UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ABBOTT BIOTECHNOLOGY LTD. and ABBVIE INC.,	)	
Plaintiffs,	)	**Civil Action No. 09-40089-FDS**
v.	)	
CENTOCOR ORTHO BIOTECH, INC.,	)	
Defendant.	)	

MEMORANDUM AND ORDER ON
MOTIONS FOR SUMMARY JUDGMENT

SAYLOR, J.

This is a patent dispute involving pharmaceutical products used to treat certain autoimmune diseases. Plaintiffs Abbott Biotechnology Ltd. and AbbVie Inc. (collectively "Abbott") seek a judgment that the drug Simponi, manufactured by defendant Centocor Ortho Biotech, Inc. infringes its patents to the extent that it is used with the drug methotrexate to treat rheumatoid arthritis.[1] Centocor seeks declarations of non-infringement and invalidity of Abbott's patents.

Both parties have moved for summary judgment. Centocor has moved on the grounds that (1) the claims are invalid for lack of a written description; (2) the claims are invalid for lack of enablement because the patents indicate only a small subset of the claimed invention, not the full scope; (3) the patents are invalid for failing to list a purported inventor; (4) some claims are invalid for lack of enablement because the patents enable the creation of antibodies by only one

[1] During the pendency of this litigation, Abbott Laboratories changed its name to AbbVie Inc. Accordingly, the case caption has been altered.

method; (5) Centocor did not willfully infringe the patent, if it did infringe at all; and (6) the patents are invalid because references prior to the filing date are prior art and Abbott did not diligently reduce its invention to practice. Abbott opposes Centocor's contentions, and has cross-moved for summary judgment on the grounds that (1) the 4SE3 antibody is not prior art; (2) references prior to the date it filed its patent applications are not prior art; and (3) the patents are not invalid for failure to list a purported inventor.

For the reasons set forth below, the motions will be granted in part and denied in part.

I. Background

The following facts are undisputed, unless otherwise noted.

U.S. Patents No. 7,223,394 (the "'394 patent") and No. 7,541,031 (the "'031 patent") are part of a family of patents owned by Abbott. The parent patent, U.S. Patent No. 6,090,382 (the "'382 patent"), was filed in 1996 and issued in 2000. It is directed to certain human antibodies designed to attach to a naturally-occurring protein in the human body called tumor necrosis factor alpha ("hTNFα").

A. Development of Anti-hTNFα Antibodies

Human TNFα is involved in regulation of the immune system, a role it performs by triggering inflammation in response to invasion by a foreign entity. Overproduction of hTNFα can lead to excessive inflammation that can result in tissue damage. This occurs in diseases such as rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, and psoriasis. Such diseases are known as autoimmune diseases because of the way the body's own immune system—in this case, through hTNFα—targets healthy human tissue instead of foreign contaminants.

Antibodies are proteins that bind with harmful foreign substances, or "antigens," such as

viruses or bacteria. An antibody attaches itself to an antigen by binding with a portion of the antigen called an "epitope." By occupying the antigen's epitope, the antibody diminishes the antigen's ability to bind with other receptors in the body, and therefore minimizes the harmful effect.

The human immune system rarely produces antibodies that target hTNFα, because hTNFα is a protein that the body itself produces, not a foreign contaminant. To prevent an overabundance of hTNFα from causing tissue damage, researchers have sought to develop an antibody that binds to hTNFα. The process of binding is known as "neutralization" of hTNFα. In order for an antibody to neutralize hTNFα effectively, it must attach to it with sufficient strength. The strength of an antibody's interaction with hTNFα is called its "affinity" for hTNFα. Affinity is expressed in term of K_d—the propensity that the objects will dissociate—and a lesser K_d indicates a higher affinity.[2] Also, the longer that the antibody attaches to hTNFα, the more effective it is at neutralizing the antigen. The rate at which the antibody and antigen dissociate is expressed in terms of K_{off}, with a lower number indicating that the objects bind for a longer period of time.[3]

Researchers have long sought to develop antibodies that neutralize hTNFα and bind to it with high affinity. An antibody that inhibits hTNFα in this manner could become a treatment for, among other things, autoimmune diseases. In the 1980s, researchers invented a high-affinity, neutralizing anti-hTNFα antibody that derived from mouse DNA. It could not

[2] For the purposes of the patents-in-suit, K_d is defined as "the dissociation constant of a particular antibody-antigen interaction."

[3] For the purposes of the patents-in-suit, K_{off} is defined as "the off rate constant for dissociation of an antibody from the antibody/antigen complex."

effectively treat human autoimmune diseases, however, because humans often exhibit adverse reactions to non-human antibodies.

The development of chimeric antibodies, or antibodies with components that derive from both mouse and human DNA, advanced treatment options for autoimmune diseases. Centocor, together with the Kennedy Institute, obtained a patent in 2001 that disclosed a method for treating arthritis by co-administering chimeric anti-hTNFα antibodies with a pre-existing drug called methotrexate. (*See* U.S. Patent No. 6,270,766).[4] In 1999, the FDA approved Remicade, a drug manufactured by Centocor and based on chimeric antibodies, for treatment of rheumatoid arthritis.

During the same time period, Abbott was also seeking to develop effective antibodies. In 1993, BASF Bioresearch Corporation, later acquired by Abbott, and Cambridge Antibody Technology ("CAT") were collaborating on the development of antibodies. Three CAT scientists, all of whom are inventors of the patents-in-suit, succeeded in isolating a human antibody called 4SE3 by July 1993. However, 4SE3 did not have the sought-after qualities, and does not fall within the scope of the claims of the patents-in-suit.

