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# IP Insight

*Recent Intellectual Property Caselaw and Developments of Interest*

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## Federal Circuit Holds Isolated DNA Is Statutory Subject Matter Under S101

*By Karen Axt*

*Assoc. Molec. Pathol. v. USPTO, Myriad Genetics et al.*, 10-1406 (Fed. Cir., July 29, 2011)

In a decision long awaited by the biotechnology industry, the Federal Circuit has held that claims to isolated DNA are patent-eligible subject matter under 35 USC §101 as compositions of matter that do not occur in nature, reversing the lower court ruling. *Assoc. Molec. Pathol. v. USPTO (Myriad Genetics)*, 10-1406 (Fed. Cir. July 29, 2011). The asserted composition claims are directed to isolated DNA related to the BRCA1 or BRCA2 gene. Mutations or alterations in the BRCA genes have been found to be associated with particular types of breast cancer, and the characterization and isolation of the genes was critical in developing diagnostic screens for cancer and potential therapeutic products.

**Summary**

While all members of the *Myriad* panel agreed that cDNA was patent eligible subject matter because it is man-made in the laboratory and does not include the non-coding introns, the panel did not agree entirely on whether or why isolated DNA was statutory subject matter under §101, hence the decision is a plurality decision; the decision includes the opinion of the Court (J. Lourie), a concurrence (J. Moore) and a dissent (J. Bryson).

The opinion of the *Myriad* Court relies on the observation that isolated DNA is cleaved from the larger native (chromosomal) DNA by breaking chemical bonds and therefore exists in a distinct chemical form. The Court determined that isolated DNA molecules are markedly different from DNA molecules that exist in nature. The Court opinion and concurring opinions relied in part on the long-standing Patent Office practice of issuing patents for isolated DNA, stating: "The Supreme Court has repeatedly stated that changes to longstanding practice should come from Congress, not the courts." Slip Op. at 47 (citation omitted). The concurrence found the composition claims to cDNA to be an easy analysis in favor of patent eligible subject matter, claims to short fragments of isolated DNA to be a bit more difficult, and claims to isolated DNA containing a full gene sequence to potentially fall either way, because while technically a different structure, its utility is tied up in the parent structure. The dissent did not find the fact that covalent bonds had to be cleaved to extract a gene from a genome to be a compelling basis for finding the isolated DNA to be a "different material" under §101 compared to what is found in nature. Rather, the dissent opined that isolating a gene was "akin to snapping a leaf from a tree," because the boundaries of the gene are predefined by nature, which determines in the transcription process the starting and stopping point for the gene.

The *Myriad* panel agreed: (1) that at least one plaintiff had standing to challenge the validity of Myriad's patents and satisfy the jurisdictional requirements for declaratory judgment actions, (2) to affirm that the claimed methods for comparing or analyzing steps fall outside the scope of patent eligibility under §101 because they included no transformation and were merely directed to abstract mental processes, and (3) to reverse the holding that a claim to a method for screening which included "growing" and a "determining" steps in addition to a "comparing" step, was not statutory subject matter under §101.

## Background

The Supreme Court has stated that §101 should be construed broadly. "Congress intended statutory subject matter to 'include anything under the sun that is made by man.' " *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (emphasis added).

The Supreme Court has added three exceptions to subject matter eligibility: "laws of nature, physical phenomena, and abstract ideas," describing them as "part of the storehouse of knowledge of all men ... free to all men and reserved exclusively to none." *Chakrabarty*, 447 U.S. at 309 (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948). These exceptions also preclude the patenting of "products of

nature", "phenomena of nature", and "mental processes". *Id*. at 313; *Gottschalk v. Benson*, 409 U.S. 63, 37 (1972). In the multi-decade boom of biotechnology, the issue of whether particular forms of DNA – the building blocks of life – are statutory subject matter has now been directly addressed by the Federal Circuit.

By way of background, isolated DNA is a particular portion of native DNA that has been excised, or extracted, from the whole. It is the location of the ends in the nucleotide sequence and the length of the sequence that represent the greatest differences between isolated DNA and native DNA. Generally, an entire isolated gene (and certain fragments thereof) will include introns (the non-coding portion of the sequence) and exons (the coding portion of the sequence). By contrast, so-called cDNA will contain no introns, because it is reconstructed in the lab by reverse transcription from "messenger RNA," which by definition do not contain introns.

