



# Intellectual Property Law Information Memo

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## RECENT DEVELOPMENTS AFFECTING ACADEMIC RESEARCH INSTITUTIONS AND COMMERCIAL DRUG ROYALTIES

### “Reach Through” Claims Successfully Challenged

In March 2003, the District Court for the Western District of New York dealt the University of Rochester a significant setback by finding that its patent claims purportedly covering the highly successful painkiller Celebrex® were invalid. The University had spent more than ten years investigating the physiological pathways underlying the drug before identifying the particular cellular receptors that produced the desirable and undesirable reactions that accompany conventional painkillers. Although the University's patents included disclosure of specific assays for finding effective human drugs, the patents did not disclose any sample drugs that operated according to the discoveries. Because of this omission, the court determined that the University's claims covering the treatment of a patient using a drug that was found by using the assays failed to comply with the written description and enablement requirements of the Patent Act, 35 U.S.C. § 112, ¶ 1.

Claims similar to those invalidated by the Western District are commonly referred to as “reach through” claims, and are often included in patents filed by the research institutions that perform basic scientific research, but do not engage in drug

development. See Bond, Schoeneck & King Information Memos, Articles, White Papers, *The Scope Of Patent Protection Available To Research Entities In The Wake Of Recent Cases Rejecting “Reach Through” Claims* (10/03). While the underlying discoveries at research institutions may have only marginal commercial value, the products that stem from this basic research may be multi-million or even billion dollar drugs.

### Federal Circuit Affirms Decision Holding “Reach Through” Claims Invalid

Soon after the lower court held the patent claims invalid, the University appealed the decision to United States Court of Appeal for the Federal Circuit, the exclusive court for all patent appeals. On appeal, the University presented three primary arguments. First, the University argued that the Patent Act did not include a separate written description requirement. Second, the University argued that if the Patent Act did contain a written description requirement, its patent claims were adequately supported by the specification of the patents. Finally, the University argued that denying “reach through” claims to research institutions and universities unduly hampered technology transfer to the private

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sector and was therefore contrary to congressional and public policy.

With regard to the first two arguments, the Federal Circuit pointed to its own precedent and a recent Supreme Court decision recognizing the written description requirement as one of three distinct requirements under Section 112 of the Patent Act. The requirement is grounded in the principle that an inventor must disclose everything that is known about an invention to the public to be entitled to a patent grant. Recognizing that the written description requirement was more frequently applied when determining priority of invention or in addressing claims covering DNA, the Federal Circuit subsequently held that its decisions relating to the written description requirement are equally applicable to DNA and non-DNA inventions.

Turning to the sufficiency of the University's patent disclosure, the Federal Circuit held that the failure to disclose any effective compounds that were found by the newly discovered pathways and assays was a mere wish or plan for obtaining the claimed invention and the University therefore failed to meet its obligations under the patent laws. The Federal Circuit also rejected the public policy argument, noting that while Congress enacted laws to allow universities to profit from government sponsored work, the legislation did not change the statutory requirements for patentability.

### **Strategies for Capturing the Value of Basic Research**

At first glance, the Federal Circuit has sounded the death knell for "reach through" claims and has restricted the ability of Universities to profit from basic research. The reality, however, is that research, development, and technology transfer at universities and research institutions need not suffer. Instead, Universities may rely on resourceful patent drafting and creative licensing to close the gap between research and commercial success opened by the invalidity of inadequately supported "reach through" claims.

Distinguishing the University of Rochester's case from several others, the Federal Circuit identified that the written description requirement could be fulfilled by describing an actual compound, describing the characteristics of an example of the claimed invention in enough detail so that one of ordinary skill could make it, or describing the process of making the claimed invention. Thus, a patent specification that includes a description of any one of these could support

generic "reach through" claims to commercial drugs discovered by assays disclosed in the patent specification.

If university researchers cannot easily or affordably discover and describe a sample drug to support a "reach through" claim, all is not lost. Should private enterprises proceed at peril by commercializing a drug discovered by a patented assay without first obtaining a license, the profits realized by a successful drug are not necessarily beyond reach, as the commercial value of a drug discovered by the infringing use of an assay arguably qualifies as one factor used by courts to determine the amount of infringement damages.

A much simpler, and certainly less costly, means for capturing the commercial value of successful drugs is to improve the legal structure of the transfer of new discoveries and assays to the private sector. For example, licensing fees for the use of an assay may include kickers or additional payments based on the successful isolation of a particular drug product or the approval of a drug by the Food and Drug Administration. Alternatively, cooperative research and development agreements or joint ventures with established drug companies have been successful methods by which governmental research laboratories and private concerns that perform basic research have captured lucrative drug profits. While these arrangements may be more complicated to structure, the possibility of more lucrative royalties and the avoidance of costly patent litigation provide a long-term solution to the problems faced by universities and institutions performing basic research.

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