



The members of Venable's Technology Division are pleased to present this edition of **IP News & Comment**, covering topics generating the greatest interest in the areas of patents, trademarks, copyrights, and IP litigation. We welcome your comments and look forward to being of service.

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In re Nijten – Supreme Court Bound?

By Joan Ellis, Ph.D., J.D., Partner, Venable LLP

On September 20, 2007, the Court of Appeals for the Federal Circuit (CAFC) rendered two separate decisions concerning what constitutes patentable statutory subject matter under 35 U.S.C. § 101. See, *In re Comisky* (Slip Op. 2006-1286) and *In re Nijten* (Slip Op. 2006-1371). The Court's decision in *Comisky* came about in an unusual manner. In the appeal as originally presented to the Federal Circuit, the United States Patent and Trademark Office (USPTO) had rejected the claims as being unpatentable under 35 U.S.C. § 103. The court *sua sponte* requested additional briefing on the patentability of the claimed subject matter under 35 U.S.C. § 101. This approach appears to have been taken so that the court could use *Comisky* to clarify its position in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998) as to the requirements for patentability of a business method. *Nijten*, on the other hand, presented a case of first impression. The issue in this case was whether the invention fell under one of the four categories of patentable subject matter elucidated in §101.

In *Nijten*, the invention was directed to a signal which is used as a watermark on sound and video recordings to prevent unauthorized copying. Watermarks previously used in the industry introduced some level of sound distortion. *Nijten*'s invention was an improved process of modifying the watermark in a manner which minimized the distortion of the original sound wave and; thus, maintained the fidelity of the sound.

The USPTO had granted *Nijten*'s claims directed to a process of embedding supplemental data in the signal, an encoder means for recording the signal and a storage medium holding the signal, but rejected the claims directed to the signal itself.

Claim 14, the only independent claim on appeal, read as follows:

A signal with embedded supplemental data, the signal being encoded in accordance with a given encoding process and selected samples of the signal representing the supplemental data, and at least one of the samples preceding the selected samples is different from the sample corresponding to the given encoding process.

The question before the court was “What is the claimed signal?” Is it simply numerical information without any physical embodiment, as argued by the USPTO, or something having sufficient physical substance to be recognized by a recipient as argued by the appellant? In construing the claim, the majority partially agreed with the appellant that a signal is the conveyance of information, but found in order to do so it required a physical medium such as wires, air or a vacuum. Here, the majority determined that the claims included “physical but transitory forms of signal transmission such as radio broadcasts, electrical signals through a wire, and light pulses through a fiber optic cable.” After careful analysis of the invention under the four different categories of patentable subject matter set forth in 35 U.S.C. § 101¹ (process, machine, manufacture or composition of matter), the majority found that the claimed signal did not fall within any of them.

The most troublesome category of statutory subject matter for the majority (also the point of contention with the dissent) was whether the signal constituted a “manufacture.” The majority acknowledged that the signal was man-made; however, this was not found to be sufficient. According to the majority, the signal did not conform with the Supreme Court’s definition of “manufacture” as a verb meaning “the production of articles for use from raw or prepared material by giving to these materials new forms, qualities, properties, or combinations, whether by hand labor or by machinery.” *Diamond v. Chakrabarty*, 447 US 303, 308 (1980). Nor did they find that it corresponded with the definition of “manufacture” in its noun form, i.e., as articles produced by means of manufacture. *Bayer AG v. Housey Pharms., Inc.*, 340 F.3d 1367, 1373, (Fed. Cir. 2003).

Accordingly, the majority held that because the claimed signal is fleeting by nature and not permanent, it was not directed to statutory subject matter.”

In a strongly worded dissent, Judge Linn argued that the panel must reconcile cutting edge technology with a statute whose language dates back to approximately 1790. In the dissent’s view, this case was being decided against a backdrop of ongoing controversy regarding the wisdom of software patenting and that the court should be mindful of its duty to interpret the law as Congress wrote it rather than attempt to “preempt congressional action by judicially decreeing what accords with ‘common sense and the public weal.’” Slip op. dissent at 1. The dissent further opined that the signal was both new and useful and not an abstract idea. Therefore, he agreed with the majority that the Supreme Court’s decision in *Diamond v. Chakrabarty*, 447 U.S. 303, 309, is controlling. The dissent concluded that the claimed signal qualifies as patentable subject matter because it (1) is a “manufacture” produced from raw materials and given a new form; (2) is “made by man”; and (3) does not encompass any of the unpatentable exceptions enumerated by the Supreme Court, i.e., “laws of nature, physical phenomena and abstract ideas.”

