No. 2010-1144

United States Court of Appeals
for the Federal Circuit

CENTOCOR ORTHO BIOTECH, INC. AND NEW YORK UNIVERSITY,
Plaintiffs-Appellees

v.

ABBOTT LABORATORIES, ABBOTT BIORESEARCH CENTER, INC., AND ABBOTT BIOTECHNOLOGY LTD.,
Defendants-Appellants

Appeal from the United States District Court for the Eastern District of Texas in Case No. 07-CV-0139, Judge T. John Ward.

BRIEF OF *AMICUS CURIAE*
ELI LILLY AND COMPANY,
SUPPORTING ABBOTT LABORATORIES

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Eli Lilly and Company submits this brief as *amicus curiae* in compliance with Rule 29 of the Federal Rules of Appellate Procedure and with this Court's Rule 29. Lilly has no stake in the result of this appeal. The parties to this case have not contributed in any way to the preparation of this brief. Centocor Ortho Biotech, Inc. did not consent to the filing of this brief. Therefore, a motion for leave to file this brief as *amicus curiae* pursuant to Rules 29(a) and 29(b) of the Federal Rules of Appellate Procedure is filed contemporaneously.

I. STATEMENT OF INTEREST OF *AMICUS CURIAE*

Eli Lilly and Company is a research-based pharmaceutical company headquartered in Indianapolis, Indiana that discovers, develops, and markets important and valuable new medicines, including antibody therapeutics. This appeal is significant because an unjustified and unwarranted scope of patent rights in the area of antibody therapeutics, as with any other emerging technology, may chill continued research and development. Permitting a patent scope so broad that it excludes all competition in the important field of anti-TNF antibodies, yet is grounded on no more than the identification of a single chemical entity, has adverse implications for investment in innovation and the resulting competition such investment would engender.

II. INTRODUCTION

The pharmaceutical industry spends tens of billions of dollars annually on research and development related to bringing new medicines to the market. A large percentage of that spending is devoted to medicines based on antibodies. Rapid growth in the field of antibody research has led to the introduction of nineteen monoclonal antibody drugs into the U.S. market since 1994, while only one such monoclonal antibody drug was approved by the FDA prior to 1994. W. Wang et al., *Monoclonal Antibody Pharmacokinetics and Pharmacodynamics*, 84 Clinical Pharmacology and Therapeutics 548, 549 (2008). These medicinal antibodies treat and prevent a broad range of diseases or disorders including cancer, cardiac complications, rheumatoid arthritis, transplant rejection, and infectious diseases to name a few. Additionally, approximately five hundred antibodies are currently in clinical trials. *Id.*

In view of this rapid growth and the importance of this technology to the industry as a whole, clarity in the application of patentability criteria to antibody medicines is vital and urgent. It is imperative that traditional patentability principles, applied for over two hundred years to all fields of technology, apply to antibody patents. If the patent law that is common to

all technologies is to be applied similarly to antibody claims, it is essential that this Court's precedent neither be misunderstood nor misapplied.

In this case, the inventors of U.S. Patent No. 7,070,775 ("'775 patent") described nothing more than preexisting knowledge about the TNF-α antigen and a novel amino acid sequence of a single variable region from a mouse antibody that bound this well-characterized antigen.[1] Yet, the court below denied Abbott's motion for judgment as a matter of law, apparently agreeing that the specification provided an adequate written description for any human antibody that shares the mouse antibody's antigen binding function.

In reality, the structure of this variable region, which is the most critical structural element of the antibody and the segment that determines whether the antibody can be a medicine for rheumatoid arthritis or a new agent to treat cancer, has never been successfully predicted from the knowledge of the antigen to which the antibody binds. *See infra* Part III.B. Further, the sequence of one antibody capable of binding to an antigen does not lead to the identification of the other antibodies encompassed within

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[1] Although the '775 patent specification focuses on both the A2 and CA2 antibodies, these antibodies have an identical variable region. Thus, the patent discloses only a single variable region capable of binding the TNF-α antigen.

these potentially vast genus claims, even using the best current scientific tools. These basic scientific facts should be dispositive of this appeal.

The controlling patent law, outside the antibody context, has been particularly clear on what is required to adequately describe a chemical compound where the inventor lays claim to it in broad, dominating, functional terms. Such claims require the inventor to have completed a conception (and demonstrate the same in the patent specification) that identifies the purported genus through an adequate identification of its constituent embodiments. Here, the actual identification is not of those constituent embodiments, but rather merely a description of what function the embodiments are to perform. No relevant identifying characteristics, no structure-function relationship, and no representative number of species is disclosed. Thus, the scope of this patent vastly exceeds the claim scope merited given the nature of the benefit to the public supplied by the limited disclosure in the specification.

