

## New rules signal changes in patent practice

Working to speed its examination process while eliminating an ongoing backlog, the Patent Office has issued new rules that limit the number of continuation applications inventors may file. Continuation applications maintain the priority date of the original filing.

The final rules are less restrictive than those proposed in January, but they will have a significant effect on patent practices, says Phillip Pippenger, a member in LVM's Chicago office.

"Everyone will need to be more thoughtful with patent prosecution," he says. "Applicants will have fewer additional chances."

Under the new rules, inventors may file no more than two continuations and only one request for continued examination (RCE) for any application family unless they meet very strict requirements that allow them to file additional applications. Until now, there have been no limits on the number of continuations and RCEs allowed. This meant that inventors could use continuations to subsequently pursue other subject matter that was disclosed in the initial filing.

Additionally, once they file a first application, inventors sometimes need to continue to prosecute the application. They may, for example, need to submit additional art. In such cases, they have traditionally used RCEs to make the art of record. Now only one RCE may be filed.

According to the Patent Office, the new rules are intended to eliminate a backlog caused, it feels, by excessive numbers of continuations. Examination of new applications now may take from one to four years. Continuations accounted for 11 percent of Patent Office filings in 1998; in 2006 they were nearly 30 percent of total filings. By limiting continuations, the Patent Office hopes to help examiners address the backlog.

Jeremy Jay, a member in LVM's Washington, D.C., office, says the new rules require inventors to plan ahead.

"Before the new rules, you could draft claims in continuing applications in response to market changes," he says. "Now it will be more important than ever to work with experienced patent counsel to devise long-range plans. Not only are there limits on continuations, there are also limits on the number of claims that can be submitted. You need to work very closely with counsel to anticipate problems and try to project probable shifts in the market."

There will still be ways to obtain protection for inventions that are similar but patentably distinct, Pippenger adds. One is to file claims to several inventions in a single case.

"You are entitled to five independent claims and 25 total claims in each patent application," he says. "If you use them for five entirely different inventions, you may get, or may suggest, a restriction requirement from the Patent Office that requires you to file a divisional application. You may then withdraw four of the five claims and file new applications on them. Those applications won't count as continuations of the original application, but will maintain the priority date of the original filing."

Another option, he adds, is to file all five applications at the outset. The new rules

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# KSR ruling reopens obviousness defense

For the first time in many years, obviousness has become a viable option in defending against claims of patent infringement. In opening that door, however, the U.S. Supreme Court offered little guidance on the particular tests that should determine whether an obviousness defense is valid.

An invention is obvious under patent law if a person of ordinary skill in the art would predictably have arrived at it after reviewing applicable prior art. Applying the definition has proved problematic, however, and courts have struggled to find a reasonable solution.

In the late 1960s, the courts required unpredictable results to disprove a claim of obviousness. That began to change when the Court of Appeals for the Federal Circuit was established in 1982. As part of its efforts to make patent laws less arbitrary and to remove the improper use of hindsight, the Federal Circuit began rigorously applying the teaching, suggestion or motivation (TSM) test for obviousness. When applied rigidly,

the TSM test was very difficult to meet, and obviousness became a rarely used defense.

Now, with its ruling in *KSR v. Teleflex*, the Supreme Court has rejected the rigid application of the TSM test, saying that such rigid application does not provide for the inferences and creative steps that a person of ordinary skill in the art would employ without rising to the level of invention.

“The obviousness pendulum has swung back and forth since the ‘60s,” says Michael Hartmann, a member in LVM’s Chicago office. “This is another swing. In time, the pendulum will stabilize, but for now patentees will need to be prepared to demonstrate that their inventions are not obvious. Just saying an infringer hasn’t proved obviousness may not be enough.”

In rejecting the rigid application of the TSM test, the Supreme Court declined to address alternative obviousness measurements. Instead, the court left it to lower courts to use common sense in deciding questions of obviousness.

“The question of obviousness can be inherently subjective and perceived as arbitrary without clear guiding principles,” says Eley Thompson, a member in LVM’s Chicago office. “When the inquiry moves from corroborated facts to subjective creativity of the person of ordinary skill in the art, there is more room for divergent outcomes.”

While the full effect of the KSR ruling will not be evident for some time, it is highly probable there will be more rejections for obviousness than in the past.

“The Patent Office will apply the KSR case just as the courts do,” Hartmann says. “We’ll see more obviousness rejections, and the burden will be back on the patentee.”

In the end, though, Thompson says, “The tools people used in the past to demonstrate that something was inventive are all still useable. Inventors won’t establish patentability all that differently. KSR just makes it more important that they actually provide affirmative evidence.”

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# Merck ruling creates research tool conundrum

A widely anticipated ruling from the Court of Appeals for the Federal Circuit in the case of *Integra Lifesciences v. Merck KGaA* may have clarified some points of law surrounding drug research, but it did nothing to alleviate uncertainty over research tools.

“Both the U.S. Supreme Court and the Federal Circuit specifically said they wouldn’t touch the issue of research tools,” says Bruce

Gagala, a member in LVM’s Chicago office. “There’s uncertainty as to how they’ll apply the statute relating to those tools, and it’s left matters open-ended.”

The case, remanded to the Federal Circuit for reconsideration in view of the Supreme Court’s ruling, centered on when research is protected under the §271(e)(1) exemption. The provision allows researchers to avoid patent infringement when their

work is reasonably related to federal Food and Drug Administration (FDA) activities.

For compound-related patents, the issues are relatively straightforward, says Steve Sklar, a member in LVM’s Chicago office.

“The use of patented compounds in research conducted after the biological mechanism and physiological effect of a candidate drug have been recognized are protected, non-infringing uses,” he says.

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# Protecting trademarks in foreign languages

As American companies continue to expand internationally, they are becoming more interested in how best to trademark their names in languages that are not written in the