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Gene Patenting after *In re Kubin*: The Sky is Not Falling

On April 3, 2009, the Federal Circuit issued its opinion in *In re Kubin*,¹ a case watched with great interest by the biotechnology community. While the court did not make a blanket decision that "DNA is obvious," it did restrict the scope of nucleic acid sequences that will be patentable thereafter, and held that the Supreme Court's decision in *KSR v. Teleflex*² overturned the Federal Circuit's *In re Deuel*³ decision. Since *Deuel* has been used over the past 14 years to support the patentability of DNA, the Federal Circuit's finding that the *Deuel* decision's principles were abrogated by the Supreme Court is disquieting for DNA-patenting applicants and patentees. But *Kubin* also provides a veritable roadmap on how its more stringent effects can be avoided.

Kubin involved claims to a cDNA encoding human Natural Killer Cell Activation Inducing Ligand (NAIL). The Board of Patent Appeals and Interferences of the U.S. Patent and Trademark Office had upheld an examiner's rejection that the claims were unpatentable on grounds of both obviousness and inadequate written description. The only claim at issue was claim 73:

73. An isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide at least 80% identical to amino acids 22-221 of SEQ ID NO:2, wherein the polypeptide binds CD48.

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The USPTO's New Written Description Training Materials: Impact on Biotech

It has been just over a year since the USPTO released an updated set of training materials for use in the examination of patent applications for compliance with the written description requirement of 35 U.S.C. § 112, first paragraph.¹ The new training materials, which supersede and replace an older set of training materials issued by the Patent Office in 1999, are intended to assist patent examiners in applying the "Guidelines for Examination of Patent Applications Under the 35 U.S.C § 112, first paragraph 'Written Description' Requirement," which were originally published in the Federal Register on January 5, 2001, and which are now incorporated in the M.P.E.P. at § 2163.²

In the new training materials, the Office explains that revisions to the materials were necessitated by changes in both the case law and technology

that have occurred in the decade since the prior training materials had been issued.³

In view of several recent decisions by the Court of Appeals for the Federal Circuit addressing the written description requirement in the biotechnology context—including *Enzo Biochem, Inc. v. Gen-Probe Inc.*,⁴ *Noelle v. Lederman*,⁵ *University of Rochester v. G.D. Searle & Co.*,⁶ and *In re Wallach*,⁷—the updated training materials, not surprisingly, skew heavily towards biotech subject matter. In fact, of the seventeen examples provided in the training materials, fourteen specifically relate to biotech inventions. In particular, the biotech-specific examples address expressed sequence tags (ESTs) (example 4), a partial protein structure (example 5), DNA hybridization (example 6), allelic variants (example

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The Patent Office cited two prior art references against Kubin's claims: a U.S. patent to Valiante,⁴ disclosing the existence of a protein, p38, that turned out to be the protein encoded by Kubin's NAIL cDNA and a monoclonal antibody specific for p38; and the Sambrook cloning manual.⁵ A third reference, a scientific journal article by Matthew,⁶ was cited for its teachings on the cloning of a mouse cDNA that encoded the mouse ortholog of NAIL. The Board did not rely on this reference, but instead used it to show that the human monoclonal p38 antibody could be used, along with routine cloning methods, to isolate a cDNA encoding the mouse protein. The Office raised several specific distinctions between the facts of this case and the facts in *Deuel*, including ones having to do with improvements in the predictability of cloning methods in the years since the *Deuel* decision.

The court addressed the factual distinctions summarily:

This emphasis on similarities or differences in methods of deriving the NAIL DNA misses the main point of this obviousness question. Of note, the record nowhere suggests that the technique in Valiante's Example 12 for isolating NAIL (p38) DNA, even if slightly different than the technique disclosed in the claimed invention, would not yield the same polynucleotide claimed in claim 73. Stated directly, the record shows repeatedly that Valiante's Example 12 produces for any person of ordinary skill in this art the claimed polynucleotide.⁷

(In this, the court seems to have misconstrued the facts; Kubin's representative during oral argument emphasized that merely following the teachings of the Valiante and Sambrook references would not result

in NAIL cDNA, since human cells (unlike Matthew's mouse cells) needed special treatments to induce expression of detectable amounts of p38/NAIL.)

Nevertheless, the court then reversed the rationale used in *Deuel* to uphold the non-obviousness of DNA:

More to the point, however, any putative difference in Valiante's/Sambrook's and appellants' processes does not directly address the obviousness of representative claim 73, which

snippets.

The Federal Circuit found that Kubin's claims fell within the class of situations when something that is obvious to try is also obvious.

claims a genus of polynucleotides. The difference between Valiante's and the application's techniques might be directly relevant to obviousness in this case if Kubin and Goodwin had claimed a method of DNA cloning or isolation. But they did not. Appellants claim a gene sequence. Accordingly, the obviousness inquiry requires this court to review the Board's decision that the claimed sequence, not appellants' unclaimed cloning technique, is obvious in light of the abundant prior art.⁸

Turning to *In re Deuel*, the court focused on its reliance on when "obvious to try" can rise to the level of obviousness; as a starting point, the court cited this portion of the *Deuel* decision:

The existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNAs. . . . "Obvious to try" has long been held not to constitute obviousness. A general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out.⁹

The court then opined that the Supreme Court had disavowed *Deuel's* application of the "obvious to try" doctrine:

In fact, the Supreme Court expressly invoked *Deuel* as a source of the discredited "obvious to try" doctrine. The KSR Court reviewed this court's rejection, based on *Deuel*, of evidence showing that a particular combination of prior art elements was obvious because it would have been obvious to one of ordinary skill in the art to attempt such a combination:

