

# Is Recent Written Description Requirement Jurisprudence a Symptom of an Emerging Equitable Legal Doctrine Exempting Significant Embodiments from Dominating Patents?

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The written description requirement ("WDR") is a U.S. patent law doctrine that has evolved rapidly in the past 15 years, and practitioners and commentators have experienced difficulty understanding, explaining, and predicting the contours of modern WDR doctrine.

A February 23, 2011 decision by a three-judge panel of the Court of Appeals for the Federal Circuit ("CAFC") may shed light upon the Court's thought processes regarding application of the WDR. In the decision ("*Centocor*"),<sup>1</sup> the CAFC held a U.S. patent invalid on WDR grounds because the specification of the invalidated patent described only a "wish or plan" to make the accused product, rather than the product itself.

However, the facts of the case suggest that recent developments in the CAFC's WDR jurisprudence do not represent mere application of an existing legal doctrine to new technology. Instead, those developments may be the embryonic stages of an emerging legal doctrine that the CAFC expresses under the WDR rubric merely because its WDR jurisprudence represents the Court's most analogous treatment of the equitable concerns motivating development of that doctrine.

## *WDR – An Evolving Doctrine*

In the U.S., as elsewhere, individuals who invent technological subject matter can secure the exclusive right to practice their invention by obtaining a patent. In order to obtain a U.S. patent, the inventor(s) must submit a patent specification to the U.S. Patent and Trademark Office for its examination. The specification must include a description of the invention and a set of claims which define the invention. Just as words in a deed or title document define the boundaries of a plot of land, so do patent claims define the boundaries, within a field of technology, of the subject matter for which exclusive rights are sought.

A U.S. patent issues when the Patent Office determines that the specification and claims satisfy certain requirements defined in the U.S. patent statutes. Should the Patent Office issue a patent that fails to satisfy the requirements of the patent statutes, a court may declare the patent invalid (as the CAFC did in *Centocor*), eliminating the patent owner's exclusive rights. One of those statutes<sup>2</sup>, includes the WDR, which reads:

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*The specification shall contain a written description of the invention, and of the manner and process of making and using it . . .*

Written disclosure of the claimed invention is considered the *quid pro quo* received by the public in exchange for the grant to the inventor of patent exclusivity,<sup>3</sup> so that the public possesses and can practice the invention following expiration of the patent.

Prior to about 1997, the WDR requirement was invoked by courts and the Patent Office primarily to prevent patent applicants from adding new subject matter to a patent application after it had been filed. However, in a landmark decision that year, the CAFC held that a U.S. patent must be held invalid when its specification fails to include a written description that sufficiently demonstrates that the inventor made (i.e., was in possession of) the invention that is claimed.<sup>4</sup>

Subsequent cases emphasize that the written description of the invention provided in the specification must correspond in scope to the claims for which patent rights are sought.<sup>5</sup> For example, a patent having claims directed to a broad class of compounds must have a specification that includes a correspondingly broad written description of those compounds. However, for technical subject matter readily understood by skilled workers in the relevant technical field, relatively narrow written description can suffice.

Issues regarding compliance with the WDR tend to arise in patent litigation relating to biotechnology inventions in particular. This is likely because biological molecules are often more simply (and interestingly) described by *what they do* (i.e., their function) than by *what they are* (i.e., their structure).

By way of a first example, even though different species of animals can express proteins having highly similar functions and structures, the CAFC has held that a patent specification that includes a writ-

ten description of the gene encoding the protein in one animal fails to satisfy the WDR for a claim directed broadly to genes encoding the protein in all animals.<sup>6</sup>

By way of a second example, the CAFC has held that a patent claim directed broadly to all antibodies that bind with a particular protein can satisfy the WDR if the specification includes a sufficient written description of the antigen with which it binds.<sup>7</sup> (An antibody is a type of protein characterized by having several regions of highly conserved structure, by having a few regions of highly variable structure, and by being capable of binding specifically with a target, called an "antigen," which can vary for different antibodies.)

The dispute resolved by the *Centocor* decision related to antibody technology.

#### *The Dispute*

Humira<sup>®</sup> is an antibody marketed by Abbott Laboratories, Inc. ("Abbott") as a drug for treatment of rheumatoid arthritis and several other conditions. Humira<sup>®</sup> exerts its effect by binding with an antigen target named "TNF."<sup>8</sup>

TNF-binding antibodies were made as early as the mid-1980s by various groups. Unlike previous TNF-binding antibodies, Humira<sup>®</sup> can be used as a drug in humans because it was engineered by Abbott to include conserved and variable regions that are not rejected by the human body (i.e., it is an antibody having "human" conserved and variable regions — in other words, a "fully-human" antibody).

