High hurdles for biotechnology patents: The written description requirement

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Biotechnology patents face rigorous disclosure requirements, as confirmed by a recent court ruling. The “written description” requirement has been reinforced as a difficult hurdle for obtaining biotechnology patents, and also as an expedient vehicle for invalidating biotechnology patents on summary judgment. The written description requirement was the downfall of key claims of Carnegie Mellon’s patents in Carnegie Mellon University v. Hoffmann-La Roche, which teaches important lessons for patent applicants and their challengers.

Carnegie Mellon’s invention—Beyond E. coli?

In Carnegie Mellon, the US Federal Circuit invalidated broad claims of several patents held by the university relating to the production of polymerase enzymes. By the early 1980s, it was known that polymerase enzymes could be produced by cloning the polA gene into a plasmid and introducing the plasmid into a bacterium, where it would replicate to produce the polymerase enzyme. The problem at hand, and known in the prior art, was that the increased production of polymerase was lethal to the host cell, effectively killing the goose that was laying the golden egg. Carnegie Mellon’s solution was to damage the natural polA promoter sequence for the polA gene and introduce a foreign promoter. The foreign promoter suppressed the production of polymerase while colonies of bacteria were grown. At the desired time, the controllable promoter could be “switched on,” resulting in production of large amounts of polymerase.

Carnegie Mellon developed this technology through experimentation with the bacterium E. coli. However, Carnegie Mellon claimed its invention as more than simply the use of genes cloned from E. coli, and most of its patent claims were directed to plasmids containing polA genes from any bacterial source. In the university’s view, the invention was the use of a gene having a mutant promoter sequence that could be “switched off” to allow a colony of bacteria to grow, and then “switched on” to allow production of polymerase once the colony reached an appropriate size. According to Carnegie Mellon, this invention was generic to any particular bacterial source. However, after Carnegie Mellon sued Roche Molecular Systems and other defendants for alleged patent infringement, the trial court struck down on summary judgment Carnegie Mellon’s broad “genus” claims as lacking adequate written description, and the court of appeals affirmed.

The “written description” requirement in biotechnology

All patents must contain a detailed description of the claimed invention. This requirement is codified at 35 USC § 112, ¶ 1, which mandates that the patent 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 make and use the same.” The level of detail required by this written description of the invention is a critical question, and it is clear that the bar is higher in biotechnology than in other fields.

In the “predictable” sciences, such as software and the mechanical sciences, the courts are far more lenient in what they demand of a detailed description. For example, software developers need not disclose their source code. Frequently, flow charts illustrating the overall software architecture are sufficient to satisfy the written description requirement for software inventions. In general, the governing principle is that a person of general skill in the field must be able to determine—from the patent specification—that the inventor was “in possession” of the claimed
invention. In the predictable sciences, this principle sets a low bar, and such patents are rarely invalidated for lack of written description.

By contrast, the courts treat biotechnology as an “unpredictable art,” and the Federal Circuit seems to have singled out biotechnology in imposing a particularly strict written description requirement. At a high level, the rule is that “[t]he disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described.” As a more practical matter, and although there is no mandatory rule that requires this level of disclosure, it is typical for patentees to provide exacting descriptions of their inventions in the specification, including particular sequences of the genes or amino acids underlying their inventions.

A biological deposit is one way that courts have allowed patentees to satisfy the written description requirement. Functional descriptions of the invention, while not categorically prohibited, are generally inadequate, as reflected in the mantra that “[a] description of what a material does, rather than of what it is, usually does not suffice.”

The written description requirement for biotechnology inventions tightened in the 1997 case of Regents of the University of California v. Eli Lilly. In that case, the Federal Circuit considered claims to a genetic sequence for encoding mammalian and vertebrate insulin, including for humans. The patent specification disclosed rat insulin-encoding cDNA and provided a general method for obtaining human cDNA for insulin, along with the amino acid sequences of human insulin A and B chains. Because the patent did not provide a written description of the cDNA for encoding human insulin, the Federal Circuit found that the patent lacked an adequate written description, and invalidated the claims at issue. Lilly constituted a major doctrinal shift in patent law, because it expanded the role of the written description requirement to impose an independent, substantive requirement for patentability, separate and apart from the enablement requirement and distinct from the written description requirement’s role in governing priority dates of inventions. Lilly thus shifted the focus from what the patent taught a person of skill in the art, to whether the four corners of the patent document recited the invention in sufficient detail. Lilly is a controversial decision within the Federal Circuit, and several judges have sought to have it overturned.

Judge Rader, a leading critic of the Lilly decision, predicted the decision would create a shortcut for patent challengers. The written description requirement is evaluated more centrally in view of the four corners of the patent, as opposed to the “more indulgent” enablement requirement, which is satisfied when “the specification teaches those in the art enough that they can make and use the invention without ‘undue experimentation.’” Although there are factual components to both the written description requirement and the enablement requirement, the written description requirement’s more confined focus on the patent specification makes it a cleaner vehicle for attacking a patent on summary judgment. This is exactly what happened in Carnegie Mellon.

Genus claims: Vulnerable on summary judgment

Carnegie Mellon lost its broad claims on summary judgment. Despite declarations of expert witnesses stating that people of skill in the art (as it existed at the time of the invention) would have understood that the inventors were in possession of the invention as it applied across all bacteria, Carnegie Mellon lost its claims other than those that were expressly limited to E. coli.