It is highly likely that *Nuitjen* will request an *en banc* hearing at the Federal Circuit. If denied, this case is perfectly postured to be granted *certiorari* by the Supreme Court. Recently, the Supreme Court has not been looking kindly on some of the bright line rules the Federal Circuit has been imposing. This was the case with *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007), where the Federal Circuit’s reliance on a rigid “teaching, motivation, suggestion” test to determine obviousness was curtailed by the Court. The Federal Circuit’s bright line rule – that a licensee could not establish an Article III case or controversy concerning a patent’s validity and, thus, could not get a declaratory judgment as long as they were paying licensing fees – was reversed in *MedImmune Inc. v. Genentech, Inc.* 127 S. Ct. 764 (2007), (holding that a licensee could be in eminent threat of litigation and need not terminate its licensing agreement before seeking a declaratory judgment that the patent was invalid). Finally, in *eBay Inc. v. MercExchange L.L.C.* 126 S. Ct. 1837 (2007), the Federal Circuit’s long-standing rule that permanent injunctions will be issued in patent infringement cases absent exceptional circumstances was reversed. The Supreme Court held that permanent injunctions “may” be acceptable provided the plaintiff [patentee] satisfies a four factor test.

¹ 35 U.S.C. § 101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

It will be interesting to watch how the *Nuitjen* case progresses. Will the Supreme Court object to the Federal Circuit's application of a rigid rule that transitory embodiments are not patentable regardless of their informational content and ability to be perceived? Will the Court agree that transitory signals are not patentable subject matter *per se*?

USPTO Proposes Changes in Rules for Presentation and Examination of Markush Claims

By Keith Haddaway, Ph.D., J.D., Partner, Venable LLP

BACKGROUND

On August 10, 2007, the United States Patent and Trademark Office (USPTO) published a Notice of Proposed Rulemaking (NOPR) in the Federal Register setting forth changes in patent practice for "claims containing alternative language." In particular, the proposed rules are directed toward changes in the presentation and examination of Markush claims, which are traditionally common in chemical practice, but can now be found in other technologies as well. Written comments on the proposed rules are being accepted until October 9, 2007.

The stated purpose of the proposed rule changes is to "limit each claim to a single invention and to define acceptable formats for claims that set forth alternatives" in order to "enable the Office to do a better, more thorough and reliable examination of such claims." The USPTO alleges that the search and examination of Markush claims, and other claims that recite alternatives (collectively referred to here as "Markush claims") can require individual patentability considerations for each of the alternative species within a single claim, resulting in the use of a disproportionate amount of resources.

These rules are related to its recently issued final claim rules. (See Venable IP alert, September 2007; <http://www.venable.com/docs/pubs/1767.pdf>) The proposed Markush rules discussed here were published before the claim rules issued on August 21, 2007.) The NOPR notes that the claim rules did not explain how the USPTO will handle Markush claims and issued this rulemaking to fill that gap. In general, the proposed rules set forth requirements resulting in a limitation on the scope of species that can be recited in a Markush claim, "encourage" applicants to explain why a Markush claim relates to a single invention, and permit the office to restrict species recited in a single claim.

Current Office practice allows presentation of a Markush claim if there is unity of invention. Unity exists among multiple chemical compounds where the compounds (1) share a common utility and (2) share a substantial structural feature essential to that utility. Unity exist for alternative process steps where (1) all members of the group possess a property in common that is mainly responsible for their function and (2) it is clear from the prior art that all of the group members possess the property. All species encompassed in a Markush claim are examined when the alternatives are sufficiently few in number or so closely related that examination can be made without serious burden. However, the Office alleges that it "cannot" refuse to examine all species in a claim that has unity of invention. Current office policy requires that, when presented with a Markush claim, examiners may require election of species for initial examination. However, if the elected species is determined to be allowable, the non-elected species must subsequently be examined, even if a separate search and examination is required for each species. The new rules provide procedures for examining claims lacking unity of invention and for restricting an application to one invention where the office determines that "multiple independent and distinct inventions are recited as alternatives in a single claim." Among other things, the proposed rules are intended to avoid applicants circumventing the new claim rules by using Markush claim language instead of multiple claims.

RULES DISCUSSION

The NOPR implies that the proposed rules will not affect the ability of an applicant to present and have issued generic claims. The rules do not suggest issuing a restriction in a generic claim, but do permit a requirement for an election of species for initial examination. However, if any part of a claim uses Markush language, the new rules kick in and restriction may be required. In such circumstances, the office will determine whether the members of the Markush group recite a single invention, although that task may be relatively complex.

The proposed rules specify that any claim, including a Markush claim, must be limited to a single invention (§ 1.75(a)). This condition is met when either (1) all of the species encompassed by the claim share “a substantial feature essential for a common utility” or (2) all of the species “are *prima facie* obvious over each other.” (§ 1.140(a)) A common feature could include a structural feature, material or act necessary for a shared specific substantial and credible utility. The rules encourage applicants filing a Markush claim to submit an explanation as to why the claim is directed to a single species. Such an explanation could identify the common feature shared by the species that is responsible for a substantial utility or explain why the group members are *prima facie* obvious over each other. The rules do not require an applicant to submit a statement, but provide that the office “shall” consider such a statement if filed at the time the claim is presented and “may” consider such a statement if offered after the claim is presented. (§ 1.140(b)) The proposed rules specifically state that a restriction may be made even if the plural inventions are recited as alternatives within a single claim. (§ 1.142(b)) Where a single claim is directed to allegedly different inventions, the claim will not be allowed until the non-elected subject matter is cancelled or it will be objected to as failing to comply with § 1.75(a). (§ 1.142(d)) The rules further describe processes for traversing, requesting reconsideration of and petitioning for removal of a restriction requirement.