By April 14, 1995, BASF and CAT scientists had succeeded in isolating a high affinity, neutralizing anti-hTNFα antibody, which they labeled "D2E7." BASF then undertook pre-clinical and clinical testing of the antibody.

At some point, BASF scientists conceived of the idea to co-administer such an antibody

[4] Methotrexate was invented in the 1940s, initially as a chemotherapy drug. It is now categorized as a disease-modifying anti-rheumatic drug ("DMARD") and can be an effective treatment for rheumatoid arthritis. Physicians may prescribe only methotrexate—which was the standard treatment in April 1995—or may prescribe it in combination with a drug developed from anti-hTNFα antibodies. The prescribing physician determines the frequency and dosage of methotrexate administrations.

with methotrexate to treat rheumatoid arthritis. Abbott contends that one of the BASF scientists came up with the idea prior to the development of D2E7, because it was a well-known and obvious treatment. None of them has taken credit for the concept nor remembers who is responsible. Centocor contends that the idea was not obvious and that the BASF scientists co-opted the idea from Dr. Michael Weinblatt, who consulted with them about clinical development of an anti-hTNFα drug in January 1995. Dr. Weinblatt, however, denies that he introduced the concept to the BASF scientists.

In 1996, Abbott filed the '382 patent and for the first time disclosed a class of fully-human, high-affinity, neutralizing anti-hTNFα antibodies as well as certain uses of those antibodies. The '382 patent did not address co-administration of the antibodies with methotrexate.

From April 14, 1995, to February 10, 1997, other references to purportedly the same invention became public: two international patent applications, Kucherlapati WO 96/33735 and Kucherlapati WO 96/34096; the 1995 Kennedy Institute of Rheumatology Annual Report; two scientific papers, published in 1996 and 1997; a presentation by Dr. Salfeld, an Abbott scientist, in 1996; and two patent applications, U.S. Patent No. 6,075,081, filed April 27, 1995, and U.S. Patent No. 6,150,584, filed October 2, 1996.

B. The Asserted Patents

Abbott filed two patent applications on February 10, 1997—the '394 and '031 patents, the patents-in-suit—that are continuations of a patent in the '382 family. The listed inventors were Jochen G. Salfeld and twelve others; Dr. Weinblatt was not included. The '394 patent, issued in 2007, is directed to a method for treating rheumatoid arthritis by administering the

human anti-hTNFα antibody with methotrexate. The '031 patent, issued in 2009, shares the same specification and claims substantially the same invention. Both patents claim priority to the 1997 Patent Cooperation Treaty application; Abbott contends that the date of invention was, at the latest, April 14, 1995, when it first developed D2E7.

The patents describe a genus of human anti-hTNFα antibodies, of which D2E7 is a member. They define the genus by its functional characteristics: a high affinity for hTNFα, defined as a K_d of -10^{-8} M or less; a slow rate of dissociation, defined as a K_{off} of -10^{-8} sec^{-1} or less; and an ability to neutralize hTNFα in vitro and in vivo. The patents indicate possible methods of creating other antibodies within the genus, starting by making changes to D2E7, but do not indicate the total number of qualifying antibodies that exist.

Based on the technology disclosed in the '382 patent and its progeny—in particular, the '394 and '031 patents—Abbott developed a drug called Humira. The FDA approved Humira in December 2002 to treat rheumatoid arthritis, either alone or in combination with methotrexate or other DMARDs. Rheumatoid arthritis patients typically take a combination of Humira once every two weeks and methotrexate weekly, but may take Humira weekly when it is not prescribed in combination with methotrexate.

In the past decade, Centocor researchers also developed a fully-human, high-affinity, neutralizing anti-hTNFα antibody that meets the functional limitations of the '394 and '031 patents. In 2009, Centocor obtained approval from the FDA to manufacture and sell a drug called Simponi that contains the antibody it developed. Simponi is indicated for the treatment of moderate to severe rheumatoid arthritis, to be used in combination with methotrexate. It is also indicated for the treatment of psoriatic arthritis, either alone or in combination with

methotrexate, and ankylosing spondylitis. For all three conditions, patients are administered monthly subcutaneous injections.

D. The Licensing Agreement

In late 2002, Abbott and Centocor agreed to cross-license a series of patents directed to anti-hTNFα antibodies. Centocor extended to Abbott rights under its 2001 patent, which covered a method for treating arthritis by co-administering chimeric anti-hTNFα antibodies with methotrexate. In exchange, Abbott extended to Centocor rights under the '382 patent and other patents in the family, including U.S. Patent No. 6,509,015, which covered a method for treating rheumatoid arthritis (among other diseases) by co-administering human anti-hTNFα antibodies with a therapeutic agent.

E. Procedural History

Abbott initiated this action against Centocor in May 2009. The parties then proceeded to arbitrate whether the 2002 agreement extended to Centocor an implied license under Abbott's '394 and '031 patents. The arbitrator determined in June 2010 that the agreement did not cover the subject matter claimed in those patents.

In August 2011, after a *Markman* hearing, this Court construed the disputed claim terms. Among other things, the Court construed the term "administering to the subject both an antibody and methotrexate" to mean "administering to the subject an antibody and methotrexate in combination."

Both Abbott and Centocor have moved for summary judgment, in two instances cross-moving as to the same issue. Centocor contends in its first motion that the claims are invalid for lack of a written description; in its second motion that the claims are invalid for lack of

enablement because the patents do not indicate the full scope of the claimed invention; in its third motion that the patents are invalid for failure to list an inventor; in its fourth motion that some claims are invalid for lack of enablement because the patents enable the creation of antibodies by only one method; in its fifth motion that it did not willfully infringe the patent; and in its sixth motion that the patents are invalid because references prior to the filing date are prior art and Abbott did not diligently reduce its invention to practice.