III. ARGUMENT

A. This Court's precedent does not hold that characterization of the antigen sufficiently describes all antibodies that bind to that antigen.

This Court has considered the written description requirement for claims involving antibody compounds in a limited number of cases, and in

those cases the Court found that the claims were invalid based on lack of written description. *In re Alonso*, 545 F.3d 1015, 1020-22 (Fed. Cir. 2008) (written description lacking because antibodies required to perform the claimed method "vary substantially in their composition"); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004) (no written description support that provided evidence of possession for claims to chimeric antibodies because chimeric antibody technology did not exist at the time of filing); *Noelle v. Lederman*, 355 F.3d 1343, 1349 (Fed. Cir. 2004) (no written description support for claims to the human CD40CR antibody because there was no disclosure of "the structural elements of the human CD40CR antibody or antigen" in the application).[2] In each of these cases, however, the Court suggested that a description of the *structure of the antigen*, had it been provided, might somehow impact whether the claimed antibodies that bind to the relevant antigen meet the written description requirement. *Alonso,* 545 F.3d at 1022; *Chiron*, 363 F.3d at 1251; *Noelle*, 355 F.3d at 1349. These suggestions, which are clearly dicta, could only be

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[2] In *Capon v. Eshhar,* 418 F.3d 1349 (Fed. Cir. 2005), the Court considered claims to chimeric genes encoding antibody binding regions coupled with cell surface proteins. The Court remanded the case, noting that information in the art at the time of filing should be considered in evaluating whether the claims meet the written description requirement.

relevant to a "written description" analysis if there were some universal antibody structure correlation that allows one to relate an antibody's structure with its antigen binding function. There is no such correlation.

B. A rule that characterization of an antigen is sufficient to describe an antibody that binds to that antigen would conflict with scientific reality.

Even with today's most advanced scientific tools, it is impossible to predict the actual structure (or otherwise provide a non-functional identification) of a not-yet-known antibody based on the structure of an antigen or even the structure of another antibody that binds that same antigen. *See, e.g.,* Julien Lescar et al., *Crystal Structure of a Cross-Reaction Complex Between Fab F9.13.7 and Guinea Fowl Lysozyme*, 270 J. Biol. Chem. 18067-76 (1995) (comparing the crystal structures of two antibodies that bind the same 12-residue antigenic epitope).[3]

Unlike the direct relationship between DNA and the proteins they encode, which is correlated by the "genetic code," there is no "antibody

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[3] The antibodies have completely different combining sites with no sequence homology at any of their CDRs (hypervariable regions) demonstrating that binding of the same structural antigen does not require the existence of sequence homology or other chemical similarities between different antibody binding sites. Consequently, the same antigenic site can be recognized by two different antibody binding sites having no sequence similarity whatsoever.

code" to correlate an antibody's structure with its antigen binding function. The relationship between an antigen and an antibody is much more akin to the relationship between a receptor and its corresponding ligand or an enzyme and its inhibitors. Certainly the description of a receptor on the surface of a cell would not be sufficient to describe all complex chemicals that bind to that receptor. A similar fact pattern involving enzymes has already been addressed by this Court. *See Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004) (COX-2 enzyme inhibitors not described even though the structure of COX-2 was known).

Antibodies are chemical compounds. Like any chemical compound, each antibody has a specific molecular structure and can be readily characterized by that structure. Antibodies typically contain two heavy chains and two light chains aligned in a "Y-shaped" configuration. Each chain of an antibody is conventionally discussed in terms of certain "regions" known as "constant regions" and "variable regions." Constant regions are generally not involved in antigen binding, and their structures are relatively consistent. Variable regions are the regions primarily responsible for antigen binding as well as for the great structural diversity among antibodies. It has been estimated that the total antibody diversity in humans

may be as high as 10^{11} different antibodies. Janis Kuby et al., *Immunology* 196 (2d ed. 1994).

Further, variable regions are comprised of "framework regions" and "hypervariable regions."[4] Framework regions, whose precise structures can vary significantly from one antibody to another, orient the hypervariable regions such that the antibody or antibody fragment can bind the antigen. The hypervariable regions, which display even greater variability, directly interact with and bind to the antigen.