The rules propose adding a unity of invention requirement similar to that used in International applications during examination of US applications. Specifically, the rules allow alternative language where “each alternative within a list of alternatives must be substitutable for one another” (§ 1.75(j)(4)) and “the number and presentation of alternatives in the claim does not make the claim difficult to construe.” (§ 1.75(j)(1))

As an additional means of simplifying examination of Markush claims, the proposed rules prohibit the presentation of a claim containing alternatives that are defined by another set of alternatives, unless there is no other practical way to claim the invention. This rule is intended to prevent difficulties in examination where overlapping alternatives makes it difficult to determine whether a claim encompasses more than one invention. Specifically, the rules set forth that:

- No alternative is defined as a set of further alternatives within the claim (§ 1.75(j)(2)) and
- No alternative is encompassed by any other alternative with a list of alternatives (§ 1.75(j)(3)).

For example, a claim may not include, as alternatives, “an adhesive agent, glue or tape” or “citrus fruit or tropical fruit.” In the first case, the second two members are completely encompassed by the first member; in the second case, there is only partial overlap. Instead of such claims, the office suggests presenting separately claims having broad scope (e.g., an adhesive agent or fruit) and claims of more narrow scope (e.g., glue or tape or citrus fruits or tropical fruits).

In one of the more oppressive aspects of the rules, the office is proposing a requirement in applications that claim priority to a prior application, but disclose subject matter that was not disclosed in the prior filed application. In such a case, the applicant **must** identify which claims are adequately supported under 35 U.S.C. § 112 by the earlier application. (§ 1.75(d)(2)) The USPTO asserts that this rules is imposed to simplify examination in cases where a prior art reference anticipates or renders obvious one species in a claim where the reference would not be available against another species within that claim if that species were presented in a separate claim. However, the burden on applicants and ramifications of such a statement are potentially devastating.

The manner in which the proposed rules will be applied is unclear in some circumstances and will result in difficulties with claim strategy.. This is particularly true in the chemical arts. For example, consider a base structure with two variable “R” groups. Is the base structure sufficient to impart a “substantial feature essential for a common utility?” In all likelihood, this determination may be dependent upon the circumstances of a particular application.

Thus, without clear guidance, application of this rule is potentially variable and could be the cause of considerable contention. Will the presence of two R groups within the compound be considered “alternative(s) encompassed by other alternatives(s)” or otherwise run afoul of Rule 1.75(j)?

PRACTICE TIPS

- 1) When considered in conjunction with the August 21, 2007 claim rules, the proposed rules will require very careful claim drafting and consideration of strategy. Applicants should use special care in drafting Markush claims to avoid alternatives of alternatives. If the USPTO requires that some alternatives be placed in a second claim, an applicant could find themselves pushed close to the 25 claim limit.
- 2) Applicants should be prepared to file multiple divisional applications when an examiner objects to particular Markush groups, and may take the proactive step of filing a suggested restriction requirement. The advantage of a suggested restriction requirement is that (a) the applicant gets greater input into how the application will be divided; (b) applicants can encourage examiners to issue restriction requirements when it is advantageous to prosecute multiple claim sets, and c) a restriction will allow parallel prosecution of divisional applications with an increased number of possible continuations whereas the absence of a restriction will require serial prosecution with a smaller total number of allowable continuations.
- 3) Initial presentation of claims should include multiple claims with variable scope that may be subject to restriction, even if a suggested restriction requirement is not filed. If the claims are restricted in a reasonable way, divisional applications can be filed and the broad claims expanded to the allowed 25 claims. Unreasonable restriction requirements can be traversed and, if necessary, petitions can be filed. If a restriction is not issued, it may be necessary to carefully consider strategies that include the filing of continuation applications.
- 4) To avoid restriction, use means plus function or step plus function claims under 35 U.S.C. § 112, ¶ 6. The NOPR states that a claim reciting “means for attaching” is a single invention treated as a generic claim and not treated as reciting multiple species. A dependent claim can present a list of particular species. On the other hand, a claim reciting “an attachment means selected from the group consisting of staples, glue and tape” would be considered as reciting alternatives and potentially subject to possible restriction.
- 5) Use generic claims that do not recite alternative language whenever possible. Alternatives can be presented in dependent Markush claims, but the generic claim will reduce the possibility of restriction.
- 5) Do not argue that members of a Markush group are patentably indistinct, substitutable or *prima facie* obvious over one another unless required to do so. Although the rules do not require consideration of such assertions after a claim is presented, it is hard to imagine that such arguments would not be considered if they would advance prosecution. Furthermore, it would be advantageous to wait for the examiner to allege reasons for objecting to the claim and rebut as appropriate. Making these representations prematurely is too likely to lead to estoppels. For example, arguing that species are *prima facie* obvious over one another, patentable indistinct or substitutable can lead to problems should a search during examination uncover art that renders a single species obvious or anticipated. If the wrong statements are made, all species could potentially fall.

