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Patent Board Challenges Federal Circuit To A Deuel

Friday, Jul 27, 2007 --- Ex parte Kubin (Appeal 2007-0819 (May 31, 2007)) is one of three recently decided precedential decisions from the Board of Patent Appeals and Interferences (Board) interpreting the Supreme Court's decision in KSR v. Teleflex (127 S. Ct. 1727 (2007)).

In Wednesday's guest column, our colleagues discussed Ex Parte Smith (Appeal 2007-1925 (June 25, 2007)) and Ex Parte Catan (Appeal 2007-0820 (July 3, 2007)) wherein the Board dealt with the obviousness of inventions in the mechanical and electrical arts, respectively.

In Kubin, the Board affirmed an examiner's rejection of DNA claims as being obvious and failing to meet the written description requirement, but overturned a rejection for lack of enablement. The exemplary claim in Kubin recites "[a]n 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."

SEQ ID NO:2 is the amino acid sequence of human NK Cell Activation Inducing Ligand NAIL (also referred to as p38 below), with amino acids 22 to 221 corresponding to the extracellular (exposed) portion of the protein. Provided below is our analysis of the Board's decision.

* Is Deuel Controlling on the Question of Obviousness? *

In Kubin, the polynucleotide claims were rejected during examination as being obvious over three prior art references. The first described human p38 [NAIL] polypeptide via its binding to monoclonal antibody C1.7, and suggests that a cDNA encoding p38 could be cloned and sequenced by standard methods, such as those described in the second cited reference, a standard molecular biology textbook.

The third reference disclosed the gene encoding the mouse ortholog of NAIL by sequence. According to the Examiner, the claims were obvious given the availability of a monoclonal antibody to NAIL and routine methods for cloning and sequencing the human NAIL cDNA. The Board affirmed, relying in part on the Supreme Court decision in KSR.

The Board's obviousness determination is arguably contrary to longstanding Federal Circuit precedent relating to structural non-obviousness, exemplified by In re Deuel 51 F.3d 1552 (Fed. Cir. 1995).

In Deuel, as in Kubin, the claims were to an isolated polynucleotide which encodes a polypeptide. The polypeptide was in the prior art, and had been

isolated, purified and partially sequenced.

The Examiner rejected the polynucleotide claim based on the isolated polypeptide, in view of standard methods to isolate and sequence cDNAs, citing an earlier edition of the same textbook cited by the Examiner in Kubin.

The Board affirmed, but the Federal Circuit reversed, noting that "a conceived method of preparing some undefined DNA does not define it with the precision necessary to render it obvious over the protein it encodes."

The Board in Kubin justified the departure from precedent in part by noting that "Deuel is not controlling and thus does not stand in the way of our conclusion, given the increased level of skill in the art and the factual differences."

However, virtually no factual distinctions or analysis of the level of skill in the art is provided by the Board in support of this conclusion.

Granted, certain factual distinctions can be made, and the level of skill in molecular biology no doubt advanced between 1990, the filing date of Deuel, and Kubin's filing in 2000.

Nonetheless, the methodologies and level of skill pertinent to cDNA cloning have remained relatively unchanged. For example, the prior art in Deuel identified the isolated protein and a partial N-terminal sequence, which allowed construction of a hybridization probe used to isolate the cDNA ("hybridization cloning").

In contrast, the prior art in Kubin identified the isolated protein and a monoclonal antibody which bound to the protein, allowing isolation of a cDNA clone from an expression library via antibody screening ("expression cloning").

Expression cloning and hybridization cloning, as well as polynucleotide sequencing, were well established, routine procedures by the mid 1980s, well before Deuel's filing in 1990.

Thus, no apparent groundbreaking advances in the art occurred to make the isolation of the cDNA by Kubin any more predictable than the isolation of the cDNA by Deuel. Accordingly, it is unclear how factual differences or an increased level of skill in the art justify the Board's conclusion that Deuel is not controlling.

The Board attempts to further cast doubt on the viability of Deuel by arguing that the Supreme Court in KSR left the door open to more liberal use of the "obvious to try" standard. Indeed, according to the Supreme Court, where "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."

Based on this statement, the Board concluded that the "obvious to try" standard was applicable because "[t]he 'problem' facing those in the art was to isolate NAIL cDNA, and there were a limited number of methodologies available to do so."

However, the "problem to be solved" in Kubin was not a method of isolating NAIL cDNA, rather the problem was the structure of the NAIL cDNA. The prior art provided absolutely no structure, e.g., amino acid or polynucleotide sequence, by which a human NAIL cDNA could be inferred.

Thus, it did not provide any identified predictable solutions, let alone a finite number of identified, predictable solutions to the problem. Where KSR may have opened the door, nothing in the KSR opinion mandated dispensing with the need for at least some structural similarity in the prior art.

* Written Description and Enablement *

The Board essentially relied on the same findings of fact in Kubin to arrive at opposite conclusions with regard to enablement and written description.

