalty payments on Abbott's sales, this claim necessarily fails as well.

3. Summary Judgment Is Not Appropriate with Respect to PDL's Counterclaim for Breach of the License Agreement's Inspection Provision.

PDL's seventh counterclaim is for breach of contract based on MedImmune's alleged refusal to "permit [PDL's] auditor to conduct the examination agreed to in the Patent License." MedImmune contends that the License Agreement is clear that the "examination agreed to" is one of "books and records" only, and that the undisputed facts show that MedImmune permitted such an examination.[15] Because the Court concludes that the License Agreement is ambiguous as to the scope of PDL's inspection rights and there is a conflict in the evidence as to the industry standard, summary judgment as to this counterclaim will be denied.

Although "the intention of the parties is to be ascertained from the writing alone if

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[14] PDL makes the alternative argument that MedImmune failed to calculate royalties on cash and non-cash consideration MedImmune received as a result of Abbott's procurement of regulatory approvals and trademark filings. The License Agreement does not support this claim. The agreement defines "Net Sales" as "revenues, whether in cash or in kind, derived by or payable from or *on account of the sale of Licensed Products*" including the fair market value of "non-cash consideration." License Agreement §1.05 (emphasis added). PDL has not demonstrated that the milestone payments made by Abbott in consideration for clinical and other data provided in support of regulatory approvals, *see* Fletcher Decl., Ex. 2 (MedImmune-Abbott Distribution Agreement) at 12; Abbott's own expenditures to obtain regulatory approvals; or Abbott's expenses marketing, distributing, and selling of Synagis fall within a permissible interpretation of revenues "on account of the sales of Licensed Products." Because the intent of the parties ordinarily is inferred solely from the written provisions of the contract, *AIU Ins. Co.*, 51 Cal. 3d at 821, the conclusory declarations of PDL's experts that these expenditures are payments on account of the sale of licensed products are insufficient to raise a triable issue of fact.

[15] Section 3.09 of the License Agreement reads, in relevant part: "MedImmune . . . agrees to permit its books and records to be examined by an independent accounting firm selected by PDL and reasonably satisfactory to MedImmune, from time-to-time to the extent necessary, during normal business hours and upon reasonable notice, but not more than once a year."

possible," *AIU Ins. Co.*, 51 Cal. 3d at 821, a contract "apparently unambiguous on its face may still contain latent ambiguity that can only be exposed by extrinsic evidence." *Wolf,* 162 Cal App. 4th at 1133. PDL contends that MedImmune's agreement to "permit its books and records to be examined by an independent accounting firm," entails several other obligations. Based on expert testimony regarding the scope of typical inspection provisions, PDL claims that MedImmune's conduct was inconsistent with standard industry practices. For example, MedImmune required PDL's accounting firm to submit all requests for information in writing to MedImmune's outside counsel and refused to allow the auditors any direct access to MedImmune personnel. According to PDL's expert, these restrictions would have made it very difficult for an accounting firm to investigate and verify the accuracy and completeness of the data it received from MedImmune and would have required the auditors to expend significantly more resources than otherwise would be required for an inspection consistent with standard industry practice. O'Bryan Decl. ¶¶ 4-6.

MedImmune's expert, while agreeing that the inspection provision was typical, disagrees with PDL's expert regarding industry practice. LaMagna Decl., Ex. 27 at 50, 76-77. MedImmune cites three cases for the proposition that audit requests "unmoored from the text of License agreement" cannot form the basis for a counterclaim. *See Revson v. Claire's Stores, Inc.*, 120 F. Supp. 2d 322, 326 (S.D.N.Y. 2000); *Nano-Proprietary, Inc. v. Keesmann*, No. 06 C 2689, 2007 WL 433100 (N.D. Ill. Jan. 30, 2007); *Discovision Assocs. v. Toshiba Corp.*, No. 08-cv-3693, 2008 WL 4500693 (S.D.N.Y Oct. 7, 2008). However, none of the cases supports summary judgment when there is a dispute among experts as to the scope of an inspection provision; the courts in two of the cases denied motions for summary judgment, and the other involved a motion for preliminary injunction. The court in *Discovision Assocs.* denied summary judgment expressly on the basis of a dispute concerning the permissible scope of the inspection. *Discovision Assoc.*, 2008 WL 4500693, at *4.

