PATENT PRIMER

Reach-through claims: how far a reach?

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The US patent laws protect inventions and investment at every step of the drug development process, but do not guarantee that each such patented step commands its proportionate share of the value of a clinically approved drug. Indeed, early innovators in the drug discovery pro cess often strive to capture a predominant share of the overall value of a pharmaceutical through use of so-called 'reach-through' claims — patent claims that rely on early discovery efforts to cover later-discovered pharmaceutical compounds.

Two recent decisions from the Court of Appeals for the Federal Circuit have set the boundaries on the ability of the earliest of the innovators in the drug development process to use their patents on research methods to 'reach-through' to — that is, to command royalties based on — other party's sale of a final clinical product.

Claim categories for early innovations

The current patent statute identifies "any new and useful process, machine, manufacture, or composition of matter" as patentable subject matter, with 'process' long understood to cover both 'methods of making' a product and 'methods of using' a product.

Historically, claims to 'methods of making' — such as claims to new methods of chemical synthesis — have provided the principal avenue for protecting innovations made early in the drug development process. With the US Process Patents Amendments Act of 1988, 'method of making' claims became much more valuable, adding statutory section 271(g) that extends the effective territorial reach of such claims beyond US borders, and a new section 295 that lowers the initial burden.

New methods of making a compound have also classically supported 'product-by-process' claims — hybrid claims of the form 'compound X, prepared by the method comprising steps A, B, C'. Although the judges of the Federal Circuit are famously and rancorously split between mutually incompatible theories of the scope of such claims, product-by-process claiming itself has nonetheless been sanctioned by long-term usage.

Claims to methods of screening for pharmacologically active agents, which are historically quite new, seem to fall somewhere between classical 'methods of making' claims and 'products-by-process' claims in claim taxonomy.

US Federal Court decisions

In *Bayer AG versus Housey Pharmaceuticals, Inc.*, the Court of Appeals for the Federal Circuit addressed for the first time the degree to which such 'method of screening' claims could reach pharmaceuticals that were identified by a third party through use, outside the United States, of a screening method patented in the United States.

Advancing two novel theories about the breadth of section 271(g) (" [w]hoever without authority imports into the United States ... a product which is made by a process patented in the United States shall be liable as an infringer"), Housey argued that intangible data resulting from Bayer's off-shore use of its patented method constituted 'a product' made by the patented process, and further argued that a pharmaceutical product identified through such off-shore screening is a product 'made by' its patented process.

Rejecting both theories, the appeals court held that the law applies only to the importation into the United States of tangible compounds derived from manufacturing processes.

CLAIM 1 OF HOUSEY PHARMACEUTICALS' US PATENT 4,980,281

A method of determining whether a substance is an inhibitor or activator of a protein whose production by a cell evokes a responsive change in a phenotypic characteristic other than the level of said protein in said cell per se, which comprises:

- Providing a first cell line which produces said protein and exhibits said phenotypic response to the protein;
- Providing a second cell line which produces the protein at a lower level than the first cell line, or does not produces the protein at all, and which exhibits said phenotypic response to the protein to a lesser degree or not at all;
- Incubating the substance with the first and second cell lines; and
- Comparing the phenotypic response of the first cell line to the substance with the phenotypic response of the second cell line to the substance.

More recently, in *University of Rochester versus G. D. Searle & Co.*, the Federal Circuit addressed the reach of a product-by-process claim, the process recited in the claim being, in essence, a method of screening.

Finding that "the [University] patent does not disclose any compounds that can be used in its claimed methods … nor has any evidence been shown that such a compound was known," the court affirmed the lower court's invalidation of the claims that the University had attempted to assert against manufacturers of cyclooxygenase-2 inhibitors. In each of these cases, the claims to the screening methods per se were left undisturbed.

Room for reach-through claims?

Although these cases set the extreme boundaries of reach-through by 'method of screening' claims, they do not foreclose their use.

For example, although the *Housey* ruling prevents the owner of a screening method claim from charging another party with infringement based on screening activities performed outside the United States under section 271(g) of the statute, the decision is silent as to whether infringement might yet be found under section 271(a): a claim capable of supporting a charge of infringement under this latter statutory section would explicitly recite a first step of off-shore screening, followed by a second step of importing either the data from the screening, or the products identified from such data, into the United States.

To address the perceived deficiencies in the *Rochester* claims, an explicit change in the claim preamble from 'method of determining' to 'method of making,' the addition of a suitable first step of 'preparing or obtaining a combinatorial or natural products library', and a written description in the patent specification of such starting materials, should render the claim more readily understood as a 'method of making' without effecting substantial change in scope.

Either or both of these approaches might yet enable the earliest innovators in the drug discovery process to reach-through to cover a later-developed clinical product. But for now, the reach of 'method of screening' and 'product-by-screening' claims seems short indeed.

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