Summary of Recent Changes to the TTAB Rules

By Ellen W. Woodward, Staff Attorney, Venable LLP

On August 1, 2007, the Trademark Trial and Appeal Board (TTAB) changed several procedural rules for trademark opposition and cancellation proceedings. The changes to the rules are meant to facilitate communication between parties, increase the efficiency of discovery and the exchange of pretrial information, prevent unfair surprise, and lead to earlier settlement of matters. For practitioners, the drawback is that several new steps have been added to the process, which adds more dates to the docket and may lengthen the time a proceeding takes. Also, the new rules may raise costs for cases that do not settle early, especially costs in the discovery stages of the proceedings.

While some of the changes went into effect on August 31, most are effective as of November 1. The significant changes that are already in place are: (1) The TTAB's Standard Protective Order has been made applicable in all pending cases (except those with a different protective order already in place), which can only be modified by stipulation and motion or motion; (2) a pleaded registration may now be placed in evidence by submitting copies of the USPTO electronic database records, without the need for furnishing a certified copy; and (3) the option to file a submission in CD-ROM form has been deleted. Also effective August 31, the TTAB amended a rule to clarify that a table of contents, index of cases, description of record, statement of the issues, recitation of facts, argument and summary all count against the 25 page limit for a brief in support of a motion or in response to a motion and the limit of 10 pages for a reply brief. The TTAB also clarified the rule stating that any stipulation of parties to exceed the interrogatory limit requires approval of the Board; however, the interrogatory limit of 75 remains unchanged.

Several important changes will go into effect November 1 (and will apply to cases commenced on or after November 1):

- Service of the Complaint: The plaintiff will need to serve a copy of the initial pleading on the defendant at the time of filing, rather than file multiple copies of the complaint with the TTAB for distribution. The plaintiff will have to submit a certificate of service to the TTAB before it will grant a filing date. Whether a plaintiff should serve the trademark owner directly, or an attorney or other representative, depends on the correspondence address of record. The plaintiff is responsible for checking the Trademark Applications and Registrations Retrieval (TARR) system to obtain the correspondence address. If any service copy of the initial pleading is returned as undeliverable, the plaintiff must notify the TTAB within 10 days of receipt of the returned copy.
- Discovery Conference: The parties to an *inter partes* proceeding will be obligated to participate in an early discovery conference (occurring after the answer has been filed), one purpose of which is to discuss settlement. The parties can have an Interlocutory Attorney from the Board participate, if desired, which must be requested 10 days before the deadline to have the conference. Discovery will not begin until after this conference or concurrently with the conference. Also, the TTAB likely will not suspend cases for settlement discussions after the answer is filed unless the parties have held this discovery conference.
- Initial Disclosures: The parties must exchange initial disclosures similar to those required in Federal Court before they can serve written discovery or file a motion for summary judgment. These initial disclosures must identify witnesses who have discoverable information that the party may use and identify or produce documents that the parties may use to support its claims and defenses. The parties also can agree to make more extensive disclosures than those required by the rule.
- Expert Disclosures: Parties must now serve expert disclosures in accordance with Federal Rule of Civil Procedure 26(a)(2) upon the opposing party and also file the disclosure with the TTAB. Rebuttal expert disclosures are due 30 days after the adverse party's prior disclosure. These expert disclosures are only required for testifying experts. After disclosure, the TTAB may suspend proceedings to allow for related discovery.
- Pre-Trial Disclosures: Parties must now serve pre-trial disclosures 15 days prior to the opening of testimony or rebuttal periods. Disclosure must include witness list, testimony topics and witness exhibit categories, but do not require disclosure of each document or other exhibit to be used at trial. However, materials submitted in a notice of reliance do not need to be disclosed.

Driving Innovation: Intellectual Property as the Invisible Infrastructure of Innovation

By Michael Gollin, Partner, Venable LLP

This passage is excerpted from the Introduction to Venable LLP's Partner Michael Gollin's upcoming book *Driving Innovation: Intellectual Property Strategies for a Dynamic World* (*Cambridge University Press 2008*), available at <http://www.cambridge.org/us/catalogue/catalogue.asp?isbn=9780521877800>. The foreword and preface to *Driving Innovation* were included in the August edition of *Venable's IP News and Comment*. An overview of the themes and content of the book will be printed in the next edition.

* * *

Intellectual property (IP) is the invisible infrastructure of innovation. Intellectual property rights are a source of hidden wealth worth trillions of dollars, and they impose hidden costs on the same scale. The rules of intellectual property range from confusing to nearly incomprehensible, and they are in constant flux.