Centocor Ortho Biotech, Inc. ("Centocor," the plaintiff in *Centocor*) asserted a U.S. patent it owned against Abbott. Centocor's patent included a claim directed to fully-human, TNF-binding antibodies. Because Humira<sup>®</sup> is such an antibody, Centocor claimed that Abbott's use and sales of Humira<sup>®</sup> infringed Centocor's patent.

At trial, a jury agreed with Centocor's assertion that its patent claims were infringed by Humira<sup>®</sup>, declined to invalidate Centocor's patent for failure (alleged by Abbott) to satisfy the WDR, and entered a verdict in excess of \$1.5 billion. Abbott moved the trial court for judgment as a matter of law ("JMOL"), alleging that Centocor's patent failed to satisfy the WDR, but the motion was denied. Abbott appealed to the CAFC.

### *The Decision*

On appeal, the CAFC reversed the trial court's decision to deny Abbott JMOL,<sup>9</sup> holding that the WDR was not satisfied for the patent claims that Centocor asserted against Abbott and that those claims were therefore invalid and could not be asserted.

Centocor's patent specification described TNF-binding, chimeric antibodies (i.e., those having human conserved regions and non-human variable regions). The specification failed to disclose any specific human variable regions, but did disclose methods by which fully-human, TNF-binding antibodies (including human variable regions) could be obtained. The litigants disagreed as to whether those methods could have been successfully employed in 1994 to yield precisely the antibody developed by Abbott. However, in its decision, the CAFC held that the outcome of that disagreement was immaterial to satisfaction of the WDR.

The CAFC held that Centocor's specification disclosed no more than a "mere wish or plan" for obtaining fully-human, TNF-binding antibodies.<sup>10</sup> Even if the plan could be readily understood by a skilled worker in the relevant technical field and implemented by that worker in a manner likely to eventually yield those antibodies, the CAFC held that disclosure of such a plan did not suffice to satisfy the WDR. Perhaps recognizing a shortcoming in its ability to articulate its test for compliance with the WDR in a satisfying manner, the CAFC's opinion offered several alternative explanations of Centocor's failure to satisfy the WDR:

- A skilled worker cannot, relying on the disclosure in Centocor's specification of a plan for developing fully-human antibodies, "visualize or recognize" the fully-human, TNF-binding antibodies that would result from performance of that plan.<sup>11</sup>
- Centocor's specification did not demonstrate that Centocor had "constructive possession" of fully-human, TNF-binding antibodies.<sup>12</sup>
- Fully-human, TNF-binding antibodies claimed by Centocor are "beyond the scope of its disclosure," and "Centocor's right to exclude cannot overreach the scope of its contribution to the field of art as described in the patent specification."<sup>13</sup>

The CAFC concluded that Centocor sought to include within the scope of its patent technology that Abbott developed — but that Centocor had not developed with sufficient concreteness. Even though Centocor could essentially demonstrate that all of the aspects of Abbott's technology were described in Centocor's patent specification,<sup>14</sup> the CAFC remained unconvinced that Centocor had "connected the dots" to arrive at the particular technological embodiment that Abbott developed before Abbott actually developed it.

In short, the CAFC seems to be cautioning patent applicants that U.S. patent law requires of patent applicants more disclosure than merely a wish for a desired product and a plan to attain it —seemingly especially for embodiments that turn out to be especially significant and are not explicitly described in the patent specification.

### *Immediate Implications*

The *Centocor* decision, as well as other WDR-related decisions cited in this article suggest that the CAFC is taking a narrow view of the subject matter that is considered to be disclosed in written documents, at

least in some technical fields. This can work both for and against the interests of patent applicants in the U.S.

Owners of existing U.S. patents and patent applications may need to reconsider the adequacy of their specification, especially with regard to claims which reach beyond the explicit scope of what is disclosed. For pending applications, applicants might be well advised to consider including claims having a scope limited to what is explicitly disclosed in the specification, in addition to claims including within their scope all subject matter which the applicant believes is fairly taught in the specification. Owners of issued U.S. patents, may wish to consider using reexamination, reissue, and filing of related applications to ensure that their patent estates include claims having a scope that is defensible under the CAFC's application of the WDR.