The only declaration offered by KSR—a declaration by its Vice President of Design Engineering, Larry Willemsen—did not go to the ultimate issue of motivation to combine prior art, i.e. whether one of ordinary skill in the art would have been motivated to attach an electronic control to the support bracket of the assembly disclosed by Asano. Mr. Willemsen did state that an electronic control "could have been" mounted on the support bracket of a pedal assembly. Such testimony is not sufficient to support a finding of obviousness, however. See, e.g., *In re Deuel* ("Obvious to try" has long been held not to constitute obviousness.).¹⁰

KSR's actual holding as to when something is obvious to try is significantly more limited:

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.¹¹

In *Kubin*, the court applied KSR to its consideration of the question from *In re O'Farrell*,¹² focusing on the following statement:

Specifically, this court observed that an obviousness finding was appropriate where the prior art “contained detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful.” Responding to concerns about uncertainty in the prior art influencing the purported success of the claimed combination, this court stated: “[o]bviousness does not require absolute predictability of success... all that is required is a reasonable expectation of success.”¹³

The Supreme Court in *KSR* reinvigorated this perceptive analysis. Under this standard, the court found that Kubin's claims fell within this class of situations when something that is obvious to try is also obvious. The court enumerated the factual predicates for applying this *O'Farrell* standard to Kubin's claim 73:

[T]he Valiante reference discloses the very protein of appellants' interest – “p38” as per Valiante. Valiante discloses a monoclonal antibody mAb C1.7 that is specific for p38/NAIL, and further teaches a five-step protocol for cloning nucleic acid molecules encoding p38/NAIL using mAb C1.7. In fact, while stating that “[t]he DNA and protein sequences for the receptor p38 may be obtained by resort to conventional methodologies known to one of skill in the art,” Valiante cites to the very same cloning manual, Sambrook, cited by Kubin and Goodwin for their proposition that the gene sequence is identified and recovered “by standard biochemical methods.” Moreover, the record strongly reinforces (and appellants apparently find no room to dispute) the Board's factual finding that one of ordinary skill would have been motivated to isolate NAIL cDNA, given Valiante's teaching that p38 is “expressed by virtually all human NK cells and thus plays a role in the immune response.” The record shows that the prior art teaches a protein of interest, a motivation to isolate the gene coding for that protein, and illustrative instructions to use a monoclonal antibody specific to the protein for cloning this gene. Therefore, the claimed invention is “the product not of innovation but of ordinary skill and common sense.” [citing *KSR*] Or stated in the familiar terms of this court's longstanding case law, the record shows that a skilled artisan would have had a resoundingly “reasonable expectation of success” in deriving the claimed invention in light of the teachings of the prior art. [Citing *O'Farrell*.]¹⁴

Stated this way, and disregarding the factual distinctions to the contrary, it is not hard to see how the panel arrived at its conclusion. And in some ways, this is actually good news for biotechnology inventions: the basis for the court's decision was not the generic “DNA is obvious” position long sought by the Patent Office. Instead, the court set forth a plethora of factual grounds unlikely to be identically (or even substantially) encountered for other genes.

The court's decision in *In re Kubin* reinforces the impression that, after *KSR*, what will be dispositive is evidence, not argument. *KSR* increases the tendency and risk of subjective hindsight reconstruction of an invention, based on a “totality of the circumstances” approach (“I may not know how to define what's obvious but I know it when I see it,” to paraphrase Justice Potter Stewart in another context). This “gut reaction” obviousness can be defeated only by evidence refuting the construction that hindsight informs. The outcome here illustrates the importance of pressing these kinds of factual distinctions.

And while the significance of the decision to biotechnology patent claims should not be downplayed, in fact its importance may be significantly diminished due to its timing in the history of biotechnology. Many (if not most) of the “known” genes in the art have been cloned and patented (or not) over the past 30 years of gene patenting, and many of these patents have expired or are nearing the ends of their terms. In addition, many of these genes were isolated at a time when the technology was much less well developed and when there were sound factual bases for concluding that there was not a reasonable expectation of successfully cloning a cognate gene, even for proteins that were well known and well characterized.

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Patents obtained during these times should be easy to distinguish from *Kubin*, since the predictability that the court found as a result of advances in modern technology was much less evident years ago. Turning to the present day, many (if not most) of the genes patented or applied for were not known prior to their discovery (usually through homology comparisons) as a result of the Human Genome Project (HGP). A fundamental pillar of the court's decision in *Kubin* was that p38 was known; that will not be the case for most of the genes identified since the late 1990's. The *Deuel* decision said that "what cannot be contemplated or conceived cannot be obvious;"¹⁵ *a fortiori*, what is completely unknown is unlikely to be determined obvious.

This leaves a class of genes and gene patents "in the middle" – granted since (and perhaps because of) the court's decision in *Deuel* but prior to identification during the HGP effort. Some of these, no doubt, have now been made more open to an obviousness challenge. However, many (if not most) of these genes will lack some if not several of the factual underpinnings of the *Kubin* decision. Such distinctions include:

- the existence of the protein encoded therefrom was not known;
- there was not a commercially-available monoclonal antibody specific for the protein;
- expression cloning was ineffective or unpredictable for that gene;
- there was no express description in the art on how to isolate the gene; and/or
- there did not exist in the art an identified cell or tissue source reliably expressing the protein.