Intellectual property surrounds us. Right now, you may be sitting in your office, reading this newsletter as an image on your computer screen, accessed through the Internet, or you may be holding a printout. Intellectual property helped give you these options. For example, the computer embodies decades of continuous innovation. Invisible and hidden within the computer are countless intellectual property rights that serve as the infrastructure of that innovation. The monitor, the hard drive, the keyboard, the printer, and the cabling each are the subject of numerous patents on electronic circuits, materials, and mechanical structures. The software programs used to write this book, edit it, and print it, and make it readable on a computer screen, embody layers of copyrights as well as trade secrets. Different vendors have branded the computer and its components with trademarks (e.g., DELL, INTEL, and SEAGATE). The hardware may be built in Korea, and the software may have been written in India.

Once you start to pay attention, you see that the same invisible infrastructure exists in the clothes you wear, the medicine you take, the books and entertainment you enjoy, your car, your home, the food you eat, and the energy you consume. The blood coursing through your veins may include various patented medicines and nutrients from your last meal – perhaps a breakfast of branded products sold internationally, like CHEERIOS® cereal, DUNKIN'® donuts, and STARBUCKS® coffee. Your clothes, too, bear trademarks – perhaps ARMANI®, if you are wealthy, or a less expensive brand sold at WALMART® – and could have been made by complex computer-driven textile equipment having patented machinery and copyright protected software, or by poor laborers in developing countries using designs created in Europe or the United States.

How did intellectual property – in the modern form of patents, copyrights, trade secrets, and trademarks – arise? How did these rights flow together into the computer on your desk, and into, on, and around your own body? What role does intellectual property play in driving engineers, scientists, and creative talent to generate such remarkable innovations? How does intellectual property serve as a social force that drives and nurtures creativity, or blocks its benefits, in so many spheres?

Intellectual property remains a “black art,” understood by few while influencing many. To shed light on that dark topic, this book provides a dynamic view of intellectual property – how it arises, grows, and flows, how it shapes global society, and how society shapes it over time. This book is directed to people who want to learn how intellectual property shapes our world, to understand the controversies over intellectual property, and more importantly to use their knowledge to help them meet their own goals.

All of us – creative individuals, inventors, authors, business people, and curious people everywhere, in corporations, academia, nongovernmental organizations, and government agencies, in rich and poor countries – can learn the fundamental concepts, dynamics, and strategies of intellectual property. We can apply this understanding to find new meaning in our surroundings, and new strategies that will best help us achieve our goals.

Globalization, innovation, and good leadership are universally recognized as driving forces in society, given the accelerating pace of technological change; the rise of a “knowledge economy;” the tightening interdependence of markets, technology, and culture; and the growing disparity between global haves and have-nots. It should be self-evident that intellectual property is a key to understanding the dynamics of global innovation, but it has not received the comprehensive attention it deserves. Instead, most books about intellectual property are written narrowly for a specialized audience.

The lack of broad attention to intellectual property’s central role in innovation may derive from the extreme legal, economic, and technical complexity of the topic, and a lack of education about its fundamental concepts. A shared global conceptual framework would help innovators, authors, readers, and ultimately society. Business people, management experts, and lawyers could avoid costly mistakes. Economists, academics, policy makers, and lobbyists could reconsider unhelpful simplistic polarized positions opposed to or in favor of the present system, and instead present more practical suggestions. If these people could gain an understanding of the duality of intellectual property and its role in driving the innovation cycle, society would benefit, and so would they.

This book begins to fill that gap by providing a brief but comprehensive account of the fundamental IP concepts and dynamics that apply broadly to all communities throughout the world – including industry, nonprofit institutions, and developing countries. Surprisingly, despite the excruciating complexity of the field, people can quickly learn the basic tools they need to understand what intellectual property is, why it is important in their lives, and how they can use this knowledge to further their own pursuits, or just to become better informed citizens.

The audience for this book includes anyone interested in innovation, and how intellectual property encourages, channels (or stifles), and puts innovation to work. That includes innovators and people who work with innovation – lawyers, business people, academics, and policy makers, in rich and poor countries, whether or not they have any experience with intellectual property, and regardless of their nationality and profession. It includes practitioners concerned with entrepreneurship, scientific research, technical and cultural innovation, and other creative endeavors around the world, as well as academics and policy analysts concerned with innovation and globalization. It also includes business students and business people in all industries (publishing, biotechnology, computer science, manufacturing, finance, entertainment, and service industries), and a broader range of academics, government officials, intellectual property and business lawyers, law students, nonprofit entrepreneurs, history buffs, and more.

Venable and the Archon X PRIZE for Genomics

By Michael Gollin, Partner, Venable LLP

Some of the most interesting work in technology law occurs at the interface between private and public innovation. One of Venable’s recent clients, the X PRIZE Foundation, is a nonprofit prize institute whose mission is to create radical breakthroughs for the benefit of humanity. The X PRIZE Foundation (www.xprize.org) awarded the \$10 million Ansari X PRIZE in 2004 for the world’s first private space vehicle to fly into space twice in two weeks. Now, the Foundation is offering new prizes to stimulate breakthroughs in the life sciences, space exploration, energy, the environment, education and global entrepreneurship. The \$10 million Archon X PRIZE for Genomics, announced in 2006, will reward the first private team to sequence 100 human genomes accurately in 10 days for under \$10,000 each. When this technical threshold is crossed, it will signify a new era of personalized preventative medicine. Teams from VisiGen Biotechnologies, Inc., 454 Life Sciences, the Foundation for Applied Molecular Evolution and Reveo, Inc. have registered to compete in the quest to develop a revolutionary sequencing tool for the benefit of global health. Venable attorneys Michael Gollin and Melissa Steinman are counseling the Foundation on intellectual property and related legal issues involved in this unique new contest model.