Thus, it is impossible to predict which of the twenty naturally occurring amino acids exists at each position in the variable region of an antibody based on the structure of the antigen or even another antibody that binds the same antigen. In addition, it is impossible to predict, even if the amino acid sequence of a particular antibody is known, whether that antibody will have the desired biological activity without testing it in a biological assay. The entire premise upon which antibody-based medicine rests is dependent on these variable and completely unpredictable chemical structures.

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[4] Hypervariable regions are referred to in the art as complementarity determining regions or CDRs.

A comparison between the antigen binding region from the A2 antibody, which is the only binding region disclosed in the '775 patent, and the antigen binding region of Abbott's Humira™ antibody, which is alleged to be encompassed by Claim 2, illustrates this point. The Humira™ heavy chain variable region has 59.3% sequence identity with A2. The Humira™ light chain variable region has 56.1% sequence identity with A2. The corresponding hypervariable regions of Humira™ and A2 have sequence identities ranging between approximately 20-36%, indicating a high degree of variability.[5] The variable regions are substantially different between the two antibodies. The variable region of Humira™ could not be predicted based on the structure of A2.

Given the current state of the technology, the best and simplest way to identify an antibody such that it can be distinguished from other antibodies that bind a different antigen is to provide the sequence of the antigen-binding portion of that antibody, although the law allows other non-functional characterizations of the molecules. The core written description

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[5] Comparison of the variable region amino acid sequences of A2 and Humira™ was performed using the AlignX program of Vector NTI (Version 10.3.1, Invitrogen Corporation). The A2 variable region amino acid sequence was taken from the '775 patent. The Humira™ variable region amino acid sequence was taken from U.S. Patent No. 6,258,562 (issued July 10, 2001).

issue in this appeal rests on the identification of the variable regions for the claimed genus of antibodies. The Court's dicta, to the extent it may have been read to suggest that description of an antigen along with the general "Y-shaped" antibody structure is a sufficient description of a genus of antibodies that bind that antigen, is inconsistent with the best current science. That science lays out a clear understanding of the variability and unpredictability associated with the relevant and important part of the antibody structure.

C. The USPTO training materials are not controlling and lack persuasive value.

Example 13 of the USPTO's Written Description Training Materials suggests that because raising antibodies to an antigen is conventional and because antibodies are of five general types with common structural, chemical and biological features, description of an antigen is a sufficient description for antibodies that bind thereto. Further, without citing any support (because there is none to cite), the Example suggests that "[i]t does not appear that persons of skill in the art consider knowledge of the amino acid sequence of the variable regions critical for purposes of assessing possession of an antibody." U.S. Patent & Trademark Office, *Written Description Training Materials* 45-46 (rev. 1 2008), *available at* http://www.uspto.gov/web/meu/written.pdf. Thus, the training materials

suggest that possession of the antigen is possession of all antibodies that bind thereto.

This statement defies logic, is completely at odds with the predictability of the science, cannot be supported by any scientific literature, and is inconsistent with the actual USPTO Guidelines as well as the law. *See Enzo Biochem, Inc., v. Gen-Probe, Inc.,* 323 F.3d 956, 969 (Fed. Cir. 2002) ("A showing of 'possession' is ancillary to the *statutory* mandate . . . and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention."). The training materials do not have the force and effect of law. They clearly lack persuasive value when in conflict with scientific reality.

D. No relevant identifying characteristics and no structure-function correlation is disclosed in the '775 patent specification to provide written description support for the human antibodies claimed.

Description of the human TNF-α antigen (which was known in the art long before the filing date), and description of a single variable region that does not even fall within the scope of the asserted claims,[6] does not provide a person of skill in the art with any relevant identifying information to support the functional claims to human antibodies.

[6] The asserted claims are to human antibodies while the disclosed variable region is of mouse origin.

Referring to the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, P 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001) ("Guidelines"), this Court stated that

> the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, *functional characteristics when coupled with a known or disclosed correlation between function and structure*, or some combination of such characteristics."

Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1324 (Fed. Cir. 2002) (emphasis added by *Enzo* Court). In *In re Wallach*, 378 F.3d 1330, 1335 (Fed. Cir. 2004), the Court reasoned that a "functional description can be sufficient only if there is also a structure-function relationship known to those of ordinary skill in the art."

The relevant claims in this case do not cover a single antibody but rather a potentially very broad genus of antibodies. The claims are completely functional except for the recitation that the human antibodies have a human constant region and a human variable region. However, this cannot distinguish the claimed antibodies from unclaimed antibodies, a conclusion readily discerned from the simple fact that all human antibodies share the structural framework of a human constant region and a human variable region, yet not all antibodies share a common function.