Part A of Abbott's motion contends that eight post-invention date references are not prior art; part B contends that the 4SE3 antibody is not prior art; and part C contends that the patents are not invalid for failure to list an inventor.

As to the cross-motions, Centocor's sixth motion corresponds with part A of Abbott's motion, and Centocor's third motion corresponds with part C of Abbott's motion.

II. Legal Framework

The role of summary judgment is to "pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." *Mesnick v. General Elec. Co.*, 950 F.2d 816, 822 (1st Cir. 1991) (internal quotations omitted). Summary judgment is appropriate when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A genuine issue is "one that must be decided at trial because the evidence, viewed in the light most flattering to the nonmovant . . . would permit a rational fact finder to resolve the issue in favor of either party." *Medina–Munoz v. R.J. Reynolds Tobacco Co.*, 896 F.2d 5, 8 (1st Cir. 1990). In evaluating a summary judgment motion, the court indulges all reasonable inferences in favor of the non-moving party. *O'Connor v. Steeves*, 994 F.2d 905, 907 (1st Cir. 1993). When "a properly supported motion for summary judgment is made, the

adverse party 'must set forth specific facts showing that there is a genuine issue for trial.'" *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (quoting Fed. R. Civ. P. 56(e)). The non-moving party may not simply "rest upon mere allegation or denials of his pleading," but instead must "present affirmative evidence." *Id.* at 256–57.

"Cross motions for summary judgment neither alter the basic Rule 56 standard, nor warrant the grant of summary judgment *per se.* Cross motions simply require us to determine whether either of the parties deserves judgment as a matter of law on facts that are not disputed. As always, we resolve all factual disputes and any competing, rational inferences in the light most favorable to the party against whom summary judgment has entered." *Wightman v. Springfield Terminal Ry.*, 100 F.3d 228, 230 (1st Cir. 1996) (internal citations omitted).

III. Analysis

A. Validity Based on Claimed Inventors: Abbott Part C and Centocor Motion 3

The parties have cross-moved for a declaration that the patents-in-suit are valid (or invalid) in light of Abbott's alleged failure to list Dr. Weinblatt as an inventor.

One condition for patentability is that all joint inventors are listed on the patent. 35 U.S.C. §§ 102(f), 116.[5] *See Pannu v. Iolab Corp.*, 155 F.3d 1344, 1349 (Fed. Cir. 1998) ("[I]f nonjoinder of an actual inventor is proved . . . a patent is rendered invalid."). To establish himself as an inventor, a person need not have made an equal contribution as the other inventors. *See* 35 U.S.C. § 116. He only must "(1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is

[5] Title 35, U.S.C. § 102 has been amended since the inception of this suit. For the purposes of this litigation, the prior version governs and all citations are to that version.

not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art." *Pannu*, 155 F.3d at 1351. However, inventors may consult with others in the course of development without rendering each consultant a co-inventor. *See O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 111 (1853) (holding that Samuel Morse's discussions with scientists in connection with invention of the telegraph did not alter his status of sole inventor).

Inventorship is a question of law. *Nartron Corp. v. Schukra U.S.A. Inc.*, 558 F.3d 1352, 1356 (Fed. Cir. 2009). There is a presumption that the listed inventors are correct. *Hess v. Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 980 (Fed. Cir. 1997). Where a summary judgment motion is based on a challenge to inventorship, a patent-holder need only present sufficient evidence to rebut any proof of invalidity the party challenging inventorship offers. *Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc.*, 134 F.3d 1085, 1088 (Fed. Cir. 1998). The party claiming misjoinder or non-joinder of the proper inventors, in turn, "must meet the heavy burden of proving its case by clear and convincing evidence." *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1358 (Fed. Cir. 2004).

Here, Centocor contends that two critical facts demonstrate that Dr. Weinblatt (1) conceived of the idea of co-administration of the anti-hTNFα antibody and methotrexate and (2) communicated it to the scientists. First, it points to Dr. Weinblatt's testimony that he "told [the scientists] that they should develop their drug with methotrexate." (Pl. Mot. Summ. J., Hartmann Decl., Ex. 24, Weinblatt Trial Tr. at 204:15-16). The Abbott team had no "clinical expertise" and therefore invited Dr. Weinblatt, "a respected rheumatologist, known for his

involvement in clinical trials, especially involving methotrexate" (*id.*, Ex. 26, at 1) to "tell [them] how to develop a RA drug." (*Id.,* Ex. 23, Kamen Tr. at 167:10-24).

Second, Centocor notes that none of the listed inventors claimed to have generated the idea of co-administration him or herself, nor could any one of them remember who did. (*See id.*, Ex. 11, Salfeld Tr. at 178:16-179:13; *id.*, Ex. 12, Roberts Tr. at 70:16-25; *id.*, Ex. 13, Allen Tr. at 108:10-13; *id.*, Ex. 19, Labkovsky Tr. at 105:6-19; *id.*, Ex. 20, White Dep. at 58:11-21; *id.*, Ex. 21, Vaughan Dep. at 47:5-16; *id.*, Ex. 27, Kaymakcalan Tr. at 15:12-17, 18:8-24, 19:18-20:3; *id.*, Ex. 28, Mankovich Tr. at 76:23-77:24; *id.*, Ex. 29, McGuinness Tr. at 78:10-79:7; *id.*, Ex. 30, Schoenhaut Tr. at 67:3-11; *id.*, Ex. 31, Wilton Tr. at 47:19-23, 49:18-21).

