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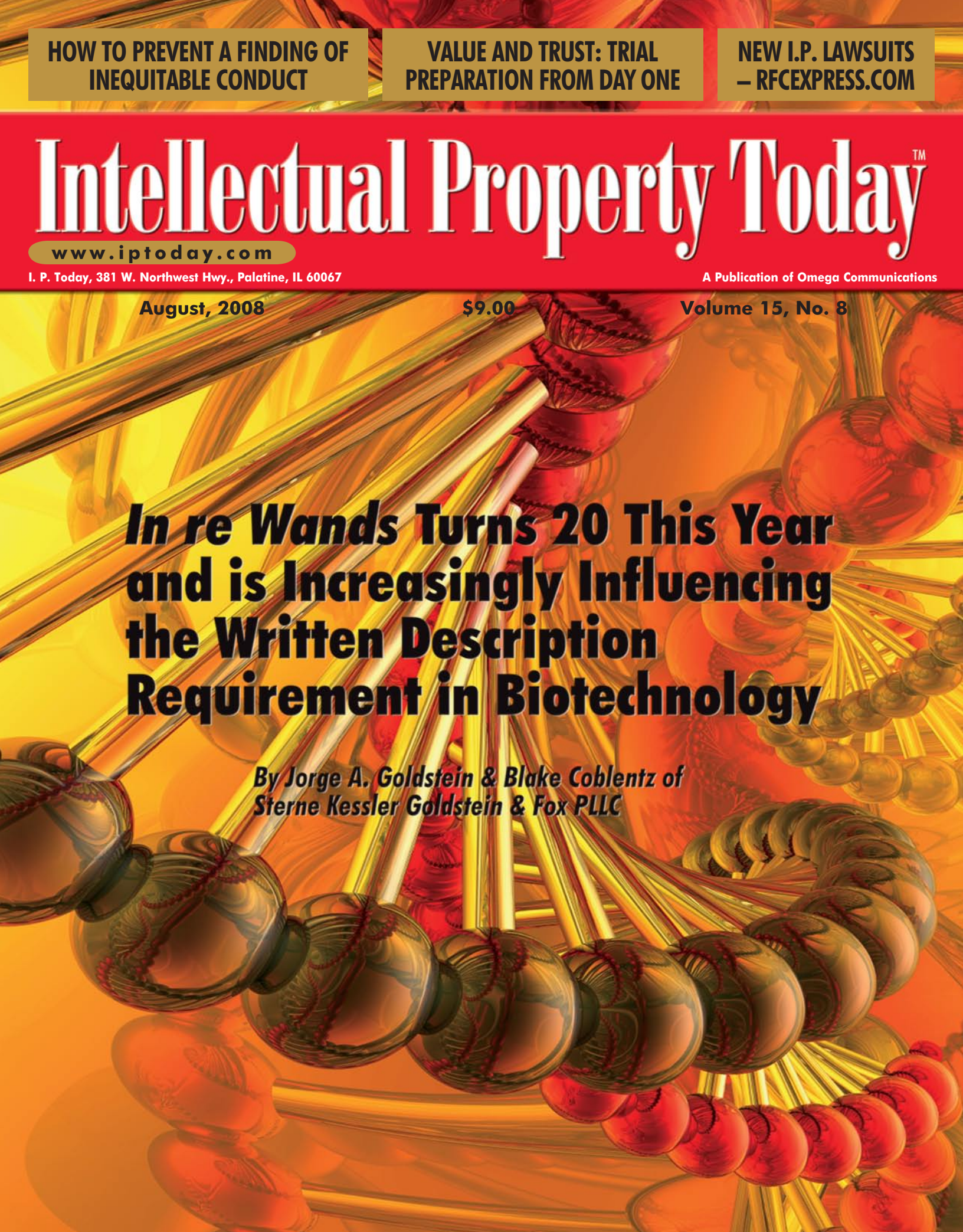

In re Wands Turns 20 This Year and is Increasingly Influencing the Written Description Requirement in Biotechnology

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In re Wands[1], the seminal decision on the enablement of biotechnology patents, celebrates its 20th birthday on September 30 of this year. In 1988, the Court of Appeals for the Federal Circuit (CAFC) in the *Wands* case outlined an eight factor analysis for determining whether the claims of a patent drawn to immunoassays using monoclonal antibodies were enabled. Since then the "eight *Wands* factors" have remained the standard for enablement not only for antibody patents, but for all biotechnology patents. The *Wands* decision has been, and continues being, cited as the cornerstone of any analysis of claim scope and breadth. One hundred and thirty four court and PTO decisions, 133 law review and periodical articles, 42 treatise citations and thousands of PTO Office Actions attest to the continued strength and validity of the *Wands* analysis.

Most interestingly, however, is the fact that the *Wands* decision has started influencing the written description requirement which, in the biotechnology field, had always been considered to be quite distinct. For example, three years after *In re Wands* was decided, the CAFC, in *Vas-Cath Inc. v. Mahurkar*, stressed the differences between the written description and enablement requirement: "The purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." [2] More recently, however, the written description requirement in biotechnology has undergone a period of unrest, evolving from the traditional "possession standard" (i.e., "did the applicant or patentee have possession in an earlier priority document of the later claimed invention?") to a "scope standard" (i.e., "did the applicant or patentee have a description of the full scope and breadth of the invention that the applicant or patentee is now claiming?").

