



### **NEW BIOTECHNOLOGY SPECIALISTS AT RP**

In October, 2007, Ms. Lisa Mead and Dr. Brian Cocca joined the biotechnology group at RatnerPrestia.



**Brian Cocca** earned a Ph.D. in Immunology at MCP Hahnemann University and a J.D. in law at The George Washington University School of Law. Brian has experience in drafting and prosecuting patent applications and in client counseling and IP management in the life sciences arena, including the fields of immunology, cell and molecular biology, drug formulations and therapeutic regimens, biochemistry, recombinant organisms, and medical devices and diagnostics. He has specialized knowledge in antibody structure and genetics.



**Lisa Mead** is a Scientific Advisor at RatnerPrestia and is studying for a law degree at Temple University School of Law. Lisa earned a Bachelor of Science in Biotechnology from The Pennsylvania State University, where she focused her independent research on the structural regulation of gene transcription. She began her career in a pharmaceutical company's drug metabolism department, conducting research on the biotransformation pathways of a major patented drug. She has also worked in clinical pharmacology, performing assays to determine drug levels in clinical trial participants. Lisa recently interned in the legal department of a pharmaceutical company where she worked on various issues within both the commercial law and patent law groups.

### **KSR GUIDELINES: NAVIGATING NONOBVIOUSNESS**

Nearly a year ago, in *[KSR International v. Teleflex](#)*, the Supreme Court made it easier to prove that an invention was obvious, and therefore unpatentable, by directing lower courts to refrain from rigidly applying an obviousness standard requiring an explicit basis in the prior art for combining teachings from different sources. Subsequently, a cloud of uncertainty has loomed over patent applicants as to how the new decision would play out during prosecution. On October 10, 2007, the U.S. Patent and Trademark Office (PTO) published "[obviousness](#)" guidelines for examiners. The guidelines provide seven rationales in support of a determination of obviousness, as well as potential arguments applicants may propose to rebut an examiner's case. While the *KSR* decision concerned technology that was primarily mechanical, the Supreme Court's decision and the PTO's

guidelines have ramifications across the technology spectrum.

A central theme flowing through the PTO guidelines is a requirement of predictability. In fact, five of the seven rationales expressly mention predictability in their summaries, and it is essential to the underlying factual findings of the other two rationales. In other words, to support an obviousness rejection using any of the guidelines, an examiner must articulate findings relating to predictability. Conversely, unpredictability may be the key for a patent applicant to prove unobviousness.

This central theme of unpredictability, more likely to be found in a biotechnological invention than in a mechanical invention, may leave an opening for applicants to argue for patentability. Factors relating to predictability include: (1) whether a reference expressly suggests the element and its likelihood of success; (2) whether the element has been successfully used in similar applications; (3) whether the choices for the element are few and defined; and (4) whether the invention merely provides for the substitution of a known element to perform its known function. Express teachings in the prior art might also be evidence of a lack of predictability, such as statements about conditions that resulted in failure or statements that key elements of the invention cannot be successfully combined.

Even if it could have been predicted that an invention would have worked acceptably, Applicants may still be entitled to patent protection if they can prove that the invention worked surprisingly or unexpectedly well. In such cases, inventors may provide experimental data demonstrating unexpectedly good results or problems in developing the invention. In this regard, it will be helpful for inventors to maintain detailed documentation of what results were expected before the tests, the actual surprising results and what aspect was surprising about them, the steps taken to arrive at an invention, and failed experiments where success was expected.

In sum, predictability is a theme that runs throughout the *KSR* decision and the PTO's obviousness guidelines. In drafting and prosecuting applications covering innovations in biotechnology, applicants would be well advised to consider how their invention could not have been predicted by the prior art and how it led to unpredictable or unexpected results.

### **THE NEXT WAVE: ENHANCED DUTY OF DISCLOSURE**

Many perceive that patent examiners are not identifying the most relevant prior art references, especially in light of the sometimes extensive citations by applicants.

Extensive citations, often including numerous references of marginal pertinence, is an unfortunate consequence of applicants' concerns for potential accusations of inequitable conduct. To address this perception (but unfortunately not this consequence), the PTO is expected to announce new duty of disclosure requirements in early 2008. Whether the new rules will actually improve the examination process is questionable. That they will make the examination process more complicated and more problematic is assured.

As originally proposed by the U.S. PTO, the new rules would require applicants to provide explanations of references submitted in certain circumstances, for example if over twenty references are submitted. This requirement could be especially problematic in the fields of microbiology, immunology and molecular biology, which [Professor Crouch](#) has identified as some of the technologies in which applicants often cite more than twenty references.

While the specific language of the final rules has not been made public, the Office of Management and Budget (OMB) recently announced its approval of a set of rules. The [OMB announcement](#) confirms that the new rules will require "information about" (possibly the "explanation" referred to in the original version of the rules) certain citations. The announcement also indicates that the new rules will allow for the filing of an IDS after a notice of allowance only if a claim is admitted to be unpatentable and a narrowing amendment is also submitted to distinguish the claim from the newly-cited reference. Upon implementation, the latter rule may present patent applicants with a dilemma if they receive a "close" reference after allowance: (1) Limit claim coverage to allow submission of the reference; (2) Refrain from submitting the reference if no claim amendments are warranted, but risk opening the door to an inequitable conduct charge during litigation (a consequence ignored by the PTO); or (3) File a continuation application, assuming the rules permit such a filing. These new rules will impact applicants across the board, including biotechnology innovators, and might encourage applicants to even more carefully consider all of the potential prior art references before submitting an IDS.

### **BOARD CHALLENGED TO A "DEUEL"**

The U.S. PTO Board of Patent Appeals and Interferences (Board) issued a precedential decision in 2007 in [Ex parte Kubin](#), an appeal of a rejection of claims directed to nucleic acids having at least 80% identity with a particular sequence. The Board decided issues relating to whether the claimed nucleic acids would have been

obvious in view of the prior art, whether the claimed nucleic acids were sufficiently described in the specification, and whether the preparation of the nucleic acids was enabled by the specification.

The Board held that, despite longstanding Federal Circuit precedent in *In re Deuel*, it was obvious to prepare cDNA to a specific protein sequence using conventional screening techniques if an antibody that specifically binds the encoded protein is known. The Board reasoned that the Supreme Court's decision in *KSR v. Teleflex* weakened *Deuel's* underpinnings, thereby lowering the threshold for an obviousness finding in situations where there are a limited number of methods for solving a problem, and a skilled artisan would have a reasonable expectation of success with such methods. In reaching this conclusion, the Board relied on the Supreme Court's statements in *KSR* that if there is motivation to solve a problem and a finite number of predictable solutions which lead to the anticipated success, then "obvious to try" might constitute obviousness.

The Board held that the enablement requirement was met because the specification described how to prepare variants having at least 80% homology to the listed sequence and screen the variants to determine if the claimed functionality is retained. The Board also held, however, that the written description requirement does not permit claims to a genus of sequences having at least 80% homology in the absence of specific examples of variants that retain the claimed functionality, and that possession cannot be shown by merely describing how to make or identify common structural features of the members of a genus.

The written description hurdle remains high. The decision, however, suggests a roadmap for getting over the hurdle: Prepare and screen panels of mutants that retain the claimed functionality. Although doing so may require an investment in time, lab resources, and human capital, the investment may pay dividends in the form of broader patent coverage and market exclusivity. In addition, the decision also may provide support for applicants to urge a broader reading of what constitutes an enabling disclosure, in some factual circumstances.

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