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Patents

When asked by BNA to discuss major issues in life sciences patent prosecutions, attorneys responded emphatically, ''Restrictions.'' Particular attention was paid to the PTO's interpretation of the phrase ''independent and distinct'' in the section of the patent law on divisional applications. Attorneys told BNA that as a result of the interpretation many life sciences patent applications may be unnecessarily restricted. Investigation by BNA and comments by life sciences attorneys show that the history of confusion over the interpretation runs deep. And a solution may be complicated.

Life Sciences Patent Restrictions Depend on Meaning of Word 'And'

U.S. Patent Law on divisional applications, 35 U.S.C. § 121, reads, ''If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions.''

The PTO has long held that ''independent and distinct'' means ''independent *or* distinct.'' A slide from the Sept. 13, 2006, meeting of the PTO's Biotechnology/Chemical/Pharmaceutical Customer Partnership (BCP) meeting on restriction petitions references 35 U.S.C. § 121 states, ''Historically the phrase 'two or more independent and distinct inventions' has been interpreted to mean two or more independent *or* distinct inventions.''[1]

Karen Canaan, a partner in the intellectual property practice group of Sheppard Mullin Richter & Hampton LLP, Menlo Park, Calif., told BNA, ''Many life sciences patent applications, which typically include composition, method, assay, and device claims, are probably being restricted unnecessarily as a result of the PTO's use of the 'independent or distinct' standard.' ''

Jane M. Love, partner and co-vice chair of the intellectual property department of Wilmer Hale, New York, told BNA, ''The PTO interpretation, which is broader than the plain language, is a problem for applicants with claims in the area of life sciences. There seem to be increasingly more restriction requirements among claims in the life sciences technologies than in other technologies. This causes increased cost for applicants to prosecute claims in separate applications that could have been retained in one application had there been a different interpretation of the language. It also causes great delay in prosecution of the restricted subject matter since a new divisional application would need to be filed prior to examination of the restricted claims.''

Love continued, ''In some cases, the number of restriction groups set out by the PTO in one application is high—it can be over 20 groups. The PTO often includes in their reasoning underlying the restriction requirement that it would be an 'undue burden' on the examiner to search. However, over the past five or so years, the search engines available to the public have improved tremendously, and nucleic acid sequence databases and peptide sequence databases have also improved dramatically.''

PTO's Definitions. The PTO justifies its interpretation of ''independent and distinct'' in comments on restrictions and double patenting in Chapter 800 of the Manual of Patenting Examining Procedures:

> If ''distinct'' means the same thing [as independent], then its use in the statute and in the rule is redundant. . . . If section 121 of the 1952 Act were intended to direct the Director never to approve division between dependent inven-

[1] *See* http://www.cabic.com/bcp/091306.

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> tions, the word ''independent'' would clearly have been used alone. If the Director has authority or discretion to restrict independent inventions only, then restriction would be improper as between dependent inventions, e.g., the examples used for purpose of illustration above. Such was clearly not the intent of Congress. Nothing in the language of the statute and nothing in the hearings of the committees indicate any intent to change the substantive law on this subject. On the contrary, joinder of the term ''distinct'' with the term ''independent'' indicates lack of such intent. The law has long been established that dependent inventions (frequently termed related inventions) [may] be properly divided if they are, in fact, ''distinct'' inventions, even though dependent.[2]

The MPEP goes on to characterize inventions as ''distinct if the inventions as claimed are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and wherein at least one invention is patentable (novel and nonobvious) over the other (though they may each be unpatentable over the prior art).''

In an April 25, 2007, internal PTO memo from the deputy commissioner for patent examination policy on communicating election of species requirements and establishing examination burden to applicants, a copy of which was obtained by BNA, the PTO appeared to be further standardizing restriction requirements regarding ''independent and distinct.''[3]

The memo states that, while the then-current form required an examiner to provide an explanation as to why the species are ''independent or distinct,'' the new form already provides the three most common reasons, requiring the examiner only to identify the species and the generic claims.

Patent Act's Legislative History. However, an examination of the legislative history of the Patent Act of 1952, which was the first revision of U.S. patent law since 1836 and was codified as Title 35 of the U.S. Code, suggests a different conclusion as to the meaning of ''independent and distinct'' than the one arrived at by the PTO.