The London Agreement – Possible Cost Reductions for European Patents

By Keith G. Haddaway, Ph.D., Partner, Venable LLP
(*And the professionals of Venable's Foreign Filing Department*)

On September 26, 2007, the London Agreement was adopted by France's National Assembly. The French Senate is set to vote on the agreement this month. If ratified, the cost of perfecting patent protection in at least some European countries could be greatly reduced.

European Patent Applications must be filed or translated into one of the official languages (English, German or French) and patent prosecution proceeds in that official language. Upon allowance (or grant), the claims must be translated into the other two languages. After grant, the application must be validated in individual member states (countries). Under current procedures, the entire application, including the claims, must usually be translated into the language(s) of the country(ies) where the patent is validated. According to the European Patent Office (EPO), translation requirements can increase the costs of obtaining a European patent by about 40% or more.

Under the London Agreement, translation costs may be significantly reduced. The agreement will still require translation of the claims into the three official languages upon grant. However, in countries that ratify the London Agreement, validation will no longer require translating the entire application into the native language. Instead, each ratifying country will select one of the three official languages and the patent will issue in that language. The agreement allows a country to require translating the claims into the native language.

In countries that ratify the London Agreement, costs for patent holders will be reduced by:

- Eliminating translation expenses
- Eliminating publication fees
- Reducing attorney fees

To date, Germany, United Kingdom, the Netherlands, Switzerland, Iceland, Latvia, Liechtenstein, Monaco and Slovenia have ratified the London Agreement. Sweden and Denmark are also expected to ratify the changes soon. Although the requisite number of countries have ratified the agreement, the final approval of France, as one of the key states for its entry, is still required for implementation.

Validation of a European patent in countries that have not ratified the agreement (for example Italy, Spain, Portugal, Greece, Turkey and others) may still require translation of the entire patent. Thus, although adoption of the London Agreement will result in savings, significant translation costs are still possible. Hopefully, these countries will ratify the agreement as well.

Because implementation of the London Agreement is imminent, it may be advisable in some cases to delay patent grant and avoid significant translation costs. This can be done, for example, by delaying filing responses to examination reports until near the deadline. If allowance is likely, it may also be beneficial to delay into the further processing period allowed under European procedures. For applicants that have already received a notice of grant, it may be advisable to delay payment of fees and filing of translations as long as possible, and possibly use the further processing procedure for further delay. With a little luck, the agreement will go into effect before expensive translations are required.

New U.S. Patent & Trademark Office Rules for Claims and Continuation Practice Including New Disclosure Rules

(Recently Published As Venable IP Alert)

By Catherine M. Voorhees

Patent applicants need to take a close look at the new final rule published August 21, 2007 by the U.S. Patent & Trademark Office (“PTO”). The PTO revised the rules of practice in patent cases relating to continuing applications and requests for continued examination, and for the examination of claims in patent applications.^{2*} This article summarizes the new rules and provides some practice tips and strategy recommendations.

While the new rules are effective as of November 1, 2007, the continuation rules apply to all applications that are pending as of that date and filed on or after that date. The rules for the number of claims and the examination of claims apply to all applications that are pending in which a first office action on the merits (office action rejecting claims, as opposed to a restriction requirement) has not been mailed, as well as all applications filed on or after November 1, 2007. Applicants should consider whether certain actions should be taken prior to November 1, 2007 and they will need to comply with the new disclosure rules by February 1, 2008.

New Continuation Rules:

- Two continuation and/or continuation-in-part (CIP) applications and one request for continued examination (RCE) may be filed in an application family³ without any justification.
- “One more” continuing application without a petition and showing may be filed for applications filed on or before August 21, 2007 (the publication date of the final rule).⁴ No more than one RCE may be filed in a family after November 1, 2007.
- A divisional application (a separate invention identified by a Restriction Requirement) also may have two continuation and/or CIP applications and one RCE (the divisional application family) without any justification.
- If a third continuation and/or CIP application is desired, a petition must accompany the subsequent continuing application that shows why the amendment, argument, or evidence sought to be entered could not have been previously submitted.⁵
- If a second RCE is desired, a petition must be filed that shows why the information sought to be entered could not have been previously submitted.⁶ At this point, it appears that the success of a petition would be in the discretion of the Examiner.

New Claims Practice:

- Applicants may present, without an Examination Support Document (ESD), up to:
 - 5 independent claims and
 - 25 total claims in an application⁷

² Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims and Examination of Claims in Patent Applications; Final Rule (72 Fed. Reg. 46716-46843, August 21, 2007).