In these and perhaps other ways, the *Kubin* decision is sufficiently narrow such that it

should not provoke a sea change in the fortunes of such gene claims. Insofar as it has a tendency to have this effect in the Patent Office, factual challenges, particularly supported by expert declarations, should have the greatest persuasive punch. Distinctions over the factual bases of the *Kubin* decision are not only the best chance of overcoming obviousness rejections, but the Office must consider such evidence (particularly declaration evidence) and refute it.¹⁶

The *Kubin* decision is likely to increase the challenges in litigation over gene claims, but this is tempered by the high standard of proving invalidity, as well as the factual distinctions mentioned above. The *Kubin* court did the biotechnology community no favors by interpreting *KSR* to have overturned *Deuel* (which *KSR* did not do explicitly). But the consequences of its overreaction may be alleviated by addressing the obviousness question for each new gene on its own facts, distinct from the considerations that supported the court's determination of obviousness in *Kubin*.

Endnotes

1. No. 2008-1184 (Fed. Cir. Apr. 3, 2009).
2. 550 U.S. 398 (2007).
3. 51 F.3d 1552; 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995).
4. U.S. Patent No. 5,688,690.
5. Joseph Sambrook *et al.*, *Molecular Cloning: A Laboratory Manual* 43-84 (2d ed. 1989).
6. Porunelloor Matthew *et al.*, *Cloning and Characterization of the 2B4 Gene Encoding a Molecule Associated with Non-MHC-Restricted Killing Mediated by Activated Natural Killer Cells and T Cells*, 151 J. IMMUNOLOGY 5328-37 (1993).
7. *Kubin* at 8 (emphasis in original).

8. *Id.* (emphasis in original).
9. *Id.* at 12 (internal citations omitted; emphasis in original).
10. *Id.* at 13 (internal citations omitted).
11. *Id.* citing (*KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 82 U.S.P.Q. 2d 1385, 1394, 1396 (2007)) (emphasis in original).
12. 853 F.2d 894, 903 (Fed. Cir. 1988).
13. *Kubin* at 15, citing *O'Farrell* at 903-04 (internal citations omitted; emphasis in original).
14. *Id.* at 15-16 (internal citations omitted, emphasis in original).
15. 51 F.3d 1552, 1558.
16. *In re Sullivan*, 84 U.S.P.Q. 2d 1304 (Fed. Cir. 2007).

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7), bioinformatics (example 8), protein variants (example 9), a product claimed by its function (example 10), a polynucleotide or polypeptide sequence sharing percent identity with another sequence (example 11), antisense oligonucleotides (example 12), antibodies to a single protein (example 13), antibodies to a genus of proteins (example 14), a genus with widely varying species (example 15), a process claim where novelty resides in the process steps (example 16), and methods of using compounds claimed by functional limitations, methods of identifying compounds, and compounds identified by such methods (example 17).⁸

DNA Hybridization and Percent Identity

While a number of these examples provide useful information for claiming and describing biotechnological subject matter, two examples in particular—DNA hybridization and percent identity—will significantly impact the way in which applicants claim and describe nucleic acid variants. Example 6, which concerns claims directed to nucleic acid molecules that hybridize to a recited sequence, provides three exemplary claims:

Claim 1: An isolated nucleic acid that encodes a protein that binds to the NDG [newly-discovered growth factor] receptor and stimulates tyrosine kinase activity.

Claim 2: An isolated nucleic acid that encodes a protein that binds to the NDG receptor and stimulates tyrosine kinase activity, and consists of the sequence set forth in SEQ ID NO: 1.

Claim 3: An isolated nucleic acid that encodes a protein that binds to the NDG receptor and stimulates tyrosine kinase activity, wherein the nucleic acid hybridizes under highly stringent conditions to

the complement of the sequence set forth in SEQ ID NO: 1.⁹

The example quickly disposes of claims 1 and 2, neither of which encompasses hybridization variants.¹⁰ According to the training materials, the exemplary specification discloses the nucleotide sequence of SEQ ID NO: 1, and therefore, the specification satisfies the written description requirement with respect to the full scope of claim 2, which uses the transitional phrase “consists of.”¹¹ However, because claim 1 encompasses a broad genus of isolated nucleic acids,



Two of the examples in the new Written Description Training Materials will significantly impact the way in which applicants claim and describe nucleic acid variants.

and the specification fails to disclose any information about the structure or location of NDG receptor binding domains in the protein encoded by the nucleotide sequence of SEQ ID NO: 1, the specification fails to satisfy the written description requirement with respect to the full scope of claim 1.¹²

With respect to claim 3, the training materials acknowledge that “nucleic acids that hybridize to the complement of SEQ ID NO: 1 must share many nucleotides in common with SEQ ID NO: 1,” and therefore, that “[t]he disclosure of SEQ ID NO: 1 combined with the knowledge in the art regarding hybridization would put one in possession of the genus of nucleic acids that would hybridize under stringent conditions to SEQ ID NO: 1.”¹³ Nevertheless, the training materials

conclude that the specification fails to satisfy the written description requirement with respect to the full scope of claim 3 because the specification does not disclose a recognized correlation between the structure of the protein encoded by the nucleotide sequence of SEQ ID NO: 1 and the encoded protein’s function.¹⁴ Without this correlation, “those of ordinary skill in the art would not be able to identify without further testing which of those nucleic acids that hybridize to SEQ ID NO: 1 would also encode a polypeptide that binds to NDG receptor and stimulates tyrosine kinase activity.”¹⁵

Example 11 concerns claims that are directed to a polynucleotide or polypeptide sequence that shares percent identity with another sequence.¹⁶ The example is divided into two sections, one in which there is no art-recognized structure-function correlation for the claimed sequence (Example 11A), and one in which there is an art-recognized structure-function correlation for the claimed sequence (Example 11B).¹⁷ The first section of this example provides two exemplary claims:

Claim 1: An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2.