In response, Abbott contends that Dr. Weinblatt's contribution was merely an explanation of known concepts, and therefore he does not qualify as an inventor. Dr. Seigel, a Centocor expert, opined that "[t]he combination of anti-TNF-α antibodies with methotrexate was already known." (Def. Mot. Summ. J., Holt Decl., Ex. 6, Seigel Report ¶ 203). Dr. Weinblatt himself explains that clinical investigators "were combining everything with methotrexate," that he "told every sponsor" to conduct combination trials, and that he "doubt[ed]" that he was the first person to tell Abbott scientist to use D2E7 in combination with methotrexate. (*Id.*, Ex. 28, Weinblatt Dep. Tr. 102:20-105:22, 118:25-119:15, 128:16-131:23; *see also id.* 126:8-127:5). The summary of his January 13, 1995 visit indicates that the focus of the discussion was designing a successful clinical trial; the sole mention of co-administration is his suggestion that the subjects should be patients with a partial response to methotrexate. (*Id.*, Ex. 26 ¶ 10). Even when presented with the information that if he were an inventor then he would have an ownership interest in the patent and that Humira was a multi-billion-dollar product, Dr.

Weinblatt did not assert any claim to inventorship. (*Id.* 129:11-20). Dr. Salfeld, the first-listed inventor, responded plainly to the question of whether the idea of co-administration came from Dr. Weinblatt: "No, it did not." (*Id.*, Ex. 5, Salfeld Tr. 181:2-6).

Furthermore, Abbott scientists considered combination treatment prior to Dr. Weinblatt's visit, although they did not name methotrexate specifically. A January 14, 1994 memorandum providing an "Overview over the Human anti-TNF-α antibody project" stated that a "combination treatment of TNF antibodies with current treatments should be another option." (*Id.*, Ex. 24). Methotrexate was the standard treatment at that time.

Although the scientists do not recall who first conceived of co-administration, they recall the idea as existing within the team. (*See*, *e.g.*, Hartman Decl., Ex. 27, Kaymakcalan Tr. at 15:12-17 ("I don't remember the specifics, whether it was any particular person's idea. I just remember the general feelings at the time."); *id.*, Ex. 19, Labkovsky Tr. at 105:6-19 ("I don't know specifically who had that idea first.")).

Viewing the evidence as a whole, Centocor cannot sustain its burden of proof that the patent is invalid for failure to list an inventor. Dr. Weinblatt disclaims being the source of the co-administration idea. His testimony that methotrexate was the prevalent, existing treatment for rheumatoid arthritis in the United States, in conjunction with the 1994 memorandum about combination with "current treatments," provides much stronger support for the opposite inference: that the scientists considered co-administration prior to his visit. The scientists need not have known that the particular combination of D2E7 and methotrexate would be successful "for conception to be complete." *See Univ. of Pittsburgh v. Hedrick*, 573 F.3d 1290, 1298 (Fed. Cir. 2009).

The scientists' failures to remember who first conceived of the idea is not unreasonable, especially given the lapse in time. "As any member of a large discussion group well knows, it is often difficult to remember who first said what." *Canon Computer Sys.*, 134 F.3d at 1088 (dismissing validity challenge to patent of joint inventors who could not recall what each team member had contributed).

Moreover, this is not an instance where the omitted inventor's idea was so novel or obscure that the concept must have come from a particular source. *See Metris U.S.A., Inc. v. Faro Technologies, Inc.*, 768 F. Supp. 2d 338, 356 *opinion vacated on other grounds*, 882 F. Supp. 2d 160 (D. Mass. 2011) ("There is no evidence that [the claimed inventor] or anyone with ordinary skill in the art could have provided a substitute mechanism that would have allowed him to reduce the conception to practice."). Instead, here, the allegedly omitted inventor himself testified that his purported contribution was obvious.

Centocor has not provided clear and convincing evidence that Abbott omitted an inventor from its patents. Abbott, in turn, has offered substantial evidence to rebut each of Centocor's contentions. The presumption of patent validity therefore has not been overcome. Accordingly, Centocor's third motion for summary judgment will be denied, and part C of Abbott's motion for summary judgment will be granted.

B. Validity Based on Prior Art: Abbott Part A and Centocor Motion 6

The parties have also cross-moved for summary judgment as to whether eight references between April 14, 1995 (the date of claimed invention) and February 10, 1997 (the date of filing)

are prior art that invalidate the patents.[6]

A patent is invalid if it is anticipated by, or is obvious in light of, prior art as defined by Section 102. 35 U.S.C. §§ 102, 103. As relevant here, that section provides:

> A person shall be entitled to a patent unless—
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> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
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> . . .
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> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language . . . .

35 U.S.C. § 102.

The statute presumes that the filing date reflects the date of invention. But an applicant can establish an earlier date, and thereby antedate prior references, by showing either an earlier reduction to practice of the claimed invention or an earlier conception followed by diligence in reducing the invention to practice. *In re Meyer Mfg. Corp.*, 411 F. App'x 316, 319 (Fed. Cir. 2010); *Singh v. Brake*, 317 F.3d 1334, 1340 (Fed. Cir. 2003); *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996).

Conception is the formation in an inventor's mind of "a definite and permanent idea of

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[6] For the purposes of Centocor's sixth motion for summary judgment, Abbott does not dispute that three additional references made prior to April 14, 1995, are prior art: (1) U.S. Patent No. 5, 530,101 to Queen et al.; (2) U.S. Patent No. 5, 698,195 to Le et al.; and (3) U.S. Patent No. 6,270,766 to Feldman et al. (*See* Pl. Opp. to Def. Sixth Mot. Summ. J. at 6 n.2). Accordingly, those references may later be considered in conducting an obviousness assessment of the claimed invention.

the complete and operative invention, as it is hereafter to be applied in practice." *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994). "An idea is sufficiently definite for conception 'when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue.'" *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1356 (Fed. Cir. 2010) (quoting *Burroughs Wellcome Co.*, 40 F.3d at 1228). Where a party seeks to prove conception through the oral testimony of the inventor, such testimony must be corroborated by other evidence. *Mahurkar*, 79 F.3d at 1576-77.