³ 37 CFR 1.78 (d)(1)(i)(A) and 37 CFR 1.114(f).

⁴ 37 CFR 1.78(d)(1)(iv) and (v).

⁵ 37 CFR 1.78 (d)(1)(vi).

⁶ 37 CFR 1.114 (g).

- (5/25 claim rule).
- If an application has a claim deemed patentably indistinct (i.e., no restriction requirement) over a claim in a commonly owned application, then **all** the claims of the other commonly owned application(s) will be counted in order to meet the 5/25 rule.⁸ That is, “patentably indistinct” applications will be treated as a single application family.
- If the Applicant files an ESD before the First Action on the Merits (FAOM), he may present more than the threshold of 5 independent claims and 25 total claims.
 - The ESD must cover each claim (both independent and dependent) and provide a pre-examination search, a listing of the reference or reference deemed most closely related to each of the claims, an identification of all of the claim limitations that are disclosed by that reference or references, a detailed explanation pointing out how each claim is patentable over the reference(s) and a showing where each limitation of the claims finds support in the written description.⁹
- If an application was filed before November 1, 2007 and a FAOM was mailed, the application is not subject to the 5/25 claim rule.
- For applications in which a FAOM was not mailed before November 1, 2007, the PTO will issue a Notice that will set a two-month time period that is extendable up to six months.
 - In order to avoid abandonment, Applicant must file a Suggested Restriction Requirement (if no Restriction Requirement is in the Notice), an ESD or amend the application to contain no more than 5/25 claims.
- Claims withdrawn from consideration and claims being prosecuted in a divisional application are not taken into account in determining the number of claims in an application unless the claims are reinstated or rejoined.¹⁰

New Disclosure Rules for Commonly-Owned Applications

- In each non-provisional application that has not been allowed, applicants must identify other commonly-owned application(s) and/or patent(s) that have:
 - At least one inventor in common with the application;
 - A claimed filing or priority date of the application within two months of the claimed filing or priority date of the application; and
 - The same owner or an obligation to assign to the same owner.¹¹
- The identification must be submitted within the later of:
 - Four months from the actual filing date of the non-provisional application;
 - Four months from the date on which the national stage commenced;
 - For applications filed with claims deemed the “same invention” or not “patentably indistinct”, the date on which a claim is presented that is not patentably indistinct from at least one of the claims in the one or more other or patented non-provisional applications

⁷ 37 CFR 1.75(b)(1).

⁸ 37 CFR 1.75(b)(4).

⁹ 37 CFR 1.256.

¹⁰ 37 CFR 1.75(b)(5).

¹¹ 37 CFR 1.78(f)(1).

- If the PTO determines that the claim, while of a different scope, is directed to the same subject matter or invention as another pending application, the claim is patentably indistinct or part of the same application family.
- Applicants are entitled, as a matter of right, to two continuation applications and one RCE per application family. Thus, a total of 15 independent claims and 75 total claims per invention is permitted without justification for each divisional application family and one continuation family of an application.
 - Two months from the mailing date of the initial filing receipt in such other non-provisional application¹²; and
 - By the Compliance Date of February 1, 2008, if the application was filed before November 1, 2007.
- A rebuttable presumption shall exist that a non-provisional application contains at least one claim that is not patentably distinct from at least one claim of another pending or patented non-provisional application (that is, that they are in the same family for purposes of counting the number of continuation applications) if the following conditions are met:
 - The non-provisional has the same filing date as that of another pending or patented non-provisional application;
 - The non-provisional application has at least one invention named in common with the other pending or patented application;
 - The non-provisional application is owned by the same person or entity, or, an obligation to assign the application to the same person or entity exists; and
 - The non-provisional application and the other pending or patented application contain substantial overlapping disclosure (written description support for at least one claim).¹³
- If the rebuttable presumption exists, the applicant must do one of the following:
 - A) Rebut the presumption by explaining how the application contains only patentably distinct claims; or
 - B) Submit a Terminal Disclaimer, if the other application is pending, applicant must also explain why there are two or more pending applications which contain patentably indistinct claims.¹⁴
 - While applicants are not required to submit a rebuttal, if the PTO deems the claims of two application patentably indistinct, the PTO will require a Terminal Disclaimer to overcome any obviousness-type double patenting rejection.
- If the rebuttable presumption exists and the application has not been allowed, applicant must submit a rebuttal or a terminal disclaimer (with an explanation, if required) within the later of:
 - Four months from the actual filing date of the non-provisional application;
 - Four months from the date on which the national stage commenced;
 - For applications filed with claims deemed the “same invention” or not “patentably indistinct”, the date on which a claim is presented that is not patentably indistinct from at least one of the claims in the one or more other or patented non-provisional applications;
 - Two months from the mailing date of the initial filing receipt in such other non-provisional application¹⁵; and
 - By the Compliance Date of February 1, 2008, if the application was filed before November 1, 2007.
 - Consequences for failing to rebut the presumption:

¹² 37 CFR 1.78(f)(2)(iii).