Moreover, all the asserted claims, indeed, all the claims in the '775 patent, claim an "isolated recombinant anti-TNF-α antibody or antigen-binding fragment thereof." '775 patent, claims 1-22. Thus, in the instant case, the claims are not only directed to all antibodies that have a particular binding activity, they encompass any fragment that might have the activity of such unknown antibodies (an even greater number of potential molecules whose structure and activity is also not *a priori* known, predicted, or predictable).

The district court's explanation that "[a]ntibodies have a structure universal to all types," *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, No. 2:07CV139TJW, 2009 U.S. Dist. LEXIS 102767 (E.D. Tex. Nov. 4, 2009), is not, of course, a literal finding that all antibodies are identical in structure; it is merely acknowledgement that the gross structural features are shared. Indeed, the court rightly goes on to explain that the biological attributes of a particular antibody are owed to the specific chemical structure of an antibody's variable region—so called because it varies from one antibody to the next. *Id.* This is certainly supported by the patent itself, which declares that "[t]he avidity and epitope specificity of the chimeric A2 is derived from the variable region of the murine A2." '775 patent col. 21, ll. 10-11.

Thus, the only distinguishing features of the claims are stated in terms of function: 1) the ability to bind human TNF-α; 2) the ability to competitively inhibit the binding of a different antibody (A2); and 3) the ability to bind with an affinity of at least 1 x 10^8 liters/mole. This type of functional claiming is only allowable if there is a structure-function correlation disclosed in the specification or known in the art.[7] Otherwise, the functional limitations do not inform the skilled artisan as to the actual identity of the claimed entities. No structure-affinity correlation is disclosed or known that would predict the relevant variable region structure of a human antibody from a well-characterized antigen or even another antibody, such as A2, that binds the same antigen.

E. The '775 specification does not provide a representative number of species to support the asserted genus claims.

The '775 specification does not disclose the structure of a single antibody binding region that falls within the scope of the asserted claims.

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[7] The Guidelines provide that "[a] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." 66 Fed. Reg. at 1108, n.14.

Further, due to this lack of disclosure, it is completely unknown how broad this claim truly is and how structurally diverse the members of the genus actually are. *See* Bryan M. Edwards et al. *The Remarkable Flexibility of the Human Antibody Repertoire; Isolation of Over One Thousand Different Antibodies to a Single Protein, BLyS* 334 J. Mol. Biol. 103 (2003) (highly diverse panel of antibodies raised to a single protein). Thus, the genus claims that encompass human antibodies to human TNF-α are not supported by an adequate written description because the structure of a representative number of species is necessary to support the claims.

In *Regents of the University of California v. Eli Lilly and Co.,* 119 F.3d 1559 (Fed. Cir. 1997), the Court considered genus claims encompassing all vertebrate or mammalian insulin genes. In holding the claims invalid, the Court reasoned that

> [a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

Id. at 1569.

What constitutes a representative number of species is not arbitrary. *See Alonso*, 545 F.3d at 1019. In *Alonso* the Court stated,

> [W]hether the single monoclonal antibody described in the Specification is representative of the genus of monoclonal antibodies required to practice the claimed treatment method . . . depends on whether or not the antibodies (and the antigens they bind) would have been expected to vary substantially within the genus. The greater the variation in the genus, the less representative any particular antibody would be.

Id. (quoting *Ex Parte Alonso*, No. 2006-2148 (B.P.A.I. July 25, 2007)). The number of species disclosed must be sufficient such that the skilled artisan can reasonably predict the structure of the undisclosed members of the genus. Otherwise, a representative number has no meaning and is completely subjective.

In the case of antibodies, substantial variation exists between variable regions that bind the same antigen or even overlapping regions on a single antigen.[8] The variation between the amino acid sequence of the murine

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[8] Although the claim is limited to human antibodies that competitively inhibit binding of A2, those antibodies are not limited to antibodies that bind the same epitope as A2. Antibodies are large immunoglobulin molecules and depending on the three dimensional structure of the epitope and how the antibody orients itself when it binds, an antibody that binds a number of different epitopes on the antigen might nevertheless compete for binding with A2. Thus, the variation of the variable region for antibodies that are encompassed by the claims will be substantial. *See, e.g.*, Sachdev S. Sidhu & Frederic A. Fellouse, *Synthetic Therapeutic Antibodies* 2 Nat. Chem. Biol. 682 (2006); Germaine Fuh et al., *Structure-Function Studies of Two Synthetic Anti-Vascular Endothelial Growth Factor Fabs and Comparison with the Avastin™ Fab*, 281 J. Biol. Chem. 6625 (2006); Paul W. H. I. Parren & Dennis R. Burton, *Two-in-One Designer Antibodies*, 323 Science 1567 (2009).