These included findings that the specification failed to teach which domains (other than the extracellular domain) of the polypeptide sequence are correlated with function (i.e, there was no disclosure of which specific residues are required for binding to CD48); and, the specification failed to teach variant "at least 80% identical" polypeptides that bind CD48.

With respect to enablement, the Board overturned the rejection while concluding that "[t]he amount of experimentation to practice the full scope of the claimed invention might have been extensive, but it would have been routine."

With respect to written description, however, the Board opined that Federal Circuit case law such as University of California v. Eli Lilly, 119 F. 3d. 1559 (Fed. Cir. 1995), among others, was deemed to mandate a conclusion that the inventors failed at the time of filing to "possess" the genus of "at least 80% identical" molecules.

The Board's written description holding relies heavily on Lilly. In Lilly, claims were granted to cDNAs encoding vetebrate, mammalian and human insulin, based solely on the isolation of a cDNA encoding rat insulin.

According to Lilly, the written description requirement is satisfied if there is either 1) recitation of a representative number of species that fall within the genus or 2) if the genus is defined structurally by features that constitute a substantial portion of the genus.

Concerning the requirement for "recitation of a representative number of species" the specification in Kubin apparently lacked explicit disclosure (i.e., recitation) of specific polypeptide variants.

However, given that one of ordinary skill in the art could envision and identify the entire genus of isolated nucleic acid molecules encoding polypeptides at least 80% identical to the specified sequence, Kubin would appear to have defined the claimed genus with adequate written description.

The Board, however, noted a lack of correlation of structure and function in the specification (i.e., the specification provided no identification of the specific residues within the EC domain that bind CD48).

However, one of ordinary skill in the art can certainly perform the routine task of creating a list of several hundred (or more) polypeptides with conservative amino acid substitutions such that these are "at least 80% identical" and retain CD48 binding activity.

Moreover, unlike the purely functional claims in Lilly (e.g., "mammalian insulin cDNA"), the claims in Kubin do recite structural features possessed by members of the genus which distinguish members of the genus from other compounds.

In other words, the members of the claimed genus in Kubin are defined by "what they are" rather than "what they do." (Defining a chemical compound by "what it does" rather than structurally was the downfall of the claims in Lilly and its progeny.)

Hence, in contrast to the claims in Lilly, it would be interesting to know if the Federal Circuit would find the percent identity claims in Kubin adequately defined by "structural features common to members of the genus, which features constitute a substantial portion of the genus" sufficient to meet the statutory written description requirement.

Interestingly, the written description/"percent identity" issue has been addressed in several previous non-precedential Board decisions (Ex parte Sun (Appeal No. 2003-1993); Ex parte Bandeman (Bandeman I) (Appeal No. 2003-805); Ex parte Au-Young (Appeal No. 2003-1817); and Ex parte Bandeman (Bandeman II) (Appeal No. 2004-2319)). In each, an Examiner's rejection of "percent identity" claims as lacking written descriptive support was overturned at the Board.

Of particular interest is Bandeman II wherein the facts appear very similar to the facts in Kubin. In Bandeman II the claims were rejected as failing to meet the written description requirement because, according to the Examiner, no guidance had been provided concerning which residues within the protein correlate with function.

However, unlike Kubin, the Board in Bandeman II overturned the rejection while relying on Enzo Biochem v. Gen-Probe 296 F. 3d 1316 (Fed. Cir. 2002):

[a]dequate written description may be present for a genus of nucleic acids based on their hybridization properties . . . because such conditions dictate

that all species within the genus will be structurally similar.

Thus, based on the rationale in Enzo, the Board held that the written description requirement was satisfied for a claim encompassing a polynucleotide encoding a polypeptide sequence at least 95% identical to the amino acid sequence of SEQ ID NO:1.

The Board summarily dismissed the Examiner's assertion that the specification provided "no disclosure of any particular structure to function/activity relationship" with the statement that "the Examiner has not adequately explained and/or provided evidence to support that assertion."

It is difficult to reconcile Kubin with Bandeman II. One distinction is that the claims in Kubin were broader, "at least 80% identical," as opposed to "at least 95% identical" in Bandeman II.

However, since the Board in Kubin did not base its holding on the degree of identity, it is unclear whether there would have been a different outcome had the claims been narrower.

* Conclusion *

In the wake of KSR, the Board has clearly taken a well-aimed shot at the structural obviousness jurisprudence of the Federal Circuit, exemplified by In Re Deuel.

In trying to distinguish Deuel based on alleged factual distinctions and advances in the level of skill in the art, the Board may, instead, have demonstrated how little things have changed. Interestingly, in a post-KSR opinion, the Federal Circuit reaffirmed the viability of Deuel in the context of small molecules. Takeda Chemical Industries v. Alphapharm PTY., Ltd. Slip Op. 06-1329 (June 28, 2007).

Further, it is not clear that the Lilly written description test mandates a conclusion that knowledge of specific "function-conferring" residues is required to have possession of "percent identity" claims of the type appearing in Kubin.

In sum, while the Board may well be affirmed if Kubin or some analogous case were taken up on appeal on either issue, this is by no means a foregone conclusion.

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