In the early 1990's, in *Fiers v Revel*, the CAFC confirmed once more the possession standard to meet the written description requirement in biotechnology. In *Fiers*, the CAFC ruled that between one interference party who had no more than a mere plan that certain DNA was part of the invention and another party who had actually obtained the DNA, the latter party complied with the written description requirement, and the former did not.[3] While actual possession of a tangible embodiment is not necessarily a requirement in other areas of the law, in biotechnology since *Fiers*, the requirements of written description need to still go beyond a "mere plan."

Things got interesting in 1997 when, in *Regents of the University of California v. Eli Lilly & Co.*, the CAFC incorporated a "scope" component into written description law. The CAFC held in *Eli Lilly* that description of a genus or family of cDNAs from different animal species by function alone did not suffice to describe the broad genus because function is only the indication of what genes do, rather than what they are. Instead, the CAFC held 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."[4]

After *Eli Lilly*, the CAFC proved to be less than harmonious on the direction to which the written description requirement was heading. No two CAFC decisions illustrate the conflict more than *Enzo Biochem, Inc. v. Gen-Probe Inc.* and *Amgen Inc. v. Hoechst Marion Roussel, Inc.* In *Enzo Biochem* the CAFC held that the reference in a patent specification to a deposit in a public depository constituted an adequate written description of the deposited material.[5] However, the CAFC remanded to the district court a determination on whether patent claims not limited to the deposited sequences would be described in light of the deposited sequences and the scope of the claims.[6] The Court distinguished *Eli Lilly* by stating that not all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if, in the knowledge of the art, the disclosed function is sufficiently correlated to a particular structure.[7] A petition for rehearing in *Enzo Biochem* exposed the discord within the CAFC. In a vigorous dissent from the court's decision not to hear the case *en banc*, Judges Rader, Gajarsa and Linn noted that *Eli Lilly* was a deviation from thirty years of precedent in written description law in that it seemed to impose a scope standard into what had been a mere possession standard. The dissent stated that "[i]nstead of invalidating under the statutory test for adequacy of disclosure, i.e., enablement, the *Lilly* court purported to create a new doctrine for adequacy of disclosure that it labeled incorrectly 'written description.'"[8] The dissent also warned that *Eli Lilly* requires far too much disclosure and that both *Eli Lilly* and *Enzo Biochem* "threaten to further disrupt the patent system by replacing enablement - the statutory test for adequate disclosure."[9],[10] The concurrence by Judges Lourie, Newman and Dyk fired back at the dissenters, saying that "[t]o interpret the written description only as an enablement provision is to let the tail wag the dog."[11]

Amgen Inc. v. Hoechst Marion Roussel, Inc. exposed even more friction within the CAFC. In *Amgen*, the CAFC dealt with claims to the use of a broad class of available mammalian and vertebrate cells to produce high levels of human erythropoietin in culture.[12] The Court affirmed the District Court's decision that the broad claims were fully described and in doing so appeared to lean towards the dissent in *Eli Lilly*. In distinguishing *Eli Lilly* and *Enzo Biochem*, the CAFC stated that those cases dealt with the written description of new and unknown genetic material and that one must look at the understanding of the skilled artisan to determine if the claimed material is known and, if so, whether it is necessary to re-describe the claimed material to the degree required in prior cases[13] In dissent, Judge Clevenger pointedly stated that the majority opinion "verges on confining *Eli Lilly* to its facts."[14]

More recently, as the written description analysis has increasingly focused on claim scope, the CAFC, rather than sharpening the split between those who see written description as clearly distinct from enablement, has paid attention instead to the similarities between both areas of law and has borrowed some of the *Wands* factors (although *sub silentio*) as an aid in written description analyses. This reached its zenith in *Capon v. Eshhar*[15], a 2005 CAFC decision that attempted to harmonize the tension between the "possession" and "scope" inquiries in written description law and ended up bringing the written description and enablement standards a little closer. *Capon* dealt with claims to chimeric genes from selected segments of known DNA sequences.[16] The Board invalidated all of the claims for failure to include in the specification the complete nucleotide sequence of "at least one" chimeric gene.[17] On appeal, the CAFC held that "the Board erred in ruling that § 112 imposes a *per se* rule requiring recitation in the specification of the nucleotide sequence of claimed DNA, when the sequence is already known in the field."[18] The *Capon* Court then borrowed a page from enablement law and molded a multi-factor test for written description that shares striking similarities with the eight *Wands* factors. The CAFC vacated and remanded to the Board for a determination of sufficiency of description based on what we may now properly start calling the "*Capon*" factors for written description (Table 1)[19]

Five of the eight *Wands* factors find their equivalents in the *Capon* factors. These have to do with the invention itself, its breadth, and how those of skill in the art at the time of filing would understand and interpret it. The inquiries for these areas are the same whether one is analyzing enablement or written description. The three *Wands* factors that do not find equivalents in *Capon* (quantity of experimentation, amount of direction or guidance and working examples) are clearly drawn to the unique reproducibility and experimentation requirements of enablement law.