variable region of A2 and the human variable region of Humira™ clearly illustrates how two variable regions that bind the same region on an antigen can vary substantially. *See supra* p. 9 and note 5. Thus, because not even a single species is characterized, and the genus is potentially quite large and varies substantially in terms of relevant structure, the asserted genus claims encompassing human antibodies are not supported by an adequate written description.

F. The claimed anti-TNF-α human antibodies could not be described in the '775 patent because the patent provides no evidence that the conception of those antibodies was completed at the filing date.

A fundamental requirement of patent law is that the act of invention must form the predicate for filing a patent application claiming the invention. The act of invention is the completion of a conception. It follows then, that a completed conception, perhaps even a reduction to practice, is a necessary predicate for drafting a patent specification with an adequate disclosure of the invention conceived. *See Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993).

A conception is not complete until "a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in

practice" is formed in the mind of the inventor. *Singh v. Brake*, 317 F.3d 1334, 1340 (Fed. Cir. 2003); William C. Robinson, *The Law of Patents for Useful Inventions* § 376 (1890). In simple terms, therefore, conception is the transition of an idea for an invention into its embodiments. Thus, conception of a genus of chemical compounds (antibodies included) requires more than proposing the hoped-for functional attributes of the genus; it requires identification of the constituent embodiments of the genus. If the claim is written to claim everything under the sun that achieves the stated function, then the identification of the corresponding embodiments must be equally expansive.

Demonstrating conception of a genus of antibodies requires disclosure sufficient to identify what antibodies fall within the generic scope and to distinguish them from antibodies not in the genus. Like any other chemical invention, this requires disclosure of more than mere function to the extent that an established structure-function relationship is unavailable. At the very least, a completed conception of antibody compounds involves knowledge of the structural parts of the antibody that are critical for its biological function. This Court has consistently recognized the link between conception and what constitutes an adequate written description. *Lilly*, 119 F.3d at 1559; *Fiers* 984 F.2d at 1171; *Amgen, Inc. v. Chugai Pharm. Co.*,

927 F.2d 1200 (Fed. Cir. 1991). In *Amgen*, this Court held that a specific probing strategy to screen a DNA library in search of the DNA encoding EPO was insufficient to constitute a conception of that DNA. 927 F.2d at 1206. The Court reasoned that "it is not sufficient to define it solely by its principle biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property." *Id.*

In *Fiers*, the Court reasoned that what is necessary to show conception also applies to the adequacy of descriptions of DNA. 984 F.2d at 1171. Applying the reasoning from *Amgen,* the Court stated, "If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, . . . then a description also requires that degree of specificity. . . . [O]ne cannot describe what one has not conceived." *Id.*

Thus, this Court has consistently held that merely providing a process to clone and characterize a complex chemical compound is not a conception of that compound. Further, because conception of a chemical compound must entail more than identifying a way of discovering the compound or screening a library in search of the compound, a description of the compound must entail more than that as well.

An antibody is a chemical compound that deserves no special dispensation. The '775 patent specification may disclose to a person of skill in the art what type of human antibodies to make (i.e., those having a desired function) and perhaps even how to make them using known methodology, but this does not demonstrate conception, nor does it otherwise describe those desired human antibodies.

G. The patentee's limited contribution to the art through the '775 patent specification underscores the magnitude of the "written description" deficiency.

The structure of the target TNF-α antigen was well-known in the art prior to the filing date. '775 patent col. 1, ll. 43-51. The '775 patent specification disclosed the sequence of a single murine variable region from antibody A2 that neutralizes human TNF-α activity and binds human TNF-α with an affinity of at least 10^8 liters/mole. Based on this limited contribution defining a very limited invention, the patent law affords—and should afford—only limited protection. The inventor should be entitled to claim only the variable region that was disclosed, with the opportunity of using comprising language to encompass any constant region sequence not involved in antigen binding, including murine and human (e.g., a chimeric antibody such as CA2) and further be entitled to whatever embodiments are rightly foreseen as equivalents. Nothing in the patent specification

demonstrates that the inventor had conceived, identified, or otherwise actually invented any other antibodies or binding fragments that comprise novel variable regions that compete with A2 for binding to TNF-α.