¹³ 37 CFR 1.78(f)(2)(i).

¹⁴ 37 CFR 1.78(f)(2)(ii)

¹⁵ 37 CFR 1.78(f)(2)(iii)

- Together, the commonly-owned indistinct applications cannot have more than 5 independent or 25 total claims;
- The PTO will require a terminal disclaimer; and
- The PTO will require an explanation was to why there are two or more pending applications containing patentably indistinct claims.

Practice Tips and Strategic Recommendations

With these changes, the PTO intends to encourage all applicants to place more emphasis on properly preparing and prosecuting patent applications. The PTO is trying to avoid having the Examiners spend time going back and forth with the Applicants to obtain patentable claims.

1. In order to meet the February 1, 2008 compliance deadline for identification of commonly-owned applications and the rebuttable presumption that applications are in the same family, patent applicants should review their portfolios so that the necessary information is timely provided to the PTO.
2. Assignees should consider using one law firm for applications with at least one common inventor so that the law firm can handle the new family-based requirements. If not, clients should inform the law firm prosecuting each application whether any commonly-owned applications with at least one common inventor was filed within two months of the filing date.
3. While it is still possible to file a continuation application before the November 1, 2007 effective date of this rule, the patent application family would not be entitled to additional continuations (on or after November 1, 2007) if two or more were already filed, without the required justification. In addition, the application(s) may not have time to receive a FAOM and thus be “grandfathered” in, thereby avoiding the limitation on the number of claims for continuation applications. Thus, applicants should carefully consider the implications of filing a continuation application before doing so.
4. Prior to November, 1, 2007, patent applicants should consider making an election via telephone in response to a restriction request from the Examiner, instead of requesting a written Restriction Requirement, to move prosecution along so that a FAOM might be received before November 1, 2007. If a FAOM is obtained prior to November 1, 2007, the patent application would not be subject to the 5/25 claim rule.
5. Prior to October 1, 2007, patent applicants may wish to consider amending pending applications without a FAOM to meet the 5/25 claim limit and requesting a refund for excess claim fees. The statutory provision authorizing the PTO to refund excess claim fees expires on September 30, 2007, and as of today, it is unclear if the provision will be extended. A refund may be requested for excess claim fees paid on or after December 8, 2004. Otherwise, patent applicants may wish to wait for the PTO Notice that the 5/25 claim limit has been exceeded.
6. New applications should be drafted with multiple claim sets directed to different statutory classes of inventions, possibly with a Suggested Restriction Requirement, so that a restriction requirement is issued, thereby allowing divisional applications families to be filed off the original patent application. Each divisional application family is entitled to two continuations and one RCE without justification.
7. If a pending application family contains an RCE filed prior to November 1, 2007 and the application is under Final Rejection, it is advisable to consider filing another RCE prior to November 1, 2007 to get claim amendments entered without a petition or a showing. After November 1, 2007, in such cases, patent applicants cannot simply file another RCE to enter an Amendment After Final Rejection. Instead, a request must be made with a sufficient showing as to why the amendments were not presented earlier. The PTO has indicated in the Frequently Asked Questions** (see E4 to E8) that there is no automatic grant of an additional RCE.

8. In appropriate situations, patent applicants may consider deleting the benefit under 35 U.S.C. § 120 of an application filed as a continuation or continuation-in-part of an initial application to break the continuation chain and create an additional family of invention. By dividing the application family into two application families, two continuations and one RCE can be obtained for each family. This strategy may be used when intervening prior art (having a date after the filing date of the initial application) and the initial application specification (e.g., the publication of the initial application) may not be problematic.

9. Patent applicants should seriously consider requesting an Examiner Interview before the first Office Action, or at the very least, request the interview after the first Office Action to expedite prosecution by discussing claim language and claim preferences prior to a final rejection where claim amendments are limited. Strategic use of Examiner Interviews could conserve the number of continuations and RCEs in an application family, as the Examiner may understand the invention better at the time of search thereby resulting in a focused search as the claims can be focused to the invention. With this approach, the issues in the application may become crystallized sooner resulting in expedited prosecution.

10. Since the PTO is discouraging the filing of multiple RCEs, and is limiting continuations, patent applicants should consider appealing final rejections to avoid wasting an RCE or a continuation. In some instances, an appeal may be the only reasonable option available. However, if the PTO's proposed rules are implemented regarding the appeal process, appealing a patent application may become more expensive and onerous.

11. Non-U.S. patent applicants may wish to consider having their patent applications properly translated into English and put into U.S. format prior to filing with the PTO. With this approach, a first Office Action that focuses on indefiniteness rejections under Section 112 and prior art that is not directed to the invention may be avoided. As such, two continuations and an RCE may be preserved for substantive prosecution.

*Federal Register publication of the final rule:
www.uspto.gov/main/homepagenews/bak2007aug20.htm.

**Answers to USPTO Frequently Asked Questions can be found at the following internet link:
www.uspto.gov/web/offices/pac/dapp/opla/presentation/ccfrfaq.pdf.

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