Claim 2: An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2; wherein the polypeptide has activity X.¹⁸

Despite the exemplary specification’s disclosure of only a single species encoding the polypeptide of SEQ ID NO: 2 (*i.e.*, SEQ ID NO: 1), and the lack of any teaching in the specification regarding the amino acid residues in SEQ ID NO: 2 that are tolerable

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to change, the training materials indicate that the specification satisfies the written description requirement with respect to the scope of claim 1.¹⁹ According to the training materials, this is so because, “[w]ith the aid of a computer, one of skill in the art could have identified all of the nucleic acids that encode a polypeptide with at least 85% sequence identity with SEQ ID NO: 2.”²⁰ However, because the exemplary specification is said to lack any teaching as to which amino acid residues in SEQ ID NO: 2 can be changed while still retaining activity X, and the art lacks any recognized correlation between structure (domains in SEQ ID NO: 2) and function (activity X), the training materials indicate that the specification fails to satisfy the written description requirement with respect to the scope of claim 2.²¹

The second section of Example 11 also provides two exemplary claims:

Claim 1: An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2.

Claim 2. An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2; wherein the polypeptide has activity Y.²²

The only difference between the exemplary specification of Examples 11A and 11B is that the latter identifies two domains that are critical to activity Y (*i.e.*, a binding domain and a catalytic domain). As a result, the training materials find that the specification satisfies the written description requirement with respect to the scope of both claims 1 and 2 of Example 11B.²³

Unfortunately, for claims directed to nucleic acid variants, Examples 6 and 11 may

raise more questions than they answer. For example, the skilled artisan would expect a nucleotide sequence hybridizing under highly stringent conditions to encode a protein having a sequence identity that is greater than 85%. So, if claim 1 in Examples 11A and 11B complies with the written description requirement, would a claim directed to a nucleic acid that hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO: 1, but lacking a functional limitation, also comply with the requirement? In the new training materials, this question goes unanswered. However, by focusing on the ability to dis-

The logo for 'snippets' features the word in a lowercase, sans-serif font. The letter 'i' is stylized with a square dot, and the letter 'p' has a square stem. The logo is set against a light green background.

Claims to hybridizing variants, or variants sharing sequence identity that lack functional limitations, may make it past one hurdle only to stumble on another.

cern hybridizing variants encoding proteins that retain a recited activity from hybridizing variants encoding proteins that do not, the training materials seem to suggest that the above claim would comply with the written description requirement.

Ultimately, the above argument is academic, since the lesson of Example 11 is to not draft nucleic acid variant claims lacking functional limitations, but rather to identify and disclose protein domains that are critical to function or amino acid residues that are tolerable to change. In fact, Example 11A notes (albeit in a practice note) that, while claim 1 may satisfy the written description requirement, “[e]nablement issues that may be raised

by the recited facts are not addressed” by the example.²⁴ Thus, claims to hybridizing variants, or variants sharing sequence identity that lack functional limitations, may make it past one hurdle only to stumble on another.

The USPTO's Position on Example 11 and *Ex parte Porro*

A few months after the new training materials were released, Dr. George Elliott, one of three Directors in Group 1600 (biotechnology and organic chemistry), addressed some of the issues concerning Example 11.²⁵ Dr. Elliott noted that, with respect to the conclusions presented in the example, the USPTO had reversed its prior position, having previously asserted that claims lacking functional language failed to comply with the written description requirement, and that claims possessing such language complied with the requirement.²⁶ Dr. Elliott explained that, when a claim contains functional language but the specification lacks any teaching regarding the amino acid residues that are tolerable to change, there is a lack of written description because “the minute you add function, you’ve limited the claim to a subset of species, and you don’t know which species are in the subset and which species aren’t.”²⁷ In other words, absent any teaching of structure-function relationships, the USPTO’s (and Dr. Elliott’s) position is that one cannot determine the species that share at least 85% sequence identity with the recited sequence and also possess the recited function. For a more thorough discussion of the rationale behind the USPTO’s reversal on functional limitations in percent identity claims, Dr. Elliott recommended that practitioners read *Ex parte Porro*.²⁸

In *Porro*, the Board of Patent Appeals and Interferences affirmed the examiner’s determination that claims to a method of making ascorbic acid (vitamin C) lacked an

adequate written description.²⁹ Claims 12-14 were at issue on appeal; representative claim 13 recites:

13. A method of generating ascorbic acid, comprising:

a) obtaining a recombinant yeast capable of converting an ascorbic acid precursor into ascorbic acid, wherein the yeast is functionally transformed with a coding region encoding L-galactose dehydrogenase (LGDH) enzyme having at least about 90% identity with SEQ ID NO: 11,

b) culturing the recombinant yeast in a medium comprising an ascorbic acid precursor, thereby forming ascorbic acid, and

c) isolating the ascorbic acid.³⁰

During prosecution of the claims at issue, the examiner noted that the specification disclosed only a single LGDH sequence (i.e., SEQ ID NO: 11), which the inventors had obtained from *Arabidopsis thaliana*.³¹ The examiner also noted that the prior art failed to disclose other LGDH enzymes sharing 90% identity to SEQ ID NO: 11.³² Concluding that the claims encompassed a very large genus of sequences, and that the specification and prior art provided a limited description of the motifs or structures responsible for LGDH activity, the examiner determined that the specification did not adequately describe the genus of LGDH enzymes sharing at least 90% identity with SEQ ID NO: 11.³³