*Myriad* involved fifteen claims in seven patents, directed to isolated DNA molecules including 5 full length genes, short fragments and cDNAs, as well as methods of using the DNAs. The composition claims to isolated full length gene DNAs were most hotly contested, and the Plaintiffs raised the possibility of ethical issues, as did some *amici curiae* and the district court: "[h]ow this genomic information is best harnessed for the greater good presents difficult questions touching upon innovation policy, social policy, medical ethics, economic policy, and the ownership of what some view as our common heritage." 702 F. Supp. 2d 181, 193 (S.D.N.Y. 2009); Three of the asserted patents included composition claims for "isolated DNA": U.S. 5,693,473 ('473) claim 1, U.S. 5,747,282 ('282), claims 1, 2, 5-7, and U.S. 5,837,492 ('492), claim 1. Exemplary are claims 1 and 2 of the '282 patent:

> 1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.
>
> 2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.
>
> The SEQ ID Nos 1 and 2 encompassed the full length and genes.

Claims 2, 6 and 7 of the '282 patent, claim 1 of the '473 patent, and claim 7 of the '491 patent are limited to cDNA. These cDNA sequences do not exist in nature. Claim 7 of the '492 patent recites an isolated DNA molecule that has "a mutated nucleotide sequence set forth in SEQ ID NO:1," but SEQ ID NO:1 is the open reading frame of the BRCA2 gene, not a mutated form of the BRCA2 gene. Claims 1 and 5 of the '282 patent are directed to an isolated DNA molecule that "codes for" the BRCA1 polypeptide having the sequence set forth in SEQ ID NO:2; claims 1 and 6 of the '492 patent are

**"The Court further explained, 'the patent eligibility of an isolated DNA is not negated because it has similar informational properties to a different, more complex natural material that embodies it.'"**

directed to an isolated DNA molecule that "codes for" the BRCA2 polypeptide having the sequence set forth in SEQ ID NO:2 of that patent, or a mutated form thereof. These claims are not limited to cDNA but may include any "isolated DNA molecule" provided it can encode the identified polypeptide.

## Isolated DNA is not a product of nature and therefore is patent eligible subject matter

### Holding of the Court

Writing the opinion of the Court, Judge Lourie said the distinction "between a product of nature and a human – made invention for purposes of § 101 turns on a change in the claimed composition's identity compared with what exists in nature." Slip. Op. at 41. Specifically, a distinction is drawn between compositions that have "similar characteristic as in nature" and composition that human intervention has given "markedly different" of "distinctive" characteristics. (citing *Hartranft*, 121 U.S. at 615; *see also Am. Fruit Growers v. Brogdex Co*., 283 U.S. 1, 11 (1931). Slip. Op. at 41. Judge Lourie described the difference between native (genomic) DNA found in chromosomes, isolated DNA and cDNA, and various types of mutations that can occur in DNA to illustrate the differences in structure of the molecules. Focusing on the differences between chromosomal DNA – native DNA packaged into chromosomes – and isolated DNA, which has been extracted from the native DNA, Judge Lourie observed that an isolated DNA molecule is not the same structure as native (chromosomal) DNA, because it is cleaved from the larger structure.

> . . . we conclude that the challenged claims are drawn to patentable subject matter because the claims cover molecules that are markedly different—have a distinctive chemical identity and nature—from molecules that exist in nature.
>
> It is undisputed that Myriad's claimed isolated DNAs exist in a distinctive chemical form—as distinctive chemical molecules—from DNAs in the human body, i.e., native DNA. ... Isolated DNA ... is a free-standing portion of a native DNA molecule, frequently a single gene. Isolated DNA has been cleaved (i.e., had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule.

Slip Op. at 41-42.

The Court further explained that "isolated DNA" is not a "purified" form of native DNA. While it is "removed from its native cellular and chromosomal environment, [isolated DNA] has also been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body." Slip Op. at 42.

In response to plaintiffs' argument that isolated DNAs retain the same nucleotide sequence as native DNA, and do not have any markedly different characteristics, the Court opinion stated that "it is the distinctive nature of DNA molecules as isolated compositions of matter that determines their patent eligibility rather than their physiological use or benefit." Slip Op. at 44. In other words, isolated DNA is a "markedly different" structure from the naturally occurring, larger structure, even if it has the same utility. The Court further explained, "the patent eligibility of an isolated DNA is not negated because it has

similar informational properties to a different, more complex natural material that embodies it." *Id*.

Finally, the Court noted the long-standing practice of the USPTO of issuing patents to isolated DNA and the responsibility of Congress, not the courts, to change that practice. The Court stated "the PTO has issued patents directed to DNA molecules for almost thirty years. ... It is estimated that the PTO has issued 2,645 patents claiming 'isolated DNA' over the past twenty-nine years ... and Congress has not indicated that the PTO's position is inconsistent with §101." Slip Op. at 48.