In 2006, in *Falkner v. Inglis*, the CAFC carried forward and expanded upon *Capon*. *Falkner* involved an appeal of the Board's decision in an interference denying Falkner's motions both challenging the written description of the claims of the Inglis' application at issue as well as the priority applications to which Inglis claimed benefit.[27] The CAFC recognized the relation of these motions and stated "we need only to resolve the following common issue: whether the Inglis benefit applications adequately describe and enable a poxvirus-based vaccine."[28] In *Falkner* the court "discerned no error in [the Board's] conclusion that the disclosures relied upon by Inglis for priority purposes adequately described and enabled the invention directed to poxvirus, ..."[29] The Court used the *Capon* factors (existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology and the predictability of the aspect at issue) to further hold that examples, an actual reduction to practice, and recitation of known structure are not required for written description.[30]

This evolution of the case law illustrates how the CAFC has been struggling to harmonize the debate between the "possession" (e.g., *Vas-Cath*, *Fiers*) and "scope" (e.g., *Eli Lilly*) components of written description law that emerged so stridently in the petition for rehearing in *Enzo Biochem*. In doing so, the Court, without so many words, started using factors in *Capon* and *Falkner* that seem to have been recruited from the eight *Wands* factors used in enablement analyses. As a consequence, while clarifying claim scope inquiries in written description law, the Court has brought enablement and written description law a little closer.

Even though the *Wands* and *Capon* factors are not identical, it is becoming increasingly apparent that the CAFC will weigh a common set of considerations when determining enablement and written description in biotechnology. A good disclosure in biotechnology patent specifications will therefore satisfy an overlapping set of legal requirements in both areas of the law.

Happy birthday, *In Re Wands*. IPT

TABLE 1

***Wands* Factors for enablement**	***Capon* factors for written description**
(1) quantity of experimentation,	
(2) amount of direction or guidance,	
(3) working examples,	
(4) nature of invention,	nature …of the invention at issue[20]
(5) state of art,	the existing knowledge in the particular field, the extent and content of the prior art,[21]
(6) relative skill in art,	the maturity of the science or technology,[22] …and … the scientific and technologic knowledge already in existence.[23]
(7) predictability of art,	the predictability of the aspect at issue,[24]
(8) breadth of claims	scope of the invention at issue[25]
	other considerations appropriate to the subject matter[26]

ENDNOTES

1. 858 F.2d 731 (Fed. Cir. 1988)
2. 935 F.2d 1555, 1563 (Fed. Cir. 1991)
3. 984 F.2d 1164, 1170-1171 (Fed. Cir. 1993)
4. 119 F.3d 1559, 1569 (Fed. Cir. 1997)
5. 323 F.3d 956, 966 (Fed. Cir. 2002)
6. *Id.* at 970
7. *Id.* at 964
8. *Id.* at 979-80
9. *Id.* at 982
10. In a concurring opinion in *Moba v. Diamond Automation*, Judge Rader in 2003 noted the serious challenges *Eli Lilly* presents to an inventor in the biotechnology field: "Confusing the *Lilly* disclosure doctrine with the traditional written description doctrine, this court has stated that written description is separate from enablement. . . Of course, this proposition is true with respect to the traditional written description/new matter doctrine. On the other hand, the only way to distinguish the *Lilly* rule from enablement is to construe *Lilly* as requiring more disclosure than necessary to enable one of skill in the art to make and use the invention, a "super-enablement" standard. Interpreting *Lilly* in those terms, however, presents severe consequences for biotechnology. For biotechnological inventions, *Lilly* purports to require the recitation, nucleotide by nucleotide, of the entire sequence of a new protein or composition. This non-statutory rule jeopardizes the validity of many inventions in biotechnology patented from the advent of the biotech era in the late 1970s. Before judicial creation of the *Lilly* rule in 1997, no inventor could have foreseen that the Federal Circuit would make a super-enablement rule. Without any way to redraft issued patents to accommodate the new rule, a large number of patents in the field of biotechnology face serious and unavoidable validity challenges." 325 F.3d 1306, 1324-25 (Fed. Cir. 2003).
11. *Id.* at 974
12. 314 F.3d 1313, 1330-32 (Fed. Cir. 2003)
13. 314 F.3d 1313, 1330-32 (Fed. Cir. 2003)
14. *Id.* at 1361.
15. 418 F.3d 1349 (Fed. Cir. 2005)
16. *Id.* at 1351-52
17. *Id.* at 1356
18. *Id.* at 1360-61
19. *Id.* at 1361
20. *Id.* at 1357
21. *Id.* at 1359
22. *Id.* at 1359
23. *Id.* at 1357
24. *Id.* at 1357
25. *Id.* at 1357
26. *Id.* at 1359
27. 448 F.3d 1357, 1362-63 (Fed. Cir. 2006)
28. *Id.* at 1362-63
29. *Id.* at 1367
30. 448 F.3d 1357, 1366-67 (Fed. Cir. 2006)