The Board affirmed the examiner's determination that claims 12-14 lacked an adequate written description, citing *University of California v. Eli Lilly and Co.*,³⁴ and *University of Rochester v. G.D. Searle & Co.*,³⁵ in support of its decision.³⁶ With respect to *Lilly*, the Board determined that "[t]he *Eli Lilly* court held that a fully described genus is one for which a person skilled in the art

can 'visualize or recognize the identity of the members of the genus,'" and in the instant case, "the Specification does not provide guidance regarding what structural features are responsible for the enzymatic activity of LGDH, nor does it describe what amino acid changes can be made in the wild-type sequence without affecting the enzymatic activity of the protein."³⁷ The Board concluded that "the Specification does not describe the recited genus adequately for those skilled in the art to distinguish the SEQ ID NO: 11 variants that are within the claims from other variants of SEQ ID NO: 11," and therefore, "does not adequately describe the recited genus under the standard of *Eli Lilly*."³⁸

With respect to *University of Rochester*, the Board stated that:

Just as in *University of Rochester*, the present application discloses a genus of chemical compounds (proteins having amino acid sequences at least 90% identical to SEQ ID NO: 11). According to Appellants' calculations, the genus encompasses 3.4×10^{41} different proteins. But the claims are limited to only those compounds having a desired characteristic (having LGDH enzymatic activity). Just as in *University of Rochester*, the present Specification does not guide the skilled artisan to the subset of proteins within the genus of 3.4×10^{41} proteins that are at least 90% identical to SEQ ID NO: 11 that have the recited enzymatic activity.³⁹

In affirming the examiner's rejection, the Board concluded that a subgenus of "functional variants" within a genus of "variants" must be described by disclosing a representative number of functional variants or by disclosing "structural features that are common to functional variants that distinguish them from the rest of the genus

(i.e., structural features that correlate with enzymatic activity regardless of other variations from SEQ ID NO: 11)," and that the application at issue provided neither.⁴⁰ Interestingly, the Board conceded that there may be other ways to describe such a subgenus, but that "the case law is a little hazy in this area."⁴¹

While the training materials (which were published shortly after the Board decided *Porro*) do not mention the *Porro* case by name, the language of Example 11 leaves little doubt that *Porro* served as the basis for Example 11. For example, the Board in *Porro* states:

Certainly SEQ ID NO: 11 is adequately described. We can also assume, for present purposes, that a description of SEQ ID NO: 11 is adequate to describe amino acid sequences that are 90% identical to SEQ ID NO: 11[.] Given a computer and sequence-comparison software, a skilled artisan may well be able to visualize or recognize the identity of members of that genus.⁴²

The Board's conclusion and reasoning in *Porro* is nearly identical to that provided by the training materials for exemplary claim 1 (including statements about using a computer to identify sequence variants).⁴³

Moreover, the Board's response to the applicants' argument that "[t]he skilled artisan would have a reasonable expectation that an LGDH . . . would be operable in the claimed methods" evokes Example 11's practice note.⁴⁴ In particular, the Board stated that such an argument was not directed to the issue raised on appeal, since the examiner had not made an enablement rejection.⁴⁵ In view of the decision in *Porro* and the training materials, it will be **continued on p. 8**

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interesting to see how the USPTO balances the issues of operability and enablement with respect to pending claims that resemble exemplary claim 1 of Example 11 (particularly since Judge Lourie did not find these issues to present a problem for hybridization variants in *Enzo Biochem*).

In re Kubin

As with the written description guidelines, the training materials do not have the force and effect of law, and the Office's failure to follow them cannot be appealed or petitioned. The Federal Circuit, however, recently touched on the persuasiveness of the guidance provided in Example 11 of the new training materials during oral argument for *In re Kubin*.⁴⁶

The claim at issue in *Kubin* recites:

Claim 73: An isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide at least 80% identical to amino acids 22-221 of SEQ ID NO:2, wherein the polypeptide binds CD48.⁴⁷

On April 3rd, the Federal Circuit affirmed a finding by the Board that claim 73, which encompasses a genus of nucleic acid molecules encoding human Natural Killer Cell Activation Inducing Ligand (NAIL) variants, was obvious.⁴⁸ (Note: an analysis of *Kubin* can be found starting on page one of this edition of *snippets*.)

However, while the Board also determined that *Kubin*'s application lacked an adequate written description of NAIL-encoding nucleic acid molecule variants, the Federal Circuit did not address the Board's written description determination in view of its decision on obviousness. Nevertheless, the issue resulted in an interesting exchange during oral arguments between the panel (specifically

Judge Rader) and USPTO Associate Solicitor Janet Gongola regarding Example 11 of the training materials.

In contrast with Dr. Elliott's assertion that the rationale behind the USPTO's reversal on functional limitations in percent-identity claims was based on the Board's decision in *Ex parte Porro*, Judge Rader speculated that the Patent Office may have reversed its position on the fact pattern set forth in Example 11 in order to support its argument that *Kubin* lacked an adequate written descrip-

snippets.

Judge Rader speculated that the PTO may have reversed its position on Example 11 in order to support its argument that *Kubin* lacked an adequate written description despite the recitation of an activity limitation.

tion despite the recitation in claim 73 of an activity limitation (i.e., binding CD48):

Gongola: I'd like to move now – if the Court has no more questions on obviousness – into the written description area. This Court found that written description was not satisfied under the only two tests that *Kubin* ever raised before the Board: the representative number of species test and the structure-function correlation test. Now, the Board found, at Finding of Fact 20 and 21, that the specification only taught how to make cDNA molecules that encode NAIL identically. That's one

subgenus. The Board found, at Finding of Fact 22, that the specification did not teach anything about any variants.

