

# Inventor's Reach Exceeds Grasp, Leading to Invalidation of Biotech Patent

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On September 8, 2008, the Federal Circuit invalidated Carnegie Mellon University's patent for a biotechnology tool because it lacked a written description adequate to demonstrate possession of the invention. *Carnegie Mellon v. Hoffman LaRoche, Inc.*

CMU claimed a tool produced by using *any* species of bacteria, but its written description disclosed only *one* species of bacteria, of a meager three species known to scientists in the field. This inconsistency left the court wondering just how many bacteria the University in fact had up its sleeve.

CMU's patents were directed to "recombinant plasmids that contain gene coding regions for the expression of DNA polymerase I from any bacterial source," or more simply, a biotechnology tool that uses bacteria to make a lot of a particular enzyme. Prior attempts at producing the enzymes in commercial quantities failed, because increases in the enzyme beyond normal levels created the unwanted and inconvenient side effect of killing the hard-working bacteria and leaving no enzyme for the scientists.

The inventors saved the bacteria from the throes of death by incorporating damaged DNA and foreign DNA into their genes to better control production of the enzyme. The feat had the inventors rubbing their hands together in happy anticipation of commercial success, and the Patent and Trademark Office cooperated by issuing patents to them.

CMU's road to disappointment originated in their understandable beliefs that those patents were valid and that a Roche product infringed those patents. The University sued Roche for infringement, but the trial court's claim construction crushed any hope of success on that allegation.

The worst was yet to come, however, as CMU found itself defending the validity of its patents against Roche's attacks based upon lack of a written description. This criterion requires the applicant to convey to those skilled in the art that, as of the filing date of the application, he or she was in possession of the invention. Demonstrating possession of an invention involving DNA demands a

precise definition in the written description, "not a mere wish or plan for obtaining the claimed chemical invention." *Regents of the University of California v. Eli Lilly & Co.*

The court relied on its previous decision in *Eli Lilly & Co.*, wherein it found that the University of California's patent claims directed to vertebrate, mammalian, and human cDNA were invalid for lack of a written description. Lilly and the court smelled a rat when they read that the University's patent *specification* disclosed only rat cDNA, but the *claims* encompassed vertebrate, mammal, and human insulin cDNA.

The court explained that "description of one species of a genus is not necessarily a description of the genus," leaving Lilly to continue its human insulin cDNA production unmolested, and the University with narrowed prospects for its once highly anticipated commercial success.

The *Eli Lilly* outcome was consistent with the Guidelines for Examination of Patent Applications ("Guidelines"), which state that "[t]he written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species . . . by disclosure of relevant identifying characteristics," including structural, chemical and functional properties.

The Guidelines further specify that "a representative number of species" requires that the species disclosed must be representative of the entire genus, so that a widely diverse genus cannot be claimed by disclosing only one species within the genus.

CMU argued that the ruling in *Lilly* was limited to specific, novel DNA sequences, whereas CMU's invention was directed to a generic biotechnology tool combining elements long known in the field. The court, however, found that the University's claims encompassed more subject matter than what was described in the specification, and that no language in *Lilly* suggested that the holding was limited.

The court, citing the Guidelines, pointed out more specifically that CMU's specification described the nucleotide sequence and other properties of the relevant gene for one bacterial species, but not any others.

Considering further that the sequence to only three bacterial species was known to those skilled in the art at the time, the claims could not convey that CMU possessed an invention encompassing all bacterial species.

The possibility of possessing only three species was not sufficiently representative to support a claim to a large and diverse genus of bacteria, and failed to satisfy the Federal Circuit's standards for a written description. Thus, like the University of California, CMU found itself characterized as an overreaching Goliath attempting to commandeer the genus when it truly possessed only the species.

Although ultimately invalidated under the *Eli Lilly* analysis, CMU's patent claims were partly vindicated when the Federal Circuit reversed the trial court's holding of invalidity under *Gentry Gallery v. Berklene*. In *Gentry Gallery*, the court invalidated the patent because the claims did not cite a limiting element that the patent specification described as "essential" to the invention. Likewise, Roche argued that CMU's patent claims lacked the "essential feature" of enzyme lethality to bacteria described in the specification.

The Federal Circuit sided with CMU on the *Gentry Gallery* issue, declaring, "we did not announce a new 'essential element' test . . . requiring that the claims incorporate [what the inventor considers to be] essential elements," rather "we applied . . . the unremarkable proposition that a broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope." Further, the Court reasoned that "lethality was only a reason for the claimed invention, and not an element of it that needed to be defined in the claims."

Although the reasoning and application to CMU's patent under *Gentry Gallery* is likely sound, it is remarkable that the Federal Circuit opined that its *Gentry Gallery* decision was unremarkable, given how much commentary that case provoked in the patent community. Notably, *Gentry Gallery* received particular attention in the Manual of Patent Examiner Procedure § 2163.05, which cited the case in its examiner guideline: "omission of a [claim] limitation can raise an issue regarding whether the inventor had possession of a broader, more generic invention." The Guideline appears inconsistent with the *Carnegie Mellon* court's current assessment that *Gentry Gallery* did not alter substantially the landscape of the written description requirement.

In apparently stepping back from its *Gentry Gallery* approach, the Federal Circuit has muddied the waters for prosecutors and examiners assessing the validity of patent claims. *Carnegie Mellon* reminds biotechnology patent prosecutors to align language in the specification and claims so that they maintain the same scope, not an easy task in a field where the scope of knowledge changes every day. In a complicated, often unpredictable field like biotechnology, it would benefit prosecutors greatly to achieve substantial familiarity, before filing an application, with the current frontiers of knowledge of persons skilled in the relevant field.

Thus, CMU won the *Gentry Gallery* battle against Roche, but lost the war under *Eli Lilly* due to its lack of a written description. In describing only one bacterium, of three known at the time of its patent filing, CMU did not provide the Federal Circuit with a written description adequate to inspire confidence that it possessed the entire genus of bacteria. ✨