The undisputed facts presented for summary judgment in Carnegie Mellon are undoubtedly applicable to many situations in biotechnology. The central fact was that, by the time of the invention, only three bacterial polA genes had been cloned (out of thousands and potentially millions of bacterial species), and it was known that DNA polymerase I was not a single enzyme, but a family of enzymes encoded by a family of genes that varied from one bacterial species to another. Variability among species, and general knowledge in the field of how to designate analogues and homologues, together with limited knowledge of particular, discrete species beyond their functional coding, are a commonplace fact pattern in the biotechnology field—and they were enough to invalidate Carnegie Mellon’s genus claims without a trial.

Undoubtedly, there are situations in which a single species could describe a full genus, particularly when the claim is restrained to a narrow, invariant one. Based on the Lilly standard, if the genus is defined by a common property, where the species within the genus are all structurally similar, such a narrow genus can successfully be described with a single example in the specification, due to the correlation (known or disclosed) between function and structure.

Carnegie Mellon’s narrower claims to E. coli did survive. However, these claims were not found infringed. The defendants, including Hoffman-La Roche, were generating polymerase enzymes encoded by the polA gene from a different bacterium (Thermus aquaticus, or “Taq”). By using genes isolated from a bacterium other than E. coli, the defendants successfully avoided infringing Carnegie Mellon’s surviving claims.

Carnegie Mellon highlights the question of how to meaningfully obtain and enforce claims to plasmids and other such materials from living organisms. Given the variability among different species, it will be especially challenging to convince the Patent Office and the courts that genus claims covering biological materials from a variety of organisms have an adequate written description. Under the Patent Office’s guidelines, applicants seeking to obtain genus claims must provide a “sufficient description of a representative number of species” of their invention, which may be performed by actual reduction to practice, reduction to drawings, or by disclosure.
of identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Generating the information needed to satisfy this disclosure is time-consuming and costly, and may put the applicant at a disadvantage by creating significant delay in filing for patent protection. And there is no bright-line number of how many examples will be sufficiently representative, which will create ambiguity in the law for the foreseeable future.

The vulnerability of genus claims is not new to patent law, but its relevance to biotechnology is stark in the Carnegie Mellon case. The court’s willingness to invalidate claims on summary judgment under the written description requirement—coupled with the inherent variability of different species within a given genus—demands extra care for applicants seeking broad patent protection.

Don’t flag the genus

At some level, every patent claim is a genus claim. In general, a patent claim is restricted only by the limitations of the claim, and extends in all dimensions not expressly limited. For example, a patent claim to an automobile with four wheels, two bumpers, a sunroof, and a child seat could be considered a “genus” claim to the extent that it covers all colors of such automobile—regardless if the claim expressly covers “any color.”

One possible downfall of Carnegie Mellon’s claims was in flagging the genus. That is, the claims expressly called out that they extended to genes isolated from any bacterial source. Consider whether this blanket statement was needed in the claims concerning the bacterial source, and whether the claims might have survived if the phrase “isolated from a bacterial source” had been omitted, as shown below:

1. A recombinant plasmid containing a cloned complete structural gene coding region isolated from a bacterial source for the expression of DNA polymerase I, under operable control of a conditionally controllable foreign promoter functionally linked to said structural gene coding region, said foreign promoter being functional to express said DNA polymerase I in a suitable bacterial or yeast host system.

Omitting this phrase focuses the claim language on what Carnegie Mellon argued its invention truly was, rather than flagging the issue that the claims extend to all bacterial sources of such genes. This silence could have been golden, because it would have forced challengers in similar situations to manufacture a genus/species argument that does not appear on the face of the claims. Just as in the automobile example above, the “genus” aspects of a patent claim are limited only by the imagination of the challenger. Thus, the genus concerns would, of course, persist, but a court may be more reluctant to invalidate patent claims based on a “genus” argument that is not rooted in the explicit claim language.

Conclusion

From Eli Lilly to Carnegie Mellon, the Federal Circuit has demonstrated its intent to hold biotech patents to a high written description standard. Patent claims may survive a written description attack when they are narrowly drawn to a particular technology developed and described in the patent; however, these narrower “species” claims might be readily circumvented by rivals. Carnegie Mellon reinforces the difficulty of obtaining broad genus claims. Particularly where there is variability among the species, the Federal Circuit has reaffirmed its stringent disclosure requirements, as well as its approval of the written description requirement as a procedural tool for ending an infringement action on summary judgment. Patent prosecutors need to remain sensitive to when their claims will be viewed as “genus” claims, and be prepared to back them up with extensive support.

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REFERENCES

2. MPEP §§ 2161.01, 2163.I.A.
4. Falko-Gunter Falkner v. Inglis, 448 F.3d 1357 (Fed. Cir. 2006).
7. Enzo, 323 F.3d at 956 at 968.
9. See id. at 1567 (reciting claims for “nucleotide sequence having the structure of the reverse transcript of an mRNA of a [human], which mRNA encodes insulin”).
10. Enzo, 323 F.3d at 976 (Rader, J., dissenting from denial of petition for rehearing en banc).
11. Amgen, 314 F.3d at 1334.
12. MPEP § 2163.I.A.3(a)(ii).