In view of *Centocor* and other WDR-focused decisions of the CAFC, technology developers may wish to carefully consider the timing of patent application filing. To the extent that national patent laws permit (as they do in the U.S.) such strategies, technology developers desiring patent claims that encompass a technology in a broad manner should consider either i) filing multiple patent applications serially over time, as inventive aspects of the technology are developed or ii) waiting to file until they can prepare a patent application that describes the technology throughout the desired claim scope. The former strategy has the disadvantages of greater cost and (for some patent-issuing authorities) impracticality, but secures the earliest-possible effective filing date for each aspect. The latter strategy can lower costs, but runs the risk that others may create prior art that precludes patenting, or may even patent the technology themselves. *Centocor* and the other decisions cited herein also suggest that patent applicants who desire claims that are considered broadly consistent with the WDR should describe relationships between claim elements and desirable characteristics of the claimed technology whenever possible.

Patent applicants may also be able to use the *Centocor* decision "offensively" to counter prior art-based rejections made by patent examiners. Applicants have always had the right to point out that a prior art reference fails to teach or suggest what the applicant claims. In view of the discussion in *Centocor* and related cases regarding the degree of detail necessary for a patent applicant to adequately describe claimed technology, it stands to reason that prior art references that merely predict that claimed subject matter could be made – without disclosing the identity of that subject matter, as the Court criticized in *Centocor* – should be open to attack for the same reason as describing the subject matter insufficiently to disqualify patenting.

#### *Broader Implications*

Despite the fact that U.S. patent statutes prohibit consideration of the manner in which an invention is made when assessing patentability,<sup>15</sup> the CAFC devoted many paragraphs of its *Centocor* opinion to describing differences between the manner in which Abbott developed its Humira<sup>®</sup> product and the manner in which Centocor developed the technology for which it sought patent protection. In addition to being irrelevant to the issue of obviousness, such differences are also irrelevant to satisfaction of the WDR, for which the focus is upon "an objective inquiry into the four corners of the specification."<sup>16</sup> The extended discussion of how the patentee's invention was made in *Centocor* and in several of the other WDR-focused CAFC decisions cited in this article suggests that the issue troubling CAFC judges is not necessarily the written contents of the specification.

As with other recent CAFC decisions addressing compliance with the WDR, the *Centocor* decision fails to set forth a single discernable standard against which satisfaction of the WDR can be objectively measured.

The apparent difficulty in articulating a WDR standard, taken together with the Court's focus on how

the patented invention was made in such cases, suggests that rather than adapting existing patent law to changing technology, modern judicial application of the WDR reflects attempts by the CAFC to deter patent practices that are considered inequitable and that have only recently been made possible by increasingly rapid advances in certain technical areas – particularly in the field of biotechnology. Such an explanation may also explain why WDR-focused opinions seem to be issued most frequently in cases involving biotechnology.

Modern biotechnology has been developed primarily in the last quarter century or so. Prior to the twentieth century, plants and animals (including humans) were largely considered "bags of chemicals" of essentially impenetrable complexity, and much of that complexity remained undeciphered until the latter part of the century. Owing to the work of many, the veil of mystery has been lifted from many aspects of biological function.

Biological systems exhibit several characteristics that distinguish biotechnology from more "predictable" technologies such as mechanics or simple chemistry. Most biological systems are characterized by a high degree of modularity, such as the ability of life forms to exhibit their immense diversity and capability largely through molecules built from various combinations of several nucleotides and a few dozen amino acids.<sup>17</sup> Biological systems also frequently exhibit redundancy (e.g., multiple systems that can achieve the same end), use of highly similar elements to achieve very different ends (e.g., some nucleotide polymers store information, others control cellular processes, still others catalyze chemical reactions), and wide variations in function resulting from relatively minor variations in structure (e.g., the ability of antibodies, such as those at issue in *Centocor*, to specifically bind particular molecules).

Although none of those characteristics are unique to biotechnology, it may be that high incidence of those characteristics in biological systems causes

biological technologies to press against the conceptual boundaries of patent law in ways that older technologies do not frequently do. After all, absent the past few decades, patent law has developed for centuries in the absence of biotechnology. It might therefore not be surprising to discover that patent law has not previously developed protocols for resolving conflicts that arise more frequently between biotechnology pioneers than between pioneers in other technical fields.