IV. PDL's Motion for Summary Judgment on MedImmune's Count VII.

Under the License Agreement, MedImmune paid approximately $42 million in quarterly royalty payments based on a PDL foreign patent that since has been invalidated. MedImmune

now seeks restitution of that sum based on the principle that a licensee that brings a successful challenge to a patent has no contractual liability for royalties after the date of its challenge even if the license agreement provides to the contrary. *See Lear, Inc. v. Adkins*, 395 U.S. 653 (1969). PDL moves for summary judgment on the ground that federal patent law does not preempt state contract law with respect to the licensing of foreign patents, and nothing in California law justifies a refund or restitution of MedImmune's payments.

A. Undisputed Facts

The License Agreement grants MedImmune a nonexclusive license to PDL's Queen patents, including one that became European Patent No. 0 682 040 ("the '040 patent"). The License Agreement states that

> MedImmune shall pay to PDL a royalty of Three Percent (3%) of the Net Sales of all Licensed Products sold by MedImmune . . . in each country in the Territory *until the last date on which there is a Valid Claim* that, but for the licenses granted to MedImmune under this Agreement, would be infringed by the making, importing using, having made or sale of that Licensed Product in the Territory or by the manufacturer of Licensed Product in the coutnry of manufacture.

License Agreement § 3.03(a) (emphasis added). The royalties were to be paid quarterly. *Id.* § 3.08(a). A "Valid Claim" is defined as "any claim in any issued patent included in the PDL Patent Rights which has not been disclaimed or held unenforceable or invalid by a governmental agency or court of competent jurisdiction by a decision *beyond the right of review*." *Id.* § 1.08 (emphasis added). The parties agreed that "[t]he validity, performance, construction, and effect of the Agreement shall be governed by the laws of the State of California without regard to choice of law principles." *Id.* § 8.05.

The '040 Patent, the sole foreign patent at issue, was issued by the European Patent Office (EPO) on August 25, 1999. On May 23, 2000, along with several other biopharmaceutical companies, MedImmune challenged the issuance of the '040 Patent by filing a formal notice of opposition with the EPO. LaMagna Decl., Ex. B, Notice of Opposition to European Patent. On March 11, 2005, the EPO's Opposition Division revoked the '040 Patent, holding that it was not validly issued. Fletcher Decl., Ex. 4 (Opposition Division Revocation Order). PDL appealed that decision to the EPO's Technical Board of Appeal, the final reviewing authority. That tribunal issued a final, unappealable decision affirming the revocation

on October 14, 2009. Fletcher Decl., Ex. 5 (Order of EPO Technical Board).

Article 68 of the European Patent Convention states that "[t]he European patent application and the resulting patent shall be deemed not to have had, *as from the outset*, the effects specified in Articles 64 and 67, to the extent that the patent has been revoked in opposition proceedings." Fletcher Decl., Ex. 7 (European Patent Convention, art. 68) (emphasis added). The foreign law experts retained by both MedImmune and PDL agree that revocation of the '040 patent is retroactive. Bausch Decl., Ex. A at ¶¶ 7-8; Fletcher Decl., Ex. 6 at 104-05.

B. Legal Standard

> "Commercial agreements traditionally are the domain of state law. State law is not displaced because the contract relates to intellectual property which may or may not be patentable; the states are free to regulate the use of such intellectual property in any manner not inconsistent with federal law. In this as in other fields, the question of whether federal law preempts state law involves a consideration of whether the law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. If not, state law governs."

Aronson v. Wuick Pint Pencil, 440 U.S. 257, 262 (1979) (quotation marks and internal citations removed).