**The Concurrence**

Writing the concurring opinion, Judge Moore said ". . . *Funk Brothers and Chakrabarty* do not stake out the exact bounds of patentable subject matter. Instead, each applies a flexible test . . ." Concurrence at 5. Judge Moore found a different basis for patent eligibility: isolating a DNA sequence "results in a substantially smaller molecule compared to the naturally occurring sequence as part of the chromosome." As a result, isolated DNA leads to additional utility, in particular for smaller fragments.

Judge Moore found cDNA patentable because "the claimed cDNA sequences do not exist in nature. Moreover, since a cDNA has all of the introns removed, thereby containing only coding nucleotides, it can be used to express a protein in a cell which does not normally produce it" in accordance with *Chakrabarty*. Concurrence at 13. Thus, cDNA sequences are distinctive in name, character and use and have markedly different chemical characteristics from any continuous native DNA sequence, even if inspired by the natural template. Concurrence at 14.

Judge Moore found the class of isolated DNA that encompasses full length gene sequence and shorter fragments, both of which have sequences found on the chromosome, to be a more difficult case. These sequences do technically have a different chemical structure, because the structural "ends" of the isolated DNA molecules are not found in nature. Concurrence at 9-11. However, Judge Moore had difficulty characterizing these structures as so "markedly different," as to make them *per se* patentable subject matter. Concurrence at 14. She found, however, that having the same sequence as a portion the native DNA does not render isolated DNA "*per se* a law of nature [product of nature] and remove it from the scope of patentable subject matter" – they are "not naturally produced without the intervention of man". Concurrence at 15.

The shorter sequences have a utility not found in nature, namely using the molecules as a basis for diagnostic genetic testing. While using a property devised by nature – the ability of a single DNA strand to interact with a complementary strand – diagnostic testing itself is not a naturally occurring utility. Concurrence at 16. Thus it can be said that the new structural properties – *e.g.*, being truncated – confer a new and significant utility, because the same sequence within the native DNA cannot be used in the same manner, at least with regard to the shorter isolated sequences which may be used as primers or probes. Concurrence at 16-17.

Ultimately, for the long isolated DNA and full gene sequence DNA, the concurrence deferred to long-standing patent office policy. The concurrence cites the overwhelming number of patents issued on isolated DNA over the past 30 years and the precedent

of over a hundred years of patent eligibility of chemical compounds isolated or purified from larger structures found in nature. Concurrence at 18, 20-21. According to Patent Office policy, "isolated DNA is no different from the isolated natural products" which also " 'do[] not occur in that isolated form in nature.' " Concurrence at 20 (citation omitted).

Judge Moore also strongly emphasized the deference owed to Congress in deciding such issues, stating "the judiciary is ill-suited to determine whether the claims at issue promote or inhibit science and useful arts in all but the clearest cases". Concurrence at 27; *see also* Concurrence at 19 ("Congress has, for centuries, authorized an expansive scope of patentable subject matter."); Concurrence at 31 ("The patents in this case might well deserve to be excluded from the patent system, but that is a debate for Congress to resolve.").

With regard to the ethical and moral issues raised by amici curiae and the Plaintiffs, Judge Moore made the following salient comments:

> This case typifies an observation by the late Chief Judge Markey, our first Chief Judge, that "[o]nly God works from nothing. Men must work with old elements." ... Human DNA is, for better or worse, one of the old elements bequeathed to men to use in their work.

Concurrence at 30 (citations omitted).

**The Dissent**

Writing the dissent, Judge Bryson took the position that "the discovery of the [BRCA gene] sequences is an unprotectable fact" although applications of that discovery may be protectable subject matter, and some of the unasserted claims fall into the latter category. Dissent at 3-4. Because the claimed sequences exist in nature, according to Judge Bryson, allowing them to be patented prevents others from sequencing the BRCA genes or any other genome that may include the gene or claimed fragments thereof, for example to search for additional mutations. Judge Bryson argued that Myriad could have claimed these segments more narrowly in alignment with their utility – for example tagged segments to achieve the probe function, or the particular segments that would actually function as primers. Dissent at 15.

The dissent criticized the opinion of the Court for framing the question as one of breaking covalent bonds linking the BRCA genes to the rest of the DNA. Judge Bryson did not find this turns the isolated genes into "different materials." Dissent at 7. Focusing on the issue of the method of "isolating" the subject matter as determining whether the product was patent eligible, the dissent presented a different analysis with respect to molecules and elements, using lithium as an example.

> Once isolated, lithium has many industrial applications, and in order to isolate lithium, it is necessary to break ionic bonds in the lithium compounds that are found in nature.

Dissent at 8. According to the dissent, the boundaries of the isolated DNA are defined by nature "at points that preserve the ability of the gene to express the protein from which it is coded." Dissent at 10. The dissent therefore analogized extracting a gene to "snapping a leaf from a tree" because a leaf "has a natural starting and stopping point.