Diligence is a question of fact that must be shown by the party of purported first conception. It must be shown from (1) a date just prior to asserted prior reference to (2) the date of reduction to practice. *In re Meyer Mfg. Corp.*, 411 F. App'x 316, 319-20 (Fed. Cir. 2010). There must be evidence of diligence throughout the entire critical period, although "there need not necessarily be evidence of activity on every single day if a satisfactory explanation is evidenced." *Monsanto Co. v. Mycogen Plant Sci., Inc.*, 261 F.3d 1356, 1369 (Fed. Cir. 2001) (upholding diligence finding where record showed "activity in every month during the critical period"). "The basic inquiry is whether, on all of the evidence, there was reasonably continuing activity to reduce the invention to practice." *Brown v. Barbacid*, 436 F.3d 1376, 1380 (Fed. Cir. 2006). However, preparations aimed at commercial practice and "pure money-raising activity" may not serve as evidence of diligence. *Scott v. Koyama*, 281 F.3d 1243, 1248 (Fed. Cir. 2002).

Priority, conception, and reduction to practice are questions of law that are based on subsidiary factual findings. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). Where the underlying facts are undisputed, however, prior art issues are amenable to summary

judgment. *See Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1377 (Fed. Cir. 2006).

Abbott contends that (1) it had conceived of the invention by April 14, 1995, by which point it had created D2E7 and (2) co-administration with methotrexate to treat rheumatoid arthritis was obvious. It also contends that it then worked diligently to reduce the invention to practice until the 1997 filing date. Alternatively, Abbott contends that it memorialized the invention by March 1996, at the latest, which predates all but one purported reference. Centocor concedes that Abbott had produced D2E7 by May 1995 but asserts that Abbott had not conceived of the whole invention even by March 1996, and that Abbott was not diligent in reducing the invention to practice.

There is a genuine issue of material fact as to when the inventors had a permanent and settled conception of the entire invention. Abbott's contemporaneous records demonstrate that it did develop an antibody that meets the patent claims and that its purpose was treatment of chronic diseases like rheumatoid arthritis. But even in the 1996 memorialization, Dr. Salfeld stated, "[i]t has been *proposed to consider* an additional toxicology and safety pharmacology program to investigate the effect of drug combinations, especially the interaction of LU200134 [D2E7] and Methotrexate" and "[a] *potential* Phase I combination study of LU200134 [D2E7] and Methotrexate (MTX) *has been suggested* to commence in the US." (Pl. Mot. Summ. J., Ex. 32) (emphases added). Such statements do not evince a "specific, settled idea" in the mind of the inventors, but instead a continuing course of research. *See Spansion, Inc.*, 629 F.3d at 1356. On the other hand, Dr. Weinblatt spoke with the scientists about combination treatment in January 1995, which may corroborate the testimony of the scientists themselves that they had conceived of the whole invention.

Abbott asserts that co-administration with methotrexate was obvious, and therefore, by the time the scientists had isolated the antibody, they had in their possession the entirety of the invention. But having the invention in one's possession is not sufficient if the inventor does not recognize the full invention. *See Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1063 (Fed. Cir. 2005). Put another way, what matters is not whether someone skilled in the art "could have thought of the invention, but whether the alleged inventors actually had in their minds the required definite and permanent idea." *Burroughs Wellcome Co.*, 40 F.3d at 1232. Furthermore, the parties genuinely dispute whether co-administration was obvious, and the jump from treating patients with the antibody alone to treating them with an antibody and methotrexate is not so small as to render co-administration obvious as a matter of law. *See Application of Dardick*, 496 F.2d 1234, 1240 (C.C.P.A. 1974).

Abbott raises an alternate argument that the Salfeld Presentation is not prior art because it is the work of the inventors here. (*See* Pl. Mot. Summ. J., Ex. 43). Section 102(a) deems "prior art" an invention known, used, patented, or described "by others." If instead the alleged prior art is the work of the inventor, that reference is prior art only if disclosure occurred more than one year before the filing of the patent application. 35 U.S.C. § 102(b). Centocor's assertion rests on its contention that Dr. Weinblatt is an unlisted inventor who was not a member of the inventive entity of the 1996 Salfeld presentation. Because the Court has granted summary judgment to Abbott on the question of inventorship, Centocor's argument in that respect fails. Thus, the Salfeld presentation is not prior art, because it is not an invention described "by others," and Centocor will not be permitted to so argue at trial. However, that is not a sufficient basis, without more, to grant summary judgment for Abbott as to part A of its motion.

Accordingly, part A of Abbott's motion for summary judgment will be denied, and Centocor's sixth motion for summary judgment will be denied.[7]

C. Validity Based on Prior Art: Abbott Part B

Abbott seeks an additional determination that the 4SE3 antibody is not prior art under 35 U.S.C. §§ 102(a), (f), and (g)(2). Those provisions state as follows:

> A person shall be entitled to a patent unless—
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> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
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> . . .
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> (f) he did not himself invent the subject matter sought to be patented, or
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> (g)(2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. § 102.

"Section 102(a) establishes that a person cannot patent what was already known to others." *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998). That is, the invention must "have been available to the public." *Id.* Based on the record, Abbott convincingly contends that 4SE3 was not available to the public, and Centocor has not raised a question of material fact as to that contention. There is no evidence that the antibody was known

[7] Having found that a factual dispute as to conception exists, the Court need not address now whether Abbott was diligent in pursuing reduction to practice.

to or used by anyone other than the CAT or BASF inventors or that it was disclosed or published prior to filing of the patents-in-suit. Accordingly, 4SE3 is not prior art under § 102(a).