The ''Proposed Revision and Amendment of the Patent Laws'' by the House Judiciary Committee, which was printed by the Government Printing Office in 1950 during the 81st Congress, shows that the wording of Section 121 on divisional applications was, ''If two or more independent or distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions; and the other invention or inventions may only be made the subject of divisional applications.'' The phrase used is ''independent or distinct.'' The same phrase appears in H.R. 9133[4], introduced on July 17, 1950. The bill was not acted on in the 81st Congress.

H.R. 3760[5] was introduced in the House on April 18, 1951, in the 82nd Congress by Rep. Joseph R. Bryson (D-NC), chairman of a subcommittee of the House Judiciary Committee that was in charge of the patent law revisions. In this bill, the section reads, ''If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions; and the other invention or inventions may only be made the subject of divisional applications.'' The phrase used in this bill and in the revised bill H.R. 7794[6], which was passed by the House and Senate is ''independent and distinct.''[7]

In other words, ''or'' was changed to ''and.''

In an address on the Patent Act of 1952, delivered at the Nov. 6, 1952, meeting of the New York Patent Law Association prior to the new law's taking effect, one of the two people on the law's drafting committee discussed ''independent and distinct.''[8]

Giles S. Rich,[9] indicates in the speech that the change from ''or'' to ''and'' was deliberate and that without a doubt ''and'' means ''and.''

Rich said, ''Section 121 is a tightening up of the law on division in favor of the patentees. The present statutes [i.e., before the 1952 amendments] do not refer to the subject. Note the conjunctive expression 'independent and distinct inventions.' Requiring the inventions be both independent and distinct makes it easier to keep two of them in one case.''

Rich went on to specifically discuss the applicability of the section to the double patenting issue.

> I believe that one patent or application may still be cited against the other for this purpose. You should not have two patents on one invention, but you should not be required to show ''invention'' in one over what is disclosed in the other where they are copending and where you have been forced to file a plurality of applications on the theory that a plurality of inventions are being claimed.

Rich acknowledged that there should not be two patents on one invention and his comments on forcing the filing of ''a plurality of applications on the theory that a plurality of inventions are being claimed'' anticipate the complaints about current PTO practices by life sciences patent attorneys.

Finally, while some have suggested that the switch from ''and'' to ''or'' was a typographical error, Rich's highlighting of the phrase indicates that it was not.[10]

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[2] MPEP, ''Chapter 800 Restriction in Applications Filed Under 35 U.S.C. 111; Double Patenting.'' *See* http://www.uspto.gov/web/offices/pac/mpep/old/E8R3_800.pdf.

[3] Memorandum from PTO Deputy Commissioner for Patent Examination Policy John Love to Technology Center Directors, Re: Changes to Restriction Form Paragraphs, April 25, 2007.

[4] *See* http://www.ipmall.info/hosted_resources/lipa/patents/patentact/file11.pdf.

[5] *See* http://www.ipmall.info/hosted_resources/lipa/patents/patentact/file14.pdf.

[6] *See* http://www.ipmall.info/hosted_resources/lipa/patents/patentact/file12.pdf.

[7] The Senate report on the bill, which can be found at http://www.ipmall.info/hosted_resources/lipa/patents/patentact/senate_report_1979.htm, states the following about Sections 120 and 121: ''Sections 120 and 121 express in the statute certain matters which exist in the law today but which had not before been written into the statute, and in so doing make some minor changes in the concepts involved.''

[8] The speech was reprinted in 1993 in a special issue of the *Journal of the Patent and Trademark Office Society*, Vol. 75, pp. 1-24.

[9] Although Bryson died in 1953, Rich lived another 46 years, serving on the U.S. Court of Appeals for the Federal Circuit where he sometimes commented in opinions on the history of the drafting the 1952 Patent Act. He also authored the opinion in *State Street & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), which allowed the patentability of business methods. He died the following year at the age of 95. In March 2009, the Federal Circuit in *In re Bilski* struck down the underpinnings of *State Street*, which attorneys indicated could have a negative effect on the life sciences industry (2 LSLR 947, 11/7/08).

[10] Note also should be made of Rich's use of the phrase ''conjunctive expression.'' A book currently available to read

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Calls to Reinterpret 'And.' The variance of the PTO's current practice with the evident intent of those who drafted the legislation has been noted before. In an Oct. 15, 2007, letter to the PTO offering comments on proposed rules related to the examination of patent applications that include claims containing alternative language, Intellectual Property Owners Association President Marc S. Adler wrote,

> We note that in many cases the Office continues to restrict applications where the inventions are independent or distinct from one another, which is contrary to the statements made in the Proposed Rules and in the plain language of 35 U.S.C. 121. We encouraged the Office to follow the language of 35 U.S.C. 121 and only restrict claims which are directed to inventions that are both independent and distinct.