Court [Judge Rader]: What about the conservative substitutions set forth at page 63?

Gongola: The language on conservative substitution, using the Board's own findings, does not demonstrate – Finding of Fact 23 – which 20% of the amino acid residues should be changed to maintain function. So that discussion of conservative substitution may teach how to make the variants, but it doesn't teach what those variants are. It doesn't describe them so that a person of skill in the art would understand that *Kubin* possessed the variants. There – the Board Finding of Fact 25 says that there are a very large number of modifications that can be made. One in five amino acids can vary. We have no idea which of the 21 to 220 – 22 to 221 portion of NAIL to change and maintain binding – which amino acids have to remain and which can be substituted. But more than that, even if this Court would accept the discussion that the conservative substitution could somehow provide written description support for variants, it wouldn't still do so for the full scope of the genus. That discussion would only apply to variants made by substitution. Applicant – *Kubin* has defined a variant to be made by a substitution, an insertion, or a deletion. Conservative substitution dialog doesn't speak to anything about variants made by insertions, or variants made by deletions. So therefore, Applicant Alonso still has – I'm sorry, *Kubin*...

Court: Yes, but the description of the variations is also linked to a protein hav-

ing activity Y. Therefore, this satisfies the function-structure alternative test for written description, doesn't it?

Gongola: No, your Honor. The function-structure test requires an identification of a structure common to all members of the genus. We do not have that identification of a common structure. Twenty percent...

Court: I'm quoting almost out of PTO's manual on written description – verbatim – when I give my example there, am I not? The variations plus the activity Y – protein having activity Y – isn't that exactly the PTO's manual on written description?

Gongola: Are you referring to the training materials?

Court: Yes, I am.

Gongola: That language may be found in the training materials, but it is not – it's guidance. It's – each case of written description has to be decided on its own facts.

Court: The Patent Office is guiding applicants on how to do things wrong?

Gongola: No, your Honor, but guidance provided in a training document cannot be taken and applied to each case. Each case has to be decided on its own facts.

Court: So it's just guidance to examiners on how to do it wrong?

Gongola: No, your Honor – respectfully – it is guidance to the public as well, but...

Court: But if we take that guidance, we don't get to your result, do we?

Gongola: No, your Honor, I respectfully disagree; we do. In *Carnegie Mellon*, this Court has explained that when there's substantial variation within a genus, an applicant has to describe a sufficient number of species to reflect the variation. Kubin has not done that here. Kubin hasn't described any variation. If we want to look at the training materials, the Board only...

Court: It's interesting that this was revised immediately after *Kubin* – the *Kubin* result – wasn't it?

Gongola: That...

Court: Which is kind of an admission that the example did track *Kubin* and was detrimental to your position, wasn't it?

Gongola: No, your Honor.

Court: So, despite your smiling defense, the facts tend to give us a different conclusion.

Gongola: No, your Honor, that's not correct. The training materials were not revised post-*Kubin* to somehow capture *Kubin*. The revisions have been in the works for a very long time.

Court: I see, okay.

Gongola: So it's just coincidence that Example 11 may seem to look like the *Kubin* fact pattern. But if we actually look at Example 11, it is distinguishable from the facts here. Example 11 goes to a nucleic acid that encodes a polypeptide that has certain homology

– 85% homology – and a certain activity. Now here's where – that sounds a lot like Kubin's claim. I agree with that. But here's where the difference resides: the specification in Example 11 disclosed two specific domains that were responsible for the activity. Kubin's specification here doesn't contain any similar disclosure. So the fact pattern here is different from the fact pattern in the revised training materials. But I also want you to know – these materials, as you point out, were not even in existence when the Board rendered its decision. So it really isn't proper to be considering them right now, since the Board didn't have a chance to consider them in the first instance. And on top of that, they're only guidance. They're not a rigid rule.⁴⁹

While Judge Rader may have felt at oral argument that the Patent Office's reversal on functional limitations in percent-identity claims had been based on less than pure motives, the panel's refusal to address the written description issue in *Kubin* (and perhaps indicate whether the training materials constitute persuasive authority) means that applicants will have to provide as much description as possible regarding protein domains that are critical to function and amino acid residues that are tolerable to change. It appears that such disclosure will be required to support a claim reciting a genus of very structurally related nucleic acid molecules, even when the claimed species encode proteins differing from a recited sequence by only 1%, and where the vast majority of species are almost certain to possess the recited function.

The high bar set by the new training materials (and arguably not imposed on non-biotech inventions) will confront applicants pursuing
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The USPTO's New Written Description Training Materials: Impact on Biotech

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such claims until the Federal Circuit has another opportunity to address the written description issue in the context of hybridization variants or percent-identity claims.

For comprehensive analyses of other examples from the new written description training materials, readers are encouraged to visit Patent Docs (<http://www.patentdocs.org>).