In the biotechnology area, probably more than in any other area, inventors seek (and often obtain) from the USPTO extremely broad claims based on a single, limited discovery. This Court, however, has properly used the written description requirement to assure that an inventor's contribution corresponds to the scope of the inventor's claims. *See Rochester*, 358 F.3d at 927 (could not claim a method using Cox-2 inhibitors because none had been described); *Lilly*, 119 F.3d at 1568-69 (could not claim DNA encoding vertebrate, mammalian, or human insulin based on a description only of the rat sequence); *Fiers*, 984 F.2d at 1170-71 (could not claim DNA encoding beta-interferon without describing the nucleotide sequence); *Amgen*, 927 F.2d at 1206 (could not define a gene solely by stating its principal biological property).

In each of these cases, the inventors had not done enough inventing to secure a broad claim. The *Rochester* case is a particularly egregious example of overreaching by the inventor. In that case, scientists at the University of Rochester developed a screening assay for compounds that inhibited COX-2 activity, but not COX-1 activity. They then went on to

claim methods using any compound that selectively inhibits COX-2 relative to COX-1, even though they did not describe how to make any such compound or give any idea about what such a compound would look like. The Court determined that the claims were invalid for failing to comply with the written description requirement. *Rochester*, 358 F.3d at 927.

The inventors named on the '775 patent, at most, accomplished what the Rochester scientists accomplished. They conceived of a problem, e.g., to find human antibodies with a particular function. The '775 patent specification, however, did not solve the problem because it does not actually describe any human antibodies with the desired function and certainly not *all* such antibodies.

Centocor asserts, "In the case of the '775 Patent, however, the patent ***does*** disclose human antibodies and does disclose the human TNF-α antigen. In fact, it discloses the human TNF-α antigen in great detail, providing its amino acid sequence and citing a reference that provides its crystal structure." *Plaintiff's Oppostion to Defendants Motion No. 1: For JMOL or for New Trial Regarding Written Description or, in the Alternative, for Reconsideration of Claim Construction and Entry of JMOL of Noninfringement*, at 16, *Centocor Ortho Biotech Inc. v. Abbott Labs.*, 2009 U.S. Dist. LEXIS 102767 (E.D. Tex. Nov. 4, 2009) (No. 2:07CV139). This

is extremely misleading. The '775 patent specification contains only the words "human antibody." No actual human antibodies are identified. In addition, an extensive human TNF-α antigen description was already in the prior art. The contribution to the art as disclosed in the '775 patent does not justify a grant of dominating claims to any and all human antibodies that might be discovered later.

IV. CONCLUSION

There is a distinct "written description" requirement that obligates an inventor to seek a patent only for what the inventor conceived and, thus, can so demonstrate in the patent specification. It precludes the patenting of mere ideas where actual embodiments to put them into practice have not been identified by the inventor. Inventors are entitled to broad and dominant patents when their conceptions are equally so. Such patents should not issue unless the patent specification provides such detailed information as to demonstrate that the inventor had a completed conception of the invention, delineating the borders of such possession to allow one of skill in the art to distinguish the invention from all other unclaimed subject matter.

There is no precise prescription by which this must be done. Nonetheless, this Court has gone to great lengths to provide guidance on various possible approaches at an applicant's disposal. In the guidance

provided, however, it is clear that an antibody claim, like any other chemical compound claim, having only functional limitations purporting to identify the claimed antibodies, does not meet the written description requirement. This is for the simple reason that, for these types of claims, functional limitations are the idea for the invention—the thing to be accomplished. They do not limit the scope of the claim to subject matter that has been invented or discovered, but only to the potential that those inventions or discoveries may be realized at some future point. In the instant case, the asserted claims in the patent at issue are flawed in just this way. Claiming "whatever works" simply fails the written description requirement.

CERTIFICATE OF SERVICE

I hereby certify that on this _____ day of March, 2010, two (2) bound copies of the foregoing BRIEF FOR *AMICUS CURIAE* Eli Lilly and Company were caused to be served, via Federal Express, to:

I also hereby certify that on this _____ day of March, 2010 copies of the foregoing BRIEF FOR *AMICUS CURIAE* Eli Lilly and Company were filed, via hand delivery, in the Office of the Clerk, United States Court of Appeals for the Federal Circuit.

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