

INTELLECTUAL PROPERTY UPDATE

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Reach Through Claims: Bust or Boon?

The United States Court of Appeals for the Federal Circuit recently let stand the holding in *University of Rochester v. G. D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004) (“*Rochester*”) regarding the validity of so-called “reach through” claims.¹ The effect of this decision will have repercussions in a number of areas, including claim drafting, freedom-to-operate analysis and even the wording of many licensing agreements. Understanding the strategic implications of the *Rochester* decision is imperative for every inventor and IP practitioner.

In general, “reach through” claims attempt to capture the value of a discovery before it may be a full invention. For example, a researcher may identify a mechanism of disease action, such as a target protein involved in disease progression

or the interaction of two proteins in the disease pathway. While these discoveries may allow the development of screening assays to identify drug candidates, the actual products, the drugs themselves, have not yet been developed. “Reach through” claims are designed to cover these drugs or the use of them, prior to identification of the drugs themselves.

The underlying discovery in the *Rochester* relates to certain enzymes well known to be involved in numerous biological responses. In particular, it was well known these enzymes were involved in both inflammation and protection of the stomach lining. As a result of this dual role, many anti-inflammatory drugs can also cause irritation of the stomach lining. Scientists at the University of Rochester discovered that two related, but

distinct, enzymes mediate these two responses. These enzymes were subsequently termed Cox-1 and Cox-2. The scientists proposed that by selectively inhibiting Cox-2 (which produced the inflammatory reaction) they could provide the anti-inflammatory effect while minimizing irritation of the stomach lining caused by inhibition of Cox-1. Pfizer’s Celebrex(r), a selective Cox-2 inhibitor used in the treatment of arthritis, generates billions of dollars in revenues a year.

The University of Rochester filed a patent application describing how to screen for compounds capable of selectively inhibiting Cox-2. However, these claims would not generate royalties on any drugs since only the screening process was claimed. Therefore, the University pursued claims

1. *University of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303 (Fed Cir. 2004)

directed to methods of administering compounds that can selectively inhibit Cox-2, even though they did not specifically describe any such selective inhibitors. These claims were classic “reach through” claims.

The University eventually received a patent that included the reach through claims and sued several major drug manufacturers, notably Pfizer, for infringement based on their sales of selective Cox-2 inhibitors. Pfizer prevailed on a summary judgment motion in the Federal District Court for the Western District of New York with an argument that the patent failed to either properly describe, or teach one how to practice, the subject matter of the reach through claims. The Court stated that the compounds were only described functionally and that the patent only enabled one of skill in the art to “attempt to discover” (i.e., screen) the compounds necessary for practicing the claimed method. The University lost on a first appeal to the Court of Appeals for the Federal Circuit, which affirmed the District Court’s finding that the

patent lacked sufficient written description to support the claimed methods. The Court specifically stated its belief that the application lacked any description of the specific compounds necessary to practice the claimed method as the rationale for their decision. The University’s appeal for an en banc rehearing was denied.

Generally, a number of different types of claims, both compound and method claims, could be considered “reach through.” In addition to the “methods of treating using a compound that inhibits protein X,” other examples include “a composition identified by a specific screen,” “a method for selectively inhibiting protein X comprising administering a compound that selectively inhibits protein X,” “a method for selectively inhibiting protein X comprising administering a compound that selectively inhibits protein X, wherein said compound is found using the screen,” and “a compound that inhibits target protein X.” Similarly, these claims arise in discoveries relating to protein-protein interactions in disease

pathways, such as “a method of inhibiting the interaction (or treating the disease) of protein X and protein Y by binding an inhibitory compound” or “a method of treating by inhibiting the interaction of protein X and protein Y.”

A similar situation to that in *Rochester* is found in the *Lilly* case (*Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); *cert denied*, 523 U.S. 1089 (1998)). In *Lilly*, the patent specifically disclosed rat insulin nucleic acid sequences, a human insulin protein sequence and general methods for isolating nucleic acid sequences. As above, the disclosure in *Lilly* could be interpreted as forming a research plan for isolating the claimed, but undisclosed, human insulin nucleic acid sequences.

It is a basic tenet of U.S. patent law that a patentee is entitled to a genus of species without identifying every species. The question in both *Lilly* and *Rochester* has boiled down to a basic issue: how many species are required to support a genus? *Rochester* tells us quite clearly

that a genus cannot be supported in the absence of any species. Unfortunately, as a practitioner, this does not clarify matters in any significant way as most inventors could include at least one species.

Where does this leave us? As a typical lawyer would answer, “it depends.” For a potential plaintiff, these discussions underscore the importance of setting up claims of varying scope, with species, subgenus and genus claims either included or available (with a goal of avoiding claim amendments in general). Evaluating the general

patent strategy and goals of a particular technology may lead to multiple filings with differing scopes. Is it worth advising clients to do some level of screening to identify some finite number of active compounds prior to filing? What about different classes of drugs? An intriguing issue lingering after *Rochester* is the scope of the language that was used; *Rochester* arguably had support for transcription inhibitors in the form of antisense molecules, a class of inhibitors much easier to define. Could claims based on this disclosure have survived?

An alternative way to protect early stage inventions is to utilize “reach through royalties.” These may, in fact, be the best way of gaining value from some inventions. While generally disliked by the licensee, this provides a contractual solution to achieve value from the initial “research” discovery, hopefully in an attempt to avoid the more complicated patent litigation.

As always, these analyses also turn on the fundamental question faced by all attorneys, namely, “what is in my client’s best interest?”

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