

Speckman Law Group PLLC

Intellectual Property Matters[®]

BIOTECH BULLETIN

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The U.S. Federal Circuit Court of Appeals recently issued several decisions affecting those working in the area of biotechnology and health sciences. The Court and the U.S. Patent and Trademark Office (USPTO) are continuing to apply strict patentability standards requiring high levels of disclosure and, in many cases, experimental validation for issuance of meaningful patent claims relating to biotechnology inventions. Broad patent coverage, particularly relating to methods for treating or otherwise affecting a human, is not likely to be available unless and until scientifically persuasive experimental validation is available.

One significant development is the distinction between the generally high level of enablement required for patentability and the significantly lower level of enablement required for prior art purposes. There are some significant implications, which are described below in the synopsis of the *Rasmusson* case. We believe the eventual outcome may be that few broad patent claims will issue for biotech inventions in the upcoming years and that patent claims for commercially important biotech inventions—both methods and compositions—may generally be quite narrow. Narrower claims have significant commercial value if they are directed to commercially important aspects of a technology, product or methodology. Identifying those commercially important aspects at an early stage in the IP development is key.

On the patentability side, it remains essential that early consideration be focused on developing patent protection strategies that anticipate commercially valuable products and methodologies. Patent counsel must work closely with R&D staff to assemble a comprehensive disclosure and to identify experimental work that has been or could be done to provide support for strategic patent claims. Clever claim drafting may be required to obtain patent coverage that is supported by the disclosure and experimental evidence and that may be interpreted to cover a broad range of downstream commercial activities.

From an enforcement perspective, it will be very interesting to see how the courts interpret broad biotech patent claims issued several years ago that may not satisfy the patentability standards as they're articulated and enforced today. Rather than invalidating previously issued claims that may have undergone less rigorous prosecution, the courts may interpret broad claim language more narrowly to preserve the validity of the claims. The convergence of questionable validity and narrower claim interpretation may reduce the risk of patent infringement liability and enhance freedom to operate for many research, development and clinical activities that have previously been of concern. The U.S. Supreme Court's recent decision providing broad application of the 271(e) exemption from patent infringement liability for research and testing activities further reduces patent infringement risks during the long research and development phase for many biotech concerns.

A brief discussion of three recent cases follows. Specifically, *Rasmusson* reinforces the need to include extensive supporting disclosure, preferably with supporting data, in early patent applications to ensure enablement of patent claims and to provide an early priority date for prior art purposes. *Capon* clarifies that prior art nucleotide sequences that are not called out in patent claims need not be specifically disclosed in a patent specification in order to comply with the written description requirement. *Fisher* limits the patentability of nucleotide fragments—specifically, expressed sequence tags (ESTs)—to those instances in which the functional properties of the claimed polynucleotides are disclosed in the patent specification.

In *Rasmusson and Reynolds v. SmithKline Beecham Corporation* (Court of Appeals for the Federal Circuit, decided June 27, 2005) both *Rasmusson* and *SmithKline Beecham* (SKB) were pursuing claims to the use of finasteride to treat prostate cancer. The Court determined that *Rasmusson* was *not* entitled to claim priority to an early patent application because the early application lacked an enabling disclosure for the later claimed treatment methods. The Court's decision was based on *Rasmusson*'s failure to provide data demonstrating the efficacy of finasteride in treating prostate cancer and the fact that, given the level of knowledge available at the time, the hypothetical person of ordinary skill in the art would *not* have believed the methods efficacious. *Rasmusson* was not awarded priority for the broad claims and SKB's claims took priority because SKB had earlier experimental support for the broad claims. *Rasmusson* was, of course, correct in his prediction of efficacy and had the earlier conception.