It buds during spring from the same place that it breaks off and falls during autumn. Yet prematurely plucking the leaf would not turn it into a human made invention." *Id*.

Judge Bryson dismissed any deference owed to the decades of Patent Office practice, stating that the Patent Office does not have substantive rulemaking authority to issues of "patentability" and its position in not granting patents on live organisms was given no weight by the Supreme Court in *Chakrabarty*. Dissent at 17. With regard to deferring changes to long-standing Patent Office practice to Congress, the dissent pointed out that the *Chakrabarty* Court did not agree that the scope of statutory subject matter should be left to Congress. "Congress has performed its constitutional role in defining patentable subject matter in §101; we perform ours in construing the language Congress has employed." *Id*., quoting *Chakrabarty*, 477 US at 315.

**Commentary**

What is clear from *Myriad* is that recombinant DNA and cDNA appear to be safely within the scope of §101. The *Myriad* demarcation also provides some certainty with respect to "isolated DNA." It leaves a clean demarcation around "isolated DNA" as patent eligible subject matter, and avoids categorically excluding inventions in this area of molecular science. Whether this clean line preserving, claims for "isolated DNA" stands up to further judicial review, and then to the test of time remains to be seen. Plaintiff filed a petition for panel rehearing which was denied on September 13, 2011. Defendant has filed a petition for panel rehearing on the standing issue which has not yet been decided.

## Prometheus Redux

*By Karen Axt*

The Supreme Court, for a second time, granted a petition for certiorari in *Mayo Collaborative Serv. v. Prometheus Labs Inc.*, No. 10-1150, on June 20, 2011, thereby vacating the Federal Circuit's December 17, 2010, opinion (628 F.3d 1347) which had been decided on remand for reconsideration in light of *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

In its December 2011 decision, the Federal Circuit held as patent eligible subject matter under 35 U.S.C. §101 Prometheus' claims directed to methods of optimizing therapeutic efficacy for a particular disorder. The representative methods include the steps of administering a particular therapeutic compound to a subject having the disorder and determining levels of metabolites of the administered compound in that subject, in addition to the "mental step", in the form of "wherein" clauses, of comparing the determined levels of metabolites to specific points of reference levels that indicate a need either to increase or decrease the amount of drug administered. *See* February 14, 2011, IP Insight article by Jeffrey Liao discussing the December decision. The Federal Circuit determined that the administering and determining steps were not just "data gathering", but were central to the claimed method of optimizing the efficacy of treatment.

The current question presented by the Supreme Court is to determine:

> Whether 35 U.S.C. §101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively preempts all uses of the naturally occur-

ring correlations, simply because well-known methods used to administer prescription drugs and test blood may involve "transformations" of body chemistry.

The question presented suggests the Supreme Court may consider the claims patent ineligible under §101. The grant of Certiorari describes the case in a similar tone: "This case concerns whether a patentee can monopolize basic, natural biological relationships."

Oral arguments are set for Wednesday, December 7, 2011. Twelve briefs have been filed by amici curiae.

## Federal Circuit Opens Reissues Proceedings to Add New Claims to Hedge Against Patent Invalidity

*By Karen Axt*

*In re Tanaka*, No. 2010-1262, 640 F.3d 1246, 98 USPQ2d 1331 (Fed. Cir. April 15, 2011)

Reissue is an appropriate means to add a narrower dependent claim, according to the April 15, 2011, Federal Circuit decision In re Tanaka, even if the original claims are retained unchanged. The Federal Circuit held that a patentee is permitted to "hedge" against possible invalidity using the reissue statute 35 USC §251, because omission of a narrower claim in an original patent can render the patent "partly inoperative" by failing to disclose the invention to the full extent permitted by law, and therefore qualifies as an "error" correctable by the reissue procedure.

Reissue is permitted where an error has occurred during prosecution:

> Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent.

35 U.S.C. § 251. Unlike the re-examination process, a patent submitted for reissue is not examined, but claims may be narrowed or, if a request for reissue is filed within 2 years of patent grant, they may broadened. A patentee must surrender the patent to the patent office for reissue, and a new "reissue patent" is issued to supplant the original patent.

The Federal Circuit has interpreted the statute to include two requirements in order to invoke a reissue proceeding: (1) a patent must be "wholly or partly inoperative or invalid" and (2) "the defective, inoperative, or invalid patent" must have arisen "through error without deceptive intent. *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 882 F.2d 1556, 1564-1565 (Fed. Cir. 1989). The term "inoperative" has been interpreted to mean "ineffective to protect the invention." *See Hewlett-Packard,* 882 F.2d at 1565.