Endnotes

1. Written Description Training Materials <http://www.uspto.gov/web/menu/written.pdf> ("Training Materials").
2. Training Materials at A-1.
3. *Id.* at 2.
4. 323 F.3d 956 (Fed. Cir. 2002).
5. 355 F.3d 1343 (Fed. Cir. 2004).
6. 358 F.3d 916 (Fed. Cir. 2004).
7. 378 F.3d 1330 (Fed. Cir. 2004).
8. Training Materials at i-ii.
9. *Id.* at 21.
10. *Id.* at 21-22.
11. *Id.* at 22.
12. *Id.* at 22-23.
13. *Id.* at 22.
14. *Id.*
15. *Id.*
16. *Id.* at 37.
17. *Id.* at 37-42.
18. *Id.* at 37.
19. *Id.* at 37-38.
20. *Id.* at 38.
21. *Id.* at 38-39.
22. *Id.* at 40.
23. *Id.* at 41-42.
24. *Id.* at 41.
25. Elliott, G. (2008, June). *The Latest News From the JPO, EPO, SIPO & USPTO*. Speech presented at 2008 BIO International Convention.
26. *Id.*
27. *Id.*
28. No. 2008-0184 (Bd. Pat. App. & Inter. March 11, 2008).
29. *Id.* at 10.
30. *Id.* at 2.
31. *Id.* at 3.
32. *Id.*
33. *Id.* at 3-4.
34. 119 F.3d 1559 (Fed. Cir. 1997).
35. 358 F.3d 916 (Fed. Cir. 2004).
36. *Ex parte Porro* at 5.
37. *Id.*
38. *Id.*
39. *Id.* at 6.
40. *Id.* at 8.
41. *Id.*
42. *Id.* at 7-8.
43. See, e.g., Training Materials at 37-42.
44. *Porro* at 9.
45. *Id.*
46. No. 2008-1184 (Fed. Cir. Apr. 3, 2009).
47. *Id.* at 2.
48. *Id.* at 18.
49. Audio of the entire Oral Argument is available at <http://oralarguments.cafc.uscourts.gov/searchscript.asp>, *In re Kubin*, case no. 2008-1184.

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The ABC's of ® and ©: Taking Note of Notice

Congratulations, you have rights in a trademark or a copyrightable work! Now, how do you give the rest of the world notice of your hard-earned rights? The answer is important, as failure to give proper notice of your rights can, in some instances, seriously impact your ability to collect damages for infringement.

Trademark rights and copyrights arise through different actions and are governed by different chapters of the United States Code, so it is not surprising that different rules apply for providing notice of trademark rights and copyrights. We will look at how these different rights are created, and what owners need to know to protect their rights.

Trademarks: How to Mark Your Mark

Trademarks indicate to a consumer or other purchaser the source of the goods or services being purchased. Purchasers come to recognize marks used in the channels of commerce in which they purchase such goods or services, and expect a certain level of quality to be associated with those marks. Trademarks have value as symbols of the goodwill a provider of goods or services has developed in the markets in which its goods or services are distributed.

Rights in trademarks are established through actual use of the marks in commerce. Common law trademark rights are established by continuous use of the mark in a geographical area. A federal trademark registration is a federal recognition of rights established at common law. An application for federal registration of a mark can be based on actual use of the mark in interstate commerce. Alternatively, such an application can be based on the applicant's bona fide intent to use the mark in interstate commerce. Regardless of whether the application is based on actual use or intent to use, a certificate of registration will not issue until

the applicant provides the Trademark Office with a statement of actual use of the mark in commerce.

Trademarks used in association with goods can be placed either on the goods themselves, or, if the nature of the product does not permit direct marking, then the trademark can be placed on the packaging in which the goods are sold, preferably in a conspicuous spot. Trademarks used in association with services can be used on advertisements and brochures that explain the services.

For an owner to establish goodwill in a mark, purchasers who view the mark have to understand that the words or symbols used on the product, packaging, or brochure are being used as a trademark or service mark to indicate the source of the goods or services. Typically, the words or symbols are presented in a distinctive font, or a particular color, or in a different size font from the surrounding text, or in capital letters, or in any combination of these aspects, so that the mark is uniquely distinguishable from any surrounding text. The unique appearance of the mark helps the purchaser identify the mark as an indicator of the source of the goods or services.

Registration of a mark provides constructive notice of the registrant's claim of ownership in the mark.¹ Registration provides the owner with all of the procedural and substantive benefits of the Trademark Act,² including the right to enjoin infringers.³ An owner whose registered mark has been infringed may also collect damages, either actual or statutory, as well as the accused infringer's profits, and costs of the action.⁴

The ability to collect monetary damages for trademark infringement requires the trademark owner to give actual notice of the

continued on p. 12

The logo for 'snippets' features the word in a lowercase, sans-serif font. The letter 'i' is unique, with a square box around its dot and a vertical line extending downwards from the bottom of the 'i'.

Failure to give proper notice of your rights can seriously impact your ability to collect damages for infringement.

The ABC's of ® and ©: Taking Note of Notice

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mark.⁵ The trademark statute provides that such notice may be given by displaying the mark with the words “Registered in the U.S. Patent and Trademark Office” or “Reg. U.S. Pat. & Tm. Off.,” or by use of the symbol “®,” which means “registered,” and can be used with both trademarks and service marks for which a certificate of registration has issued. These notations provide unambiguous notice that the owner has a claim to exclusive rights in the marks. If the trademark owner fails to display such a notice with its registered marks, then its statutory damages period may be limited to the time after the owner provides actual notice of the registration to the accused infringer, such as with a “cease and desist” letter.

What if your mark is not yet federally registered? The symbols “tm” and “sm” can be used to give notice to others that the owner is claiming exclusive rights in the marks. The “tm” and “sm” symbols indicate a claim of ownership in trademarks (used on goods) and service marks (used with services), respectively. The use of these symbols is not governed by the trademark statute. An owner can elect to use them when, for example, the mark is the subject of a federal trademark application that has not yet been granted. The use of these symbols does not in and of itself bestow trademark status. It cannot covert a generic name into a mark,⁶ or convert a non-trademark use into a trademark use.⁷ Still, use of these symbols with an unregistered mark can help to educate others as to exactly what symbols or words the user considers to be a trademark.