Rasmusson's published European patent application corresponding to the non-enabled priority U.S. patent application was, however, deemed an effective prior art reference to SKB's later, enabled U.S. patent claims. While *Rasmusson*'s European publication would *not* have been enabling for patentability purposes, the Court pointed out that the level of enablement required

to anticipate patent claims is different from, and considerably lower than, the level of enablement required for patentability purposes. SKB's patent claims were deemed to be anticipated by the unsupported early disclosure of Rasmusson. The Court further noted that Rasmusson's early European patent publication may be applied as an effective prior art reference to claims filed in Rasmusson's later U.S. CIP patent application. Thus, if an early patent application filing doesn't support commercially meaningful claims, there's a substantial risk that claims filed in a later CIP application that *are* sufficiently enabled won't be entitled to the priority benefit of the earlier filing and will be anticipated by the insufficient disclosure of the earlier filing. This, we predict, will have significant implications.

This decision has not been appealed and it is therefore precedential. It highlights the importance of filing as complete and comprehensive a patent disclosure as early as possible. To obtain strong patent claims directed to commercially valuable activities such as human treatment in an area where efficacy is unpredictable, demonstration of efficacy in a human or an experimental model that's known to be predictive of human response is essential. If supporting disclosure and experimental data is unavailable at the time of the initial U.S. application filing, it should be disclosed in a related application filed before publication of earlier patent applications disclosing the claimed invention. As a practical matter, given that all non-U.S. and most U.S. patent applications are published approximately 18 months after their priority date, this means that supporting disclosure and data must be available, and filed, within 18 months of the original filing date.

In *Capon v. Eshhar v. Dudas* (Court of Appeals for the Federal Circuit, decided August 12, 2005), both Capon and Eshhar claimed a chimeric DNA that included a heterogenous DNA segment encoding a single chain variable (scFV) domain of an antibody and an endogenous DNA segment encoding cytoplasmic, transmembrane, and extracellular domains of a lymphocyte signaling protein. The resulting chimeric genes combined the specificity of an antibody with the tissue penetration, cytokine production, and target-cell destruction capability of a lymphocyte and, thereby, had therapeutic potential in the treatment of tumors. Both parties disclosed that chimeric genes could be produced by combining known DNA segments using established recombinant DNA methodologies and that their invention involved the combining of DNA segments to achieve a novel result. However, the USPTO Board of Patent Appeals and Interferences held that each party's specification failed to provide the required written description of the full scope of the chimeric DNA and that the claims were too broad because they may include inoperative species. On appeal, the Court vacated the Board's decision, noting that the claimed chimeric DNAs were prepared from known DNA sequences of known function, and stating that "It is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention." The Court determined that the patent statute does not impose a *per se* rule requiring recitation in the specification of a claimed DNA sequence when that sequence is known in the field.

Many IP practitioners in the biotech area have long felt that the USPTO requires significantly higher standards of written description for patent applications in the biotech area than in other areas of endeavor. This decision opens a door to the possible easing of the Patent Office's often overly-strict application of the written description requirement in biotech-related patent applications.

In *In re Fisher* (Court of Appeals for the Federal Circuit, decided September 7, 2005), Monsanto appealed the decision of the Board of Appeals rejecting a claim to five plant EST sequences as lacking utility and enablement. Monsanto's patent application disclosed that the claimed ESTs may be used as research tools, for example, for the following purposes: serving as molecular markers for mapping the entire maize genome; identifying the presence or absence of a polymorphism; and controlling protein expression. No uses were disclosed, however, that related specifically to the function of the underlying genes. The Court stated that, in order to satisfy the "substantial" prong of the utility requirement, "an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research," and determined that Monsanto's application did not meet the utility requirement, as "Fisher [did] not identify the function for the underlying protein-encoding genes." This holding is consistent with the utility standard currently enforced by the USPTO and confirms that patent claims directed to polynucleotide sequences must be supported by disclosure (and perhaps experimental demonstration) of a utility that is related to the functional properties of the specific sequence and that is credible, specific and substantial.

Interestingly, this decision was not unanimous. Judge Rader dissented, expressing the view that the ESTs had sufficient utility to satisfy the patentability requirement. If this view is held by other Federal Circuit judges, we may yet have more or different guidance on the credible, substantial and specific utility requirement.

Speckman Law Group PLLC, founded in 1995, is an intellectual property law firm specializing in patent strategy and practice. Ann Speckman is joined by Victor King and Susan Friedman, Ph.D., patent attorneys, Janet Sleath, a patent agent, and highly competent support staff.