### Background

Tanaka filed a reissue application two years after the issue date, initially to broaden the claims, stating in a declaration that the original claims "did not adequately define the

invention because they were more specific than necessary." During the course of reissue, however, Tanaka ended his pursuit of broader claims and instead filed a new narrower dependent claim. The Examiner rejected the narrower claim stating that because the "original claim 1 remains in the current reissue application, [and] the broadest scope of the patent remains the same," the new narrower claim did not present the type of error correctable by reissue under 35 U.S.C. §251. See 98 USPQ2d at 1332.

The Board affirmed in a precedential opinion of a panel of seven judges. The Board reviewed a number of CCPA and Federal Circuit cases, determining that the statute was "a remedial provision, which should be construed liberally," for example, claims may be corrected by reissue, but that the appellate court had only addressed the issue before it in dicta. *Ex parte Yasuhito Tanaka*, No. 2009-000234, 93 USPQ2d 1291, 1296 (BPAI Dec. 9, 2009) Finding no controlling authority on the subject, the Board held that 35 U.S.C. §251 did not allow simply adding narrow claims to the reissue patent when there is no assertion of inoperative or invalidity of the existing claims. 93 USPQ2d at 1296. The Board found that Tanaka was impermissibly seeking an additional claim "in order to hedge against the possible invalidity of one or more of the original claims".

> [I]n the present case, the original patent claims are not being amended to correct a defect that could render the claims invalid. Rather, the original patent claims are not being corrected at all. The Appellant is simply seeking, by reissue, to add narrower claims, where no valid assertion has been made by the patentee that any error exists as to the scope of the original patent claims.

93 USPQ2d at 1296. Citing Patent Office policy that has been applied since July 2008, the Board pointed out that

> [s]ection 1402 of the MPEP states that the Patent Office's interpretation of §251 does not allow for a reissue application in which the only error specified to support reissue is the failure to include one or more claims that is/are narrower than at least one of the existing patent claims(s) without an allegation that one or more of the broader patent claims(s) is/are too broad together with an amendment to such claim(s).

93 USPQ2d at 1296.

Tanaka appealed. The issue presented on appeal was: "Has the Appellant shown that the Examiner erred in determining that the presentation of a narrower claim in a reissue application that still contains all of the original patent claims does not present the type of error correctable by reissue under 35 U.S.C. § 251?" App. Br. at 5..

The Federal Circuit reversed and remanded, finding the Board's decision "contrary to longstanding precedent of this court." 98 USPQ2d at 1331, 1332.

## Majority

The PTO had argued that omission of a dependent claim does not render a patent "partially inoperative" under §251, because the subject matter of a dependent claim is necessarily covered by the claim from which it depends. The PTO also argued that the failure to include such a new dependent claim during original prosecution did not constitute "claiming more or less than the patentee had a right to claim in the patent," *i.e.*, it was neither an "over-claiming" nor an "under-claiming" error.

Tanaka argued that the Board's conclusion was contrary to binding precedent of the Federal Circuit, because §251 allows the addition of narrower claims to existing claims as a hedge against the possibility that the existing broader claims may be found invalid. *Id.*

The Federal Circuit agreed with Tanaka, stating that "adding dependent claims as a hedge against possible invalidity of original claims" was permitted by precedent, and that the Board's determination "flies counter to principles of stare decisis". 98 USPQ2d at 1332. The Court stated that in a case before its predecessor court, the Court of Customs and Patent Appeals, that presented nearly identical facts, Judge Giles S Rich "clearly stated that adding dependent claims as a hedge against possible invalidity of original claims 'is a proper reason for asking that a reissue be granted.' " *Id*. at *1333*, *quoting In re Handel*, 312 F.2d 943, 946 n.2 (CCPA 1963). Under *Handel*, a patent may be wholly or partly inoperative under §251, if the claims do not "adequately protect the invention, which may be due to failure of the solicitor to understand the invention." *Id*., *citing Handel*, 312 F.2d at 945, n. 2. The majority determined that in *Handel*, Judge Rich felt that "less" was used in the sense of fewer claims than could have been made, rather than the scope of subject matter included within the existing claims. Id. For example, narrower subject matter may be claimed by adding limitations to an existing claim or adding dependent claims that recite the limitations. Hence, according to Judge Rich, the use of reissue to hedge possible invalidity of broader claims by adding claims of narrower scope was "a proper reason for asking that a reissue be granted". *Id., quoting Handel*, 312 F.2d at 945, n. 2.