In an April 9, 2008, letter commenting on the same proposed rules, David E. Boundy of Cantor Fitzgerald, New York, also noted that ''as a practical matter, the effect of Chapter 800 of the MPEP is to permit restriction if two inventions are independent or distinct. Chapter 800 should be redrafted to conform PTO policy to statute.''

Even the PTO has considered reinterpreting its definition of ''independent and distinct.'' In the 2005 ''Green Paper Concerning Restriction Practices,''[11] the PTO presented four options for the ''independent and distinct'' standard, the last of which was as follows:

> Under this option, the 35 U.S.C. § 121 standard would be reinterpreted to require that inventions subject to restriction be both ''independent and distinct'' (rather than ''independent or distinct'' per current practice).

Some life sciences attorneys complained that in its description of the options the PTO modified the definitions of ''independent'' and of ''distinct.'' But, regardless, the PTO rejected option 4, citing comments from reviewers that the proposal for implementing such a standard was too difficult and unpredictable to be practical.[12]

In its response to the PTO's request for comments on the Green Paper, the government affairs committee of the National Association of Patent Practitioners wrote,

> In contrast to the clear intent of the law, the PTO has, on its own initiative, erroneously interpreted the law to apply a standard in the alternative, viz, ''independent or distinct.'' The PTO has no authority to fail to adhere to that which Congress has enacted as law. Therefore, we urge the PTO to follow the law and apply the 'independent and distinct' standard for restriction, rather than risk the possibility of facing challenges in court.

The NAPP derided the PTO's ''summary dismissal'' of option 4 in the Green Paper and urged the PTO to reconsider it.

In a Sept. 14, 2005, letter responding to the Green Paper, Lila Feisee, director for intellectual property for the Biotechnology Industry Organization (BIO), also complained about the dismissal of option 4. She wrote,

> BIO finds the PTO's proposal for implementing this option unnecessarily complicated. Standards for both independence and distinctness already exist and standards for distinctness are already being applied by examiners. All that is necessary is additionally to apply standards for independence and to ensure that both requirements are met before an application is restricted.

Feisee concluded, ''Thus, many BIO members see merit in this proposal simply because it would result in fewer restriction requirements and consequently would help minimize the costs associated with fragmentary patent protection.''

Effect on Life Sciences. Sheppard Mullin's Canaan told BNA that the PTO presumes the terms ''independent'' and ''distinct'' mean the same thing and therefore are redundant. ''We disagree because you can have independent and non-distinct and independent and distinct inventions. For example, if you have two separate independent claims that have the same limitations, such as a diagnostic assay and a medical device that recite the same structural limitations, then the inventions will be independent but not distinct. By contrast, if you have a diagnostic assay with structural recitations and a diagnostic method directed to the use of the assay, then the inventions will be independent and distinct.''

Canaan continued, ''Under its current system, the PTO will classify the assay and medical device claims in two different search classifications and assert that the searches impose a serious burden on the examiner. In response, practitioners may argue that the limitations are the same and therefore there is no serious burden, but under current PTO practice, the fact that the two claims fall under different classifications is sufficient to warrant the serious burden.''

Canaan added that, under the current system, if the medical device theoretically can be used for screening as well as diagnostic purposes and the assay can be used only for diagnostic purposes, then the PTO can take the position that the medical device can be used in a materially different process, which further supports the restriction of the claims.''

Canaan concluded, ''Consequently, many life sciences patent applications, which typically include composition, method, assay, and device claims, are probably being restricted unnecessarily as a result of the PTO's use of the 'independent or distinct' standard.''

Don Pelto, a partner in the intellectual property and litigation department of Sheppard Mullin Richter & Hampton LLP, Washington, added, ''With respect to life sciences companies, the PTO's use of the term 'or' may result in restriction where restriction is not necessary or appropriate and indeed my position is that this is a real problem for life sciences companies—especially in the current economic environment where the U.S. government should be putting money into the pockets of life sciences companies to stimulate research and the economy, rather than taking it out.''