So, can you use the “®” symbol before you receive your federal registration? No! Use of the ® symbol with an unregistered mark is a misuse of the federal notice. In some circumstances, it can be deemed a fraudulent misuse of the mark, and can result in a refusal to grant a registration,

or serve as grounds for someone to challenge the owner's rights to a registration in an opposition proceeding.⁸ It can also be used as evidence of “unclean hands” in a “balancing of equities” in infringement litigation.⁹ Most often, however, the courts or the U.S. Patent and Trademark Office will not divest trademark rights based on misuse of a registration notice unless there is a deliberate intent to deceive. The Office will accept explanations of “mistaken” use of the ® symbol, such as simple inadvertence¹⁰ or misunderstanding as to the meaning of the symbol.¹¹ Nevertheless, every effort should be taken to avoid misuse of the “®”

The logo for 'snippets' features the word in a lowercase, sans-serif font. The letter 'i' is stylized with a square bracket above it, and the letter 't' has a square bracket to its left.

Remember, when dotting your “i”s and crossing your “t”s, make sure to include your “®”s and “©”s!

symbol, and to correct any misuse as soon as it is discovered.

Copyrights: Do You Need to Mark?

Copyright practice in the United States was formerly riddled with complicated requirements for registration and notice. These requirements frequently put U.S. copyright holders at a disadvantage with respect to copyright holders in other nations who did not face the same procedural hurdles to enforcing their rights. The Berne Convention Implementation Act (“BCIA”) of 1988 sought to remedy that situation by relaxing many procedural requirements, including notice. Today, whether or not copyright notice is required depends on when the work in question was created.

Works created prior to January 1, 1978 are governed by the Copyright Act of 1909. Under that statute, any work that lacked a proper copyright notice upon publication immediately became part of the public domain. The Copyright Act of 1976 was a bit more forgiving. Under that Act, a work published after January 1, 1978, without a copyright notice, became injected into the public domain, but such an omission could be cured by reasonable efforts to affix notice and to register the work within five years.¹² Under the BCIA, notice is not a prerequisite to copyright validity, such that works published on or after March 1, 1989 will not enter the public domain, even if they are published without copyright notice.

Why then, do so many copyright owners continue to use the “©” symbol (or “P” in a circle for phonographic copies) with a date and name of the copyright owner on their works? The answer lies in the benefits of actual notice of a claim of copyright ownership, both in deterring potential infringers and in recovering damages in infringement suits.

Copyright notice still serves the function of educating the public as to the true owner of the copyright in the work. Such notice can deter potential unauthorized users of the work, who might otherwise assume that the work was in the public domain and thus freely available to all. This is particularly true in the United States, where, prior to the BCIA, the absence of such notice meant exactly that. Use of an appropriate copyright notice will also defeat a defense of innocent infringement, which could otherwise reduce statutory damages.¹³

The statutory provisions for copyright notice remain, even after enactment of the BCIA.¹⁴ The form of copyright notice, as set forth in the Copyright Act,¹⁵ includes three parts: (1) the symbol “©” or the word “Copyright”

or the abbreviation “Copr.”; (2) the year of first publication of the work (the date may be omitted on certain articles such as pictorial, graphic, or sculptural works, or jewelry); and (3) the name of the copyright owner, or an abbreviation or alternate designation by which the owner can be recognized.¹⁶

Providing notice of trademark rights and copyrights can be an important part of your overall intellectual property program. So, keep in mind, when dotting your “i”s and crossing your “t”s, be sure to include your “®”s and “©”s!

Endnotes

1. 15 U.S.C. § 1115 (2007).
2. 15 U.S.C. §§ 1051-1141.
3. 15 U.S.C. § 1116 (2007).
4. 15 U.S.C. § 1117 (2007).
5. 15 U.S.C. § 1111 (2007).
6. *In re B.C. Switzer & Co.*, 211 U.S.P.Q. 644 (TTAB 1981).
7. *In re A La Vielle Russie, Inc.*, 60 U.S.P.Q. 2d 1895 (TTAB 2001).
8. *Wells Fargo & Co v. Lundeen & Assoc.*, 20 U.S.P.Q. 2d 1156 (TTAB 1991); *Copelands’ Enters., Inc. v. CNV, Inc.*, 945 F.2d 1563 (Fed. Cir. 1991).
9. *Gear, Inc. v. L.A. Gear Cal., Inc.*, 670 F. Supp. 508 (S.D.N.Y. 1987) *vacated, in part, dismissed*, 13 U.S.P.Q. 2d 1655 (S.D.N.Y. 1989).
10. *Jos. Schlitz Brewing Co. v. United Vintners, Inc.*, 166 U.S.P.Q. 493 (TTAB 1970); *Pan Am. Life Ins. Co. v. Federated Mut. Ins Co.*, 226 U.S.P.Q. 914 (TTAB 1985).
11. *Shatel Corp. v. Mao Ta Lumber & Yacht Corp.*, 697 F.2d 1352 (11th Cir. 1983).
12. 17 U.S.C. § 405 (2007) (pre-BCIA).
13. 17 U.S.C. § 401(d) (2007).
14. 17 U.S.C. §§ 401-06 (2007).
15. 17 U.S.C. §§ 101-1332.
16. 17 U.S.C. § 401(b) (2007).

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