**"The Court rejected the PTO's assertion that it is not error under § 251 to omit a narrower dependent claim from an original patent … finding that 'the omission of a narrower claim from a patent can render a patent partly inoperative by failing to protect the disclosed invention to the full extent allowed by law.'"**

The majority recognized that these statements have been characterized as dictum, and the "*Handel*" rule had "seemingly never been formally embodied in a holding of this court or its predecessor." 98 USPQ2d at 1333-1334. However, the Court found *Handel* was "not simply a passing observation – it was a considered explanation of the scope of the reissue authority of the PTO in the context of a detailed explanation of the reissue statute" and noted that neither the Federal Circuit nor its predecessor court have departed from it. *Id*. The Court determined that later cases cited *Handel* favorably or followed its dicta. *Id*. (citing *In re Muller*, 417 F.2d 1387 (CCPA 1969); and *Hewlett-Packard,* 882 F.2d 1556). Thus, in view of the adoption of the rule in *Handel* "that adding a dependent claim as a hedge against possible invalidity is a proper reason to seek reissue" and the Court's adherence to the rule in both *Muller* and *Hewlett-Packard*, the Federal Circuit rejected the Board's "contrary" ruling. 98 USPQ2d at 1334.

The Court rejected the PTO's assertion that it is not error under § 251 to omit a narrower dependent claim from an original patent because such an omission does not render the patent inoperative, finding that "the omission of a narrower claim from a patent can render a patent partly inoperative by failing to protect the disclosed invention to the full extent allowed by law." 98 USPQ2d at 1334. The Court reasoned that narrower dependent claims are less vulnerable to validity attacks than broader independent claims and noted that "each claim of a patent has a purpose that is separate and distinct from the remaining claims." *Id.* For example, dependent claims can be "useful to clarify the meaning of broader, independent claims under the doctrine of claim differentiation." *Id.* at 1334 (citation omitted).

The Court distinguished application of the *Handel* rule from the situation in which a patentee impermissibly files a reissue application in order to have the claims re-examined in view of newly discovered prior art without alleging any defect or error in the patent. The Board had raised this comparison in support of its decision. The Court stated:

> Applying for a reissue that adds only narrower claims without amending any of the original claims is not the same as a "no defect" reissue.

Tanaka, 98 USPQ2d at 1334. Rather, error in the original prosecution in accordance with §251 may be found where the applicant neglects to seek a narrower dependent claim to which he was entitled. *Id.*

## Dissent

In dissent, Judge Dyk disagreed that precedent required the majority's result, stating that, in fact, "the prior cases have 'never squarely addressed the issue, and have at most assumed the applicability of [a particular] standard,' [therefore] we are not bound by those decisions and remain 'free to address the issue on the merits' in subsequent cases." 98 USPQ2d at 1335, J. Dyk *dissenting* (citations omitted).

Distinguishing the cases cited in support of the majority opinion, the dissent's position was that the *Hewlett-Packard* court made clear it wasn't deciding whether hedging was permitted, but rather assumed that practice was in accordance with the reissue statute's remedial purpose, and that the footnote in *Handel* stating that additional narrower claims were proper in reissue as a "hedge against possible invalidity" was dicta. *Id.* Tanaka had raised *Handel* in support of its position on appeal to Board of Appeals and Patent Interferences, but the Board also had concluded that the footnote in *Handel* was dicta:

> [T]he CCPA's tacit approval in a footnote that it is proper to seek narrower claims in a reissue as a hedge against the possible invalidity of the original claims is a voluntary opinion made by the court which falls outside the holding of the court in *Handel* and which was made without argument or full consideration of the point after briefing by the parties. In other words, this statement in footnote 2 of *Handel* is dictum.

93 USPQ2d at 1295.

The dissent stated that §251 is intended to provide patentees "with an opportunity to correct errors" but in this case "applicants made no correction to the original patent; instead, they merely attempted to add claims to the original patent." 98 USPQ2d at 1336, J. Dyk *dissenting*. Judge Dyk observed that

the clear language and purpose of the statute supported the PTO's position because:

The required premise of the statute that the original claims were 'deemed' wholly or partly inoperative or invalid' as the result of an 'error' is entirely missing. There is no assertion that correction of anything in the original patent was required.

*Id*.

## ITC Opinion Sets Standards for Analyzing Portfolio Licenses and the Domestic Industry Requirement

*By Kent Stevens*

Patentees in ITC proceedings have often asserted that the domestic industry element is satisfied by substantial investments in licensing the patents in suit as evidenced by large licensing operations dedicated to licensing a large portfolio of patents, including the patents in suit. Until the ITC's opinion in *Navigation Devices*, Inv. No. 337-TA-694 (issued in public version form July, 2011) evidence of expenditures to license a portfolio of patents that included the suit patents was generally sufficient to prove the domestic industry element -- even though ITC precedent was not clear as to exactly how much proof was required to link or allocate investments to licensing the specific patents in suit.