Hans Sauer, BIO's associate general counsel for intellectual property, told BNA that it has been BIO's view that PTO restrictions actually generate more work for

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on google.com that was in the Harvard library when Rich was an undergraduate there, *Reports of Cases in Equity, Argued and Determined in the Court of Appeals [of South Carolina], Nov. 1854 to May 1855, Vol. 17*, indicates that, while ''and'' was always considered ''conjunctive,'' ''or'' was not. On p. 316 in the case *Heyward v. Heyward*, there is the statement, ''The usual and natural expression of the word 'or' is disjunctive.'' More recently, Vrae Crabbe in a book titled *Legislative Drafting*, Cavendish Press, 1993, indicates that this classification still exists: ''The use of the words 'and' and 'or' has given rise to many different problems The difference in meaning lies in this: 'or' is disjunctive and 'and' is conjunctive. 'And' connotes togetherness, 'or' tells you, take your pick (pp. 34-5).''

[11] U. S. Patent and Trademark Office, ''Notice of Availability of and Request for Comments on Green Paper Concerning Restriction Practice,'' 70 Fed. Reg. 32761 (June 6, 2005) (request for comments).

[12] *See* http://www.uspto.gov/web/patents/greenpaper.pdf.

the agency, ''more and repetitive work, work that could be reduced if not eliminated if the claims were processed together.''

As for the motivation behind the PTO's definition of ''independent and distinct'' meaning ''independent or distinct,'' Sauer said that ''the motivation runs through the PTO's activity since 2006, including its promulgation of new rules that limit the number of claims and continuations [1 LSLR 526, 9/28/07 and 3 LSLR 268, 3/27/09]. The motivation is trying to save work.''

Sauer concurred with Love's comment that the PTO's reasoning underlying the restriction requirement that it would be an 'undue burden' on the examiner to search should be mitigated by more efficient search engines. ''Genomic inventions can now be searched extremely efficiently,'' Sauer said.

Change Might Not Solve Problem. As to the effect on PTO workloads and on backlogs if ''independent and distinct'' was defined by the PTO as ''independent and distinct,'' Sauer said that on the one hand, ''since the PTO has indicated that the increase of filings last year was largely attributable to continuation applications and that divisionals have not been a big part of that, the impact of the change might not be enormous.

''On the other hand,'' Sauer continued, ''there may be some self-interest on the PTO's part in downplaying the impact on the backlog of divisionals, so what the PTO has said here may be taken with a grain of salt.''

Janet McLeod, a partner with Crowell & Moring LLP, New York, told BNA that under the PTO's interpretation of ''independent and distinct,'' an ''undocumented example of an alternative process for making or using the product is sufficient to show that the inventions are distinct. Thus, a requirement for restriction between claims directed to a product and process of using the product may be supported by a simple allegation that, for example, 'the product as claimed can be used in a materially different process such as a detection assay.' ''

But McLeod cautioned that a change in interpreting the phrase ''independent and distinct'' might not benefit applicants for life sciences-related patents because the reworked interpretation still would be contingent on the PTO's definition of ''independent.''

As previously noted, in the 2005 Green Paper the PTO presented the possibility of differing definitions of ''independent.'' McLeod noted, ''The MPEP describes independent inventions as 'unconnected in design, operation, and effect.' However, the 2005 Green Paper states that an examiner could establish that inventions are independent by showing that the inventions do not share a common feature, or that there is a common feature but it does not 'define over the prior art and/or satisfy the enablement or written description requirements.' If there is a common feature and the elected invention is found to be patentable, the examiner would then search a nonelected invention that requires the common feature, or the common feature itself. This proposed methodology for examination would significantly increase the time and cost of prosecution.''

McLeod concluded, ''In addition, an applicant could not be certain whether a requirement for restriction would be maintained or withdrawn until completion of prosecution of the initially elected invention. An applicant who is unwilling to risk loss of patent term on important embodiments of an invention would thus need to file divisional applications well before a determination that the requirement would be maintained or withdrawn.''

However, Love concludes, the problem with restrictions continues. ''I've seen one patent application with 46 divisionals! Reconsideration of PTO's patent restriction policies could be beneficial to life sciences, if it is done the right way.''

In response to BNA's request for comments on the PTO's interpretation of ''independent and distinct'' and on the requests by patent and life sciences organizations that the PTO reconsider its interpretation of the phrase, a PTO spokesperson May 4 e-mailed BNA portions of Chapter 800 of the MPEP.

BY JOHN T. AQUINO

The 2005 FDA Green Paper on restrictions can be found at http://www.uspto.gov/web/patents/greenpaper.pdf.

The NAPP and BIO comments on the Green Paper can be found at http://www.uspto.gov/web/offices/pac/dapp/opla/comments/restriction/napp.pdf and http://www.uspto.gov/web/offices/pac/dapp/opla/comments/restriction/bio.pdf, respectively.

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