In *Centocor*, it could not be seriously disputed that the desirability of using fully-human antibodies in humans, the components of human antibodies, and methods of making fully-human antibodies were all known and disclosed in *Centocor*'s specification (read in light of what was known in the art). The CAFC's underlying complaint in *Centocor* was not that the starting materials, motivation, or know-how for making fully-human, TNF-binding antibodies were not disclosed. Instead, as illustrated by the fact that the CAFC's decision highlighted differences in the manner in which each of *Centocor* and *Abbott* had developed their technologies and by the essential lack of a discernable standard against which *Centocor*'s technical contributions were considered insufficient to satisfy the WDR, the CAFC's *Centocor* decision seems to focus on a more fundamental "unfairness" in permitting *Centocor* to exercise exclusive rights over technology for which *Abbott* had performed very substantial research to achieve —essentially, if not completely, independently of *Centocor*.

It may be desirable to encourage and reward researchers who build upon the work of predecessors. An appropriate reward may include exempting extraordinarily useful developments from the underlying patent rights of their predecessors. However, it is far from clear that this is the function for which the WDR was included in the U.S. patent statutes, or that it is an effective statutory provision for effecting such motivations.

Despite many attempts in recent CAFC jurisprudence, its decisions have failed to coalesce around an articulable and generally applicable standard by which compliance with the WDR can be assessed. The CAFC is also apparently willing to hold issued U.S. patents invalid on WDR grounds in cases in which a generic patented invention is asserted against an extraordinarily desirable, but not explicitly described, embodiment of that invention. These observations suggest that the CAFC is groping for a legal or equitable doctrine for rewarding inventors of such extraordinary embodiments while denying those rewards to patentees who are entitled to a patent for their broad, generic contribution, but who failed to recognize or develop the benefits of narrower, but extraordinary useful embodiments of the broad contribution.

It remains to be seen whether an "extraordinarily useful embodiment" exclusion from the scope of valid patent claim coverage will emerge from Congress or from the CAFC's continuing jurisprudence in this area.

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<sup>1</sup> *Centocor Ortho Biotech, Inc. et al. v. Abbott Laboratories et al.*, 97 U.S.P.Q.2d 1870 (Fed. Cir. 2011).

<sup>2</sup> 35 U.S.C. § 112.

<sup>3</sup> *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609,1617 (Fed. Cir. 2002)

<sup>4</sup> *Univ. Calif. v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998).

<sup>5</sup> See, e.g., *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 94 U.S.P.Q.2d 1161 (Fed. Cir. 2010) (*en banc*) and *Reiffin v. Microsoft*, 54 U.S.P.Q.2d 1915 (Fed. Cir. 2000).

<sup>6</sup> *Univ. Calif. v. Eli Lilly and Co.*, *supra*.

<sup>7</sup> *Noelle v. Lederman*, 69 U.S.P.Q.2d 1508, 1514 (Fed. Cir. 2004).

<sup>8</sup> TNF is tumor necrosis factor alpha. The structure of TNF was sufficiently well-characterized that a claim directed generically to antibodies that bind with TNF would likely have been considered to be in compliance with the WDR at the time that Centocor's patent application was filed, applying the doctrine in *Noelle, supra*.

<sup>9</sup> More specifically, the CAFC held that the jury lacked a sufficient evidentiary basis to conclude that Centocor's patent claims satisfied the WDR and, consequently, reviewing the trial court's JMOL decision *de novo*, the trial court should have granted JMOL for Abbott on that basis. *Centocor* at 1876.

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*, citing *Univ. Calif. v. Eli Lilly and Co.*, *supra*.

<sup>12</sup> *Id.*, citing *Ariad, supra*. Note: It was undisputed that Centocor did not achieve actual possession of a fully-human, TNF-binding antibody as of the time its 1994 patent specification was filed.

<sup>13</sup> *Id.*, citing *Reiffin, supra* (internal punctuation omitted).

<sup>14</sup> Indeed, by filing claims directed to fully-human, TNF-binding antibodies in 2002, after Abbott had already developed its Humira<sup>®</sup> product, that is precisely what Centocor did. The U.S. Patent Office, by issuing Centocor's patent, presumptively concluded that the patent's claims complied with the WDR, as well as all other requirements of patentability.

<sup>15</sup> "Patentability shall not be negated by the manner in which the invention was made." 35 U.S.C. § 103(a).

<sup>16</sup> *Ariad* at 1173

<sup>17</sup> For the purposes of this article, it is sufficient to understand that nucleotides and amino acids are relatively simple chemicals that can be combined, like beads on a string, in an immense variety of ways. Thus, the untold billions of molecule types of which the multitudinous known life forms are made are all derived from a few dozen chemicals (with important contributions made by others).