In *Navigation Devices* the ITC invited and received comments from the public on how much proof is required, and what kind of proof is required, to satisfy the domestic industry requirement with respect to particular patents at issue when the patents are licensed as a part of a portfolio. Among the non-party commentators, Google, Hewlett Packard, and Cisco jointly argued for an interpretation of the statute requiring a licensing domestic industry show substantial investment in activity that genuinely advances adoption of the technology in new products with regard to the patents in suit. nVidia also supported a high standard to prove domestic industry. Tessera argued that in the portfolio context all expenditures associated with exploitation through licensing a patent portfolio should be attributable to the licensing of each patent within the portfolio with respect to Section 337(a)(3)(C). Qualcomm argued for a flexible approach that takes into account the licensor's particular commercial circumstances.

In its *Navigation Devices* opinion, the ITC found that the portfolio evidence submitted by the Complainant did not satisfy the domestic industry requirement, and the ITC made clear pronouncements about the highly factual analysis that it will undertake to ensure a connection between investments in licensing and the specific patents at issue in order to meet the statutory requirement of "substantial investments in [the patent's] exploitation . . . [by] licensing."

The ITC explained that there are three initial requirements for satisfying the domestic industry requirement in this portfolio context. "First, the statute requires that the investment in licensing relate to 'its exploitation,' meaning an investment in the exploitation of *the asserted patent*." *Navigation Comm'n Op* at 7 (emphasis added). This requirement – the nexus between the licensing activities and the asserted patent -- may be proven by a showing that the licensing activities are "particularly focused on the asserted patent" or

the asserted patent has been a key patent or "relatively important" to the licensing activities. The following were listed as considerations in showing and evaluating the nexus between an asserted patent and licensing activities: (1) it [the patent] was discussed during the licensing negotiation process, (2) it has been successfully litigated before by complainant, (3) it relates to a technology industry standard, (4) it is a base patent or a pioneering patent, (5) it is infringed or practiced in the United States, or (6) the market recognizes its value in some other way.

Prospective Complainants will be particularly interested in the ITC's pronouncement that the ITC is particularly impressed by (and will potentially find dispositive on the issue of nexus) a showing that licensing activities relate to the suit patent by way of licensee practice of a claim of the suit patent. Comm'n Op. at 10 ("if a licensee's product is an 'article protected by' the patent, then the license is by definition connected to that patent."). To satisfy this standard, a patentee would presumably have to show that a claim of an asserted patent reads upon a licensee's product – a showing that is not otherwise required when asserting a licensing industry. Although a showing of licensee practice of a claim may add to a patentee's evidentiary burden, it provides a solid standard and target for showing a nexus between licensing activity and the patents in suit. See also *Navigation Comm'n Op* at 12 ("Evidence that the patent-at-issue is practiced or infringed in the United States may also be relevant to the value of the patent and may suggest a high value relative to that of the other patents in the portolio.").[1]

The second requirement for proving a licensing industry in the portfolio context is that the activities asserted as licensing activities in fact actually relate to licensing. In other words, a Complainant may demonstrate a nexus between licenses and the patent in suit, but when the Complainant presents evidence of investment in activities with respect to those licenses, it must then show that the activities are actually related to such licensing. This portion of the ITC opinion is not lengthy or detailed, but the ITC does observe by way of example that some activities are more worthy to be counted as licensing activities when they are activities undertaken solely for licensing purposes rather than for other purposes that may have multiple purposes (*e.g.*, patent infringement analysis, that may be undertaken for a variety of purposes).

**". . . the ITC made clear pronouncements about the highly factual analysis that it will undertake to ensure a connection between investments in licensing and the specific patents at issue . . ."**

The third statutory requirement for proving a domestic industry in the portfolio context is to demonstrate that the alleged investment in licensing is *domestic* investment, *i.e.*, "it must occur in the United States." On this point the ITC clarified that its analysis is a "fact-focused and case-specific inquiry that takes into account the extent to which the complainant conducts its licensing activities in the United States, including the employment of U.S. personnel and utilization of U.S. resources in its licensing activities." *Navigation Comm'n Op.* at 14-15.

To summarize, in the portfolio context, the Complainant must make a showing of (1) a nexus between its licenses and the specific patents in suit; (2) a nexus between its asserted licensing activities and the licensing of the patents in suit; and (3) a nexus between investments in the asserted licensing activities and the United States. The ITC explained that once it has assessed these matters, the ITC will next inquire into whether the investments are "substantial," as required by the statute. On this latter assessment, the ITC has noted that it adopts a flexible approach, "whereby a complainant whose showing on one or more of the three 337(a)(3)(C) requirements is relatively weak may nevertheless establish that its investment is 'substantial' by demonstrating that its activities and/or expenses are of a large magnitude."[2] *Navigation Comm'n Op.* at 15.