Furthermore, 4SE3 is not "prior art" because it was the work of joint inventors, not "another inventor." It is possible, as Centocor points out, that a subset of a patent's named inventors independently can develop one invention before a larger group including that subset invents the patented invention, and that the older work will be prior art against the newer. But as laid out in greater detail in *Abbott GMBH & Co., KG v. Centocor Ortho Biotech, Inc.*, 870 F. Supp. 2d 206 (D. Mass. 2012), the 1984 amendments to the patent laws embraced a broader conception of joint inventorship to allow for collaboration. *Abbott GMBH & Co., KG*, 870 F. Supp. 2d 206 at 241-44. Here, as in that case, "the initial work of [the subset of] scientists was part of a larger collaborative effort that led to the patented inventions." *Id.* at 243. (*See* Ex. 19, Sept. 25, 1993 CAT Report). Those scientists are listed inventors with the larger group on the patented invention. (*See* Exs. 1, 2). None of the arguments raised by Centocor sufficiently distinguish the facts from the present case or call into question the decision's legal reasoning. Accordingly, part B of Abbott's motion for summary judgment will be granted.

D. Validity Based on Written Description: Centocor Motion 1

Section 112 provides as follows:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112.

Centocor contends that the specifications of the patents-in-suit do not satisfy the written-

description requirement, because persons of ordinary skill in the art would not clearly recognize that the inventors invented the genus of antibodies described by the claims. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (a patent claim is invalid unless the disclosure in the specification "clearly allow[s] persons of ordinary skill in the art to recognize that the inventor invented what is claimed").

The written description "must convey with reasonable clarity . . . that, as of the filing date sought, [the patentee] was in possession of the invention." *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008) (internal quotation marks omitted). The sufficiency of a patent's written description is ordinarily a question of fact, but "[a] patent also can be held invalid [as a matter of law] for failure to meet the written-description requirement based solely on the face of the patent specification." *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1347 (Fed. Cir. 2011). As with other invalidity defenses, a patentee's failure to comply with the written-description requirement must be proved by clear and convincing evidence. *Ariad*, 598 F.3d at 1354.

The challenged claims are genus claims defined both by structure and by function. That is, each claim defines a family of antibodies based in part on its shared structural features and in part on its ability to bind to and neutralize human TNFα within specific ranges of K_d, K_{off}, and IC_{50} values. Centocor asserts that the structural features are not sufficiently common and distinctive and that the patents' disclosure of a limited number of representative examples of antibodies within each family is an insufficient written description to support these genus claims.

According to the Federal Circuit, written-description problems are "especially acute with genus claims that use functional language" because such claims run the risk of "simply

claim[ing] a desired result . . . without describing species that achieve that result." *Ariad*, 598 F.3d at 1349. The specification must therefore disclose either a "representative number of species falling within the scope of the genus or structural features common to the members of the genus." *Id.* at 1350. If the specification fails both requirements, the written-description requirement has been not met.

No "bright-line rules" exist as to the number of representative species required to support a genus claim, because "this number necessarily changes with each invention, and it changes with progress in a field." *Id.* at 1351. In the biological arts, a patent "cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated." *Noelle v. Lederman*, 355 F.3d 1343, 1350 (Fed. Cir. 2004). Even in an "unpredictable art," however, "every species in a genus need not be described in order that a genus meet the written-description requirement." *Regents of Univ. of California v. Eli Lilly*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) (citing *In re Angstadt*, 537 F.2d 498, 502-03 (C.C.P.A. 1976) (noting that requiring disclosure of every species within a genus claim would require a prohibitive amount of experimental work of the patentee)).

A patent's failure to comply with the written-description requirement may generally be determined as a matter of law. *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 927 (Fed. Cir. 2004). However, summary judgment is not well-suited to the fact-intensive inquiry necessary to determine how many species are needed to represent a particular genus. *See Capon v. Eshhar*, 418 F.3d 1349, 1360 (Fed. Cir. 2005) (noting that the distinction between "generic inventions that are adequately supported, those that are merely a 'wish' or 'plan' . . . ,

and those in between" is dependent on the "facts of the specific case").

Only on rare occasions has a court found that disclosure of a particular number of species was insufficient to support a genus claim as a matter of law. Those instances include when the patent failed to disclose a single species of the claimed genus. *See Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1350-51 (Fed. Cir. 2011). But disclosure of even a single representative embodiment may, in some circumstances, be sufficient to describe a functionally-defined genus. *See Invitrogen Corp.*, 429 F.3d at 1073 (affirming summary judgment that the written-description requirement had been met where the disclosure "recite[d] both the DNA and amino acid sequences of a representative embodiment").

Here, the patents disclose one allegedly representative member of the genus: D2E7. Abbott contends that D2E7 shares structural and functional similarities with other members of the genus. The patents specify that the antibody must be a human antibody, which is comprised of two heavy and two light chains, each with a variable region and a constant region. According to Abbott's expert, the antibodies of the claims have a common structural architecture, theme, and shape (that is, "canonical loops"), and one skilled in the art would have understood the constraints imposed by the patents. (Ex. 5, Garcia Report, ¶¶ 90-111). Centocor contends that the Abbott has failed to identify structures that are both common to all members of the genus and that distinguish species within the genus from those outside the genus. It focuses on the differences between the CDR3 regions of the now-known antibodies within the genus, while Abbott emphasizes the similarities between those antibodies and the ability of scientists to make predictable changes to D2E7 to find other members of the genus. Furthermore, Centocor challenges that D2E7 does not represent the alleged variability of the genus as to the lengths of

the antibodies and the variations in amino acids.