C. Discussion

1. Interpretation of the License Agreement Under California Law

The License Agreement provides that MedImmune must make quarterly royalty payments until the last date on which there is a valid claim. It further provides that a valid claim is "any claim in any issued patent . . . which has not been . . . held unenforeable or invalid by a . . . decision beyond the right of review." License Agreement § 1.08. PDL contends that these provisions required MedImmune to make contract payments at least until the final, unreviewable decision invalidating the patent.

MedImmune does not dispute PDL's interpretation of this aspect of the License Agreement. Instead, it contends that there was a failure of consideration under California law because it received nothing of value in exchange for its royalty payments. It argues that because the '040 Patent was held void *ab initio*, PDL never possessed any patent rights relevant to foreign sales of Synagis, nor did it ever have a "Valid Claim" that would entitle it to a royalty payment on foreign sales. *See* Witkin, *Summary of California Law* § 1042(1) (10th ed. 2005).

PDL points out that under California law the adequacy of consideration to support a contract must be determined as of the date the contract was entered into and not in the light of subsequent events. *Crail v. Blakely*, 8 Cal. 3d 744, 753 (1973). When the contract was formed, PDL held enforceable patents and absent the License Agreement could have sued MedImmune for infringement and to enjoin European sales of Synagis. While MedImmune would have been entitled to raise invalidity in defense to such a suit, it elected to pursue a license agreement instead. California law long has recognized forbearance from bringing suit as sufficient consideration for a contract. *Schumm v. Berg*, 37 Cal. 2d 174, 185 (1951). Intellectual property licenses are based almost exclusively on this form of consideration. For example, under German law a European patent remains enforceable and a claim for patent infringement may be brought even while a patent is the subject of an opposition proceeding before the EPO and a subsequent appeal. Meibom Decl. Ex. A at 7, 17. This is true even if the patent is initially deemed invalid by the EPO and on appeal. *Id.*

PDL has the better of this argument. In entering into the License Agreement, MedImmune clearly received something that at least at the time it considered to be of value. MedImmune's license protected it from an infringement action that could have enjoined European sales of Synagis. Moreover, the parties obviously crafted the language concerning "Valid Claims" in contemplation of patent challenges, License Agreement § 1.08, agreeing, for example, that royalty payments would be due while any invalidity litigation was pending. Nothing in California law entitles MedImmune to a refund or restitution under such circumstances.

2. California Law Is Not Preempted.

By its express terms, the contractual provisions of the License Agreement are to be governed by California law. License Agreement § 8.05. State contract law is preempted only where its application "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Aronson*, 440 U.S. at 262. MedImmune asserts that enforcing the License Agreement would be contrary to the federal policy discouraging the restraint of ideas in the public domian. *See Lear*, 395 U.S. at 667.

In *Lear*, the Supreme Court articulated a federal policy that "the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain," and indicated that "federal law requires that all ideas in general circulation be dedicated to the common good unless protected by a patent." *Id.* Because of these considerations, the Court determined that federal law preempted state contract law enforcing royalty payments from a licensee who stopped paying them while successfully challenging the patent. *Id.* at 673. The logic behind the Court's decision was that in many cases licensees would be the only parties with incentive to challenge invalid patents, and the public benefits from such patents being challenged.

MedImmune contends that the *Lear* doctrine requires that it receive restitution of its royalty payments here. *See Warner-Jenkinson Co. v. Allied Chem. Corp*. 567 F.2d 185, 188 (2d Cir. 1977). PDL observes correctly that the Federal Circuit has limited the application of *Lear* to licensees that both (i) actually cease payment of royalties, and (ii) provide notice to the licensor that the reason for ceasing payment is that it believes the relevant claims to be invalid. *See Studiengesellschaft Kohle, m.b.H v. Shell Oil Co.*, 112 F.3d 1561 ("SGK"). MedImmune nevertheless contends that the same federal policy that requires preemption of state law contract claims upon the successful challenge of a United States patent also requires preemption of state law with respect to a successful challenge of a foreign patent.

United States patents are a "federally-bestowed monopoly," created pursuant to the powers delegated to Congress by the Constitution. *Zila, Inc. v. Tinnel*, 502 F.3d 1014 (9th Cir. 2007). The federal government has an interest in defining the scope of that monopoly that implicates the Supremacy Clause. *See id.* ("Patents are in the federal domain."). The Supreme Court observed in *Lear* that "the Sherman Act made it clear that the grant of monopoly power to a patent owner constituted a limited exception to the general federal policy favoring free competition," 395 U.S. at 663, and expressed concern about limiting access to U.S. courts to challenge a monopoly created by U.S. law, *see id.* at 622 ("A patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office.")

A foreign patent, however, is an "an entirely separate asset from [a] U.S. patent." *Zila,*

Inc., 502 F.3d at 1014 (*citing* Paris Convention for the Protection of Industrial Property, July 14, 1967, Art. 4*bis*, 21 U.S.T. 1583, ("Patents applied for in the various countries of the Union . . . shall be independent of patents obtained for the same invention in other countries . . . .")). A foreign patent is not a creature of United States law, and United States courts do not determine the validity of such patents.

In *Zila*, the Ninth Circuit held that the strictures of the *Brulotte* doctrine,[16] which limits state contract law with respect to enforcing royalties on expired patents, did not and could not apply to contracts made under state law pertaining to foreign patents. The court held that "[t]he fact that the asset is a foreign patent, as opposed to foreign real estate or other real property held outside the country, does nothing to change the propriety of state contract law to dispose of it." *Zila*, 502 F.3d at 1024. MedImmune interprets *Zila* as holding merely that a licensor could collect royalties under a valid and enforceable Canadian patent, even though its rights under a parallel U.S. patent had expired.[17] It contends that where the foreign patent is unenforceable, the federal policy precluding states from enforcing contracts that charge for the use of an idea in the public domain preempts state contract law.

This position is untenable. While MedImmune invokes federal policy limiting the restriction on ideas in the public domain, it fails to acknowledge that those cases involve federal regulation of federally- bestowed monopoly rights. In addition, MedImmune's own brief acknowledges the many differences between United States and foreign patent laws. For example, it points out that under European law invalidated patents are treated as void *ab initio*,

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[16] *See Brulotte v. Thys*, 379 U.S. 29 (1964).

[17] MedImmune relies upon *Adm'rs of the Tulane Educ. Fund v. Devio Holding, S.A.*, C.A. No. 99-2207, 2001 U.S. Dist. LEXIS 21823, at *6-*7 (E.D. La. December 28, 2001), and *Forbo-Giubiasco, S.A. v. Congoleum Corp.*, No. 78 Civ. 5390 (MEL), 1985 U.S. Dist. LEXIS 18504, *22-*24 (S.D.N.Y. June 26, 1985). In *Debio Holding*, the court found that there "valid concerns" regarding the application of the *Brulotte* doctrine to foreign patents, but it did not analyze the issue fully because the license agreement in question also included contract language terminating royalty obligations upon expiration of a patent in the country where a patent issued. 2001 U.S. Dist. LEXIS 21823, at *6-*7. Similarly, *Forbo-Guibiasco* involved the interpretation of express terms of the license, not application of U.S. patent doctrine to foreign patents. 1985 U.S. Dist. LEXIS 18504, *22-24.

while in the United States patents are considered valid until there is an adverse finding. Op. at 11:1-4.

MedImmune's position would require U.S. courts to apply an already questionable extension of the *Lear* doctrine to foreign patent schemes which may be based upon different, even conflicting, policy decisions about promoting the progress of science and the useful arts.

III. ORDER

For the reasons discussed above, MedImmune's motion for summary judgment with respect to invalidity and PDL's 6th, 8th, 9th, and 10th counterclaims is GRANTED. MedImmune's motion for summary judgment on PDL's 7th counterclaim is DENIED. PDL's motion for summary judgment on MedImmune's Count VII is GRANTED. PDL's motion for summary judgment on MedImmune's prior invention defense is terminated as moot.

IT IS SO ORDERED.

DATED: 1/7/2011

JEREMY FOGEL
United States District Judge