## Endnotes

1 The ITC also asserted that it may consider other factors, apart from a showing of licensee practice of the patent to show a nexus between a license and the patent in suit, including (1) the number of patents in the portfolio; (2) the relative value contributed by the asserted patent to the portfolio; (3) the prominence of the asserted patent in licensing discussions, negotiations and any resulting license agreement; and (4) the scope of technology covered by the portfolio compared to the scope of the asserted patent. *Navigation Comm'n Op.* at 10.

2 Other factors the ITC identified as relevant to determining whether an investment is "substantial" include: (1) the existence of other types of "exploitation" of the asserted patent such a research, development, or engineering; (2) the existence of license-related ancillary activities such as ensuring compliance with license agreements and providing training or technical support to its licensees; (3) whether complainant's licensing activities are continuing; and (4) whether complainant's licensing activities are those that are reference favorably in the legislative history of section 337(a)(3)(C).

## ITC Chief Administrative Law Judge Paul J. Luckern Retires

*By Kent Stevens*

Chief Judge Paul Luckern, who had a long, distinguished career as a chemist, attorney and Judge, has retired from the ITC. After receiving an LL.B.and an LL.M. from Georgetown University, and a master of science degree from Cornell University, he began his career as a chemist, first teaching chemistry at the University of Southern California and then working as a chemist at Eastman Kodak. In 1956 Chief Judge Luckern focused his career on patent law, first as a patent examiner at the PTO, next as a technical advisor for the late Honorable Jack Martin of the United States Court of Customs and Patent Appeals, next with the law firm of Fish & Neave, and thereafter as a trial attorney for the U.S. Department of Justice. In the early 1980s, Chief Judge Luckern became an Administrative Law Judge, and joined the ITC in that capacity in 1984, presiding over highly complex patent and trademark ITC Section 337 investigations. In 2008, the ITC appointed him Chief Administrative Law Judge. Chief Judge Luckern has received numerous awards as an outstanding jurist.

Chief Judge Luckern's retirement follows shortly after Judge Carl Charneski returned to private practice. Judge Charles Bullock, an ITC ALJ for approximately ten years, has been named as the Acting Chief Administrative Law Judge.

## Electronic Discovery at the ITC: Current Challenges and Possible Improvements

*By Kent Stevens*

At the request of the U.S. International Trade Commission ("ITC"), the ITC Trial Lawyers Association coordinated with the American Bar Association (Section Of Intellectual Property Law ITC Committee) and The George Washington University Law School to present a Program on "Electronic Discovery At The ITC: Current Challenges And Possible Improvements." The Program was held on July 18, 2011 at 9:00 a.m. – 1:15 p.m. at The George Washington University Law School.

The Program featured Keynote Speaker The Honorable Randall R. Rader, Chief Judge of the U.S. Court of Appeals for the Federal Circuit, who expressed concern about the escalating cost of patent litigation due to electronic discovery. Three panels focused on a "Comparison Between E-Discovery in the Federal District Courts and ITC," and on "Improving E-Discovery at the ITC and Proposed Solutions", including ways in which the ITC may adopt some electronic discovery practices and procedures of the Federal District Courts and Federal Rules of Civil Procedure.

Cadwalader attorney Tony Pezzano participated in the third panel, focusing particularly on a proposed early Meet-and-Confer by the parties on electronic discovery, including the production of source code and other highly confidential electronic information.

At the request of the Commission and with the approval of the ITCTLA, various participants in the program from the ITCTLA formed a working subcommittee to propose specific rules and procedures for the ITC to consider with respect to electronic discovery.

## ITC Proposed New Procedures For Electronic Filing

*By Kent Stevens*

The ITC has proposed new rules for electronic filing of documents in Section 337 cases. The new rules would require electronic filing of most documents, and significantly, permit for the first time electronic filing of documents that contain confidential business information protected from public disclosure by protective order.

Under the new proposed rules nearly all documents would be filed electronically in PDF format. The filing deadline will remain at 5:15 pm on the day a document is due. Two paper copies of the document will be due to the ITC by noon on the next business day in circumstances when the case is pending before the Administrative Law Judge. Eight paper copies are due by noon the next day when the case is pending before the full Commission. Exhibits to Complaints must be filed on CD-ROM or DVD, and other voluminous documents may be filed on portable electronic media as authorized by the ITC Secretary.

The ITC has also published a proposed Handbook on Filing Procedures that provides detailed explanations of the proposed new rules on electronic filing. The Handbook is available on-line at www.usitc.gov. It is expected that the proposed rules will be adopted in the Fall of 2011.

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