All told, the record does not clearly resolve the complex questions of fact regarding the adequacy of the written description. The breadth of the variation within the genus, the representativeness of D2E7, and the similarity of the structures all present genuine issues of material fact. Because this is not one of the rare instances in which the facts firmly establish that a party has met or failed to meet the written-description requirement, Centocor's first motion for summary judgment will be denied.

E. Validity Based on Enablement: Centocor Motion 2

To meet the enablement requirement of § 112, a patent specification must "teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (internal quotation and citation omitted). Whether a claim satisfies the enablement requirement is a question of law based on underlying factual findings. *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008). Enablement is determined "as of the effective filing date of the patent's application." *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010).

Not all experimentation is "undue." *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988). Instead, it is a "matter of degree." *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1385-86 (Fed. Cir. 2013). On one end of the spectrum, a finding of enablement is not precluded where routine screening is required or where the specification "'provides a reasonable amount of guidance' regarding the direction of experimentation." *Id.* (quoting *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1360-61 (Fed. Cir. 1998)). On the other end, the need to engage in "an iterative, trial-and-error process to practice the claimed invention," where the specification

provides "only a starting point, a direction for further research," precludes a finding of enablement. *ALZA Corp.*, 603 F.3d at 941.

The determination of what is "undue" experimentation "requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art." *In re Wands*, 858 F.2d at 737. The Federal Circuit has suggested various factors that courts should weigh, including "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.*

Centocor contends that the patents-in-suit do not enable the full scope of the claimed invention. It asserts that the testing of an antibody could take up to a week, and a person skilled in the art, following the inventors' instructions on how to alter D2E7, would not uncover the other members of the genus, such as the antibody in Simponi, without undue experimentation. Centocor contends that there could be millions or billions of antibodies within the genus.

Abbott agrees that the number of members is unknown, but possibly very large. But it contends that the experimentation required is routine, and that the specification provides a clear path for finding other members of the genus. It also disagrees with Centocor's assertion that D2E7 and Simponi are dissimilar. At the very least, Abbott contends that there are genuine issues of material fact that preclude summary judgment at this point.

The Court agrees with Abbott that summary judgment is inappropriate at this juncture. There are underlying factual disputes, including disputes as to how much direction the patents provided, how routine the required testing was, and how predictable the art was. On those and

other key points, the parties' experts disagree, and viewing the evidence in the light most favorable to Abbott, Centocor has not established that there are no genuine disputes as to any material fact.

Centocor's analogy to *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380 (Fed. Cir. 2013), is not dispositive. There, the Federal Circuit upheld a district court's finding of non-enablement based on undue experimentation. The patents were directed to methods of treating or preventing restenosis in mammals by administering an amount of rapamycin, which is a class of compounds defined by functional limitations, and disclosed a single member of that class. *Id.* at 1381-83. The court found that the specification disclosed "only a starting point for further iterative research in an unpredictable and poorly understood field," that "one of ordinary skill would need to assay each of at least tens of thousands of candidates," and that the specification offered "no guidance or predictions about particular substitutions" that would lead to other effective members. *Id.* at 1385-86. While similarities to the present case are apparent, certain facts that could distinguish the cases—such as predictability, how routine and burdensome testing was, and the utility of the guidance and direction offered by the patents—remain unknown, rendering summary judgment inappropriate.

Accordingly, Centocor's second motion for summary judgment for lack of enablement will be denied.

F. Validity Based on Enablement: Centocor Motion 4

Centocor further contends that certain patent claims also fail to satisfy the enablement requirement of § 112 because they encompass the use of non-recombinant antibodies, which neither the specification nor the prior art enable. Specifically, Centocor challenges claims 1-6 of

the ‘394 patent and claims 1-6 and 8-10 of the ‘031 patent, which claim an “isolated human antibody” without limitation, unlike dependent claims 7 of ‘394 and 7 and 11 of ‘031, which specify that the claimed antibody must have been made by recombinant methods.

Human antibodies are either naturally occurring—“non-recombinant”—or they are engineered—“recombinant.” While the human body naturally creates antibodies, the techniques for generating non-recombinant antibodies outside of the body have not proved to be effective. Human antibodies can also be engineered in a laboratory using recombinant DNA technology, which includes the technique of phage display, as utilized by the patents-in-suit.[8] Whether the antibody is created by recombinant or non-recombinant means does not change the ultimate structure and function of the antibody.

Centocor argues that the patents do not enable the full scope of the claimed invention because they do not provide a method for making and using non-recombinant antibodies, nor could a skilled artisan have created such antibodies. It points out that the unchallenged dependent claims specify that the antibody is recombinant and contends that, under the doctrine of claim differentiation, the challenged claims must therefore encompass non-recombinant, as well as recombinant, antibodies.

Abbott responds that it need enable only one method for making an invention. Because the patent includes one such method—the non-recombinant method—and because recombinant and non-recombinant antibodies share the same structure and function in their final form, Abbott contends that summary judgment is unwarranted.

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[8] The Court’s construction of the term “isolated human antibody” does not require that the antibody have been made by any particular process, recombinant or non-recombinant. (Dkt. No. 133 at 10). The Court defined “recombinant antibody” as an “antibody that is prepared, expressed, created or isolated by recombinant means.” (*Id.*).

"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). That is, "the presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004); *see Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007).

However, even assuming that the challenged claims do sweep more broadly then the unchallenged dependent claims, and that then encompass recombinant antibodies as well, a finding of lack of enablement is not required under the present circumstances. Recombinant and non-recombinant are adjectives that modify the process, not the final invention. The situation here thus is different than that in *Alza*, relied upon by defendant, where the end product itself was not enabled. *See ALZA Corp.*, 603 F.3d at 940-41 (Fed. Cir. 2010).

Instead, Centocor "can carry its burden only by showing that all of the disclosed alternative modes [of enablement] are insufficient to enable the claims, because '[t]he enablement requirement is met if the description enables any mode of making and using the invention.'" *Johns Hopkins Univ.*, 152 F.3d at 1361 (quoting *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991)). That is because "[e]nablement does not require the inventor to foresee every means of implementing an invention at pains of losing his patent franchise." *Invitrogen Corp.*, 429 F.3d at1070-71.

As in *Johns Hopkins*, defendant here makes two arguments in support of a finding of lack of enablement. First, it contends that Abbott did not teach how to make the full range of claimed antibodies, and second, that Abbott did not teach how to make the claimed antibodies using all

disclosed methods. *See AK Steel Corp. v. Sollac & Ugine*, 234 F. Supp. 2d 711, 717 (S.D. Ohio 2002) *aff'd*, 344 F.3d 1234 (Fed. Cir. 2003). The prior section, denying Centocor's second summary judgment motion, addresses the first argument. The *Johns Hopkins* court "found the second argument to be legally irrelevant, because a patent need not teach how to make the claimed invention using every alternate method disclosed in the patent." *AK Steel Corp.*, 234 F. Supp. 2d at 717. That holding applies equally here. The parties do not dispute for the purposes of this motion that non-recombinant methods can be used to produce the claimed invention. That appears to enable the full scope of the patent, and Centocor therefore is not entitled to judgment as a matter of law as to enablement.

Accordingly, Centocor's fourth motion for summary judgment will be denied.

G. Willful Infringement: Centocor Motion 5

Finally, Centocor moves for a finding that if it did infringe the patents-in-suit, it did not willfully do so. It contends that Abbott cannot prove by clear and convincing evidence that Centocor was objectively reckless, because Centocor has plausible defenses of failure to meet the written-description and enablement requirements.

To prove willful infringement of a patent, a party must show by clear and convincing evidence both that (1) objectively, the conduct of the alleged infringer was reckless, and (2) subjectively, the risk of infringing a valid patent was known or so obvious that it should have been known to the alleged infringer. *In re Seagate Technology, LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc). Objective recklessness is a question of law based on "underlying mixed questions of law and fact." *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assoc., Inc.*, 682 F.3d 1003, 1006-07 (Fed. Cir. 2012), *cert. denied*, 133 S. Ct. 932 (2013). A finding of willful

infringement allows the court to award enhanced damages under 35 U.S.C. § 284. *Beatrice Foods Co. v. New England Printing & Lithographing Co.*, 923 F.2d 1576, 1578 (Fed. Cir. 1991).

Courts have found the objective prong unsatisfied where the alleged infringers had relied on a reasonable defense to a claim of infringement, such as a challenge for lack of written description or enablement. *Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305, 1319 (Fed. Cir. 2010) (vacating district court's denial of motion for JMOL of no willfulness); *see DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1336 (Fed. Cir. 2009). Reasonable reliance on the advice of counsel is another common defense. *See In re Seagate Tech., LLC*, 497 F.3d at 1369.

As Centocor has pointed out, some courts have granted motions for summary judgment that there was no willful infringement. *See, e.g.*, *Advanced Fiber Technologies (AFT) Trust v. J & L Fiber Servs., Inc.*, 674 F.3d 1365, 1377-78 (Fed. Cir. 2012) (affirming summary judgment); *Solvay, S.A. v. Honeywell Specialty Materials LLC*, 827 F. Supp. 2d 358, 366-67 (D. Del. 2011); *LG Display Co., Ltd. v. AU Optronics Corp.*, 722 F. Supp. 2d 466, 471 (D. Del. 2010). Many others, however, have waited until the record had been further developed at trial. *See, e.g.*, *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1310-11 (Fed. Cir. 2011) (affirming district court's grant of motion for JMOL of no willfulness); *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1335 (Fed. Cir. 2009) (affirming district court's finding of no willfulness at the close of evidence); *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 585 F. Supp. 2d 636, 644 (D. Del. 2008) (granting summary judgment where there had been prior trial, appeal, and remand); *cf. Highmark, Inc. v. Allcare Health Mgmt. Sys., Inc.*, 701 F.3d 1351, 1355 (Fed. Cir. 2012) (en banc) (Dyk, J. concurring) (suggesting that a determination of no

willfulness should be made on the entire record).

The latter course seems most prudent and appropriate here. Centocor's motion is based on claims of non-infringement for failure to meet the written-description and enablement requirements. This Court has denied the underlying motions on those issues—parts 1 and 2 of Centocor's motion for summary judgment—because there are underlying issues of disputed fact. The reasonableness of those invalidity defenses therefore has not yet been determined. *Cf. Bard Peripheral Vascular*, 682 F.3d at 1007 ("When the objective prong turns on fact questions, as related, for example, to anticipation, or on legal questions dependent on the underlying facts, as related, for example, to questions of obviousness, the judge remains the final arbiter of whether the defense was reasonable, even when the underlying fact question is sent to a jury.").

Accordingly, Centocor's fifth motion for summary judgment will be denied.

IV. Conclusion

For the foregoing reasons,

1. plaintiffs' partial motion for summary judgment on the issue of whether various references are prior art (part A) is DENIED;
2. plaintiffs' partial motion for summary judgment on the issues of whether the 4SE3 antibody is prior art (part B) and whether all the inventors were listed (part C) is GRANTED; and
3. defendant's motions for summary judgment are DENIED.

So Ordered.

/s/ F. Dennis Saylor
F. Dennis Saylor IV
United States District Judge

Dated: April 16, 2014