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David De Lorenzi

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Making Research Labs Patent-Free Zones



In a widely watched patent case, the U.S. Supreme Court unanimously held last week that drug company researchers could make “reasonable” use of compounds on which they do not hold patents. The 9-year-old case stems from a claim by Integra LifeSciences of Plainsboro that Merck KGaA of Germany infringed the firm’s patent on a group of proteins called peptides by allowing them to be used in research the German company sponsored. David De Lorenzi, the head of Gibbons Del Deo’s

38-attorney intellectual property group in Newark, discussed the decision with **NJBIZ** Deputy Editor Bill Quinn. De Lorenzi was joined by colleagues Bill Epstein and Andrew Grodin.

NJBIZ: Who are the winners and losers in this decision?

De Lorenzi: I think Big Pharma is the winner and I think the people who stand to lose the most by a strict application of this decision are companies who specialize in selling or making research tools. The court went out of its way to say this decision did not apply to research tools, but it’s the first step toward that direction. You are going to see a lot of companies out there who are in the research-tool business reevaluating their business model in how they sell that technology or protect that technology. They may have considered patents their best protection. They may revisit that and keep it [their technology] proprietary know-how.

NJBIZ: How can they realize value on it then?

De Lorenzi: You could sell that technology or sell those methodologies or research. The way you sell it is you license it under a “know-how” agreement or a materials-transfer agreement. Research tools will still be protectable by patent in our view; it’s the hybrids between research and research-tool companies that will be affected.

NJBIZ: How will this affect universities that feel they must publish the results of their

research and seek patents wherever possible?

Epstein: In the past, good universities, before they published would sell a know-how license to a drug company and you had about a six-month window to work with their discovery. There may be more of that.

NJBIZ: Will this decision make life tougher for small biotechs?

De Lorenzi: It depends on what field of biotech you are in. For example, Invitrogen [of Carlsbad, California], they’re a company that sells technology, much like Integra is selling a protein or a peptide or a research tool. Those are the kind of folks who are going to have to reconsider how they go about protecting their technology.

Epstein: A lot of companies were formed by research tools [but] research tools were really looked down on by the courts all along [in patent rulings]. Now that this Supreme Court decision gets publicized people are going to think twice about stock in that type of company.

Grodin: This might also open some opportunities for some smaller companies. In cases where Big Pharma is already doing research [on a patented compound] and shutting out smaller companies, the smaller companies

can take that technology that Big Pharma already had a patent on and work with it.

NJBIZ: What message do you think the court was sending with its ruling?

De Lorenzi: The court here is furthering the policies of enabling continued innovation of new products in the pharmaceutical industry. I think they are trying to reach a balance. Congress and the courts over the last five years, in the context of the Hatch-Waxman Act [which defines the rights of generic drugmakers to bring copies of brand-name products to market], have been affording the generic industry additional tools of their own to develop their business. I think this balances those decisions by giving to Big Pharma some tools of their own to develop new products in their pipelines by being able to explore with a little more freedom.

NJBIZ: Do you think small companies will stop patenting altogether because of this decision?

De Lorenzi: I don’t think the small companies are going to stop patenting. I think the decision furthers biotech generally and Big Pharma generally. The companies that will be impacted by the decision are the ones that fall somewhere between.

NJBIZ: Some big drug companies, like Pfizer, Eli Lilly and Wyeth, were arguing for a looser interpretation of the patent laws in this case. Was it odd for them to be in that position?

De Lorenzi: Usually they are arguing for strict construction of Hatch-Waxman, while generic companies are always trying to expand this. In this case, I think it’s a fair construction of [Section 271(e)(1) of the act]. I don’t think anyone has gone beyond the boundaries.

NJBIZ: Do you think this will end up being the patent case of the year?

De Lorenzi: There is another important federal circuit decision pending—*Phillips v. AWH Corp.* From a patent lawyers standpoint, it will likely overshadow this decision because it deals with basic issues of how broadly or narrowly to construe patent claims. Every patent case deals with [this issue]. Very few deal with Section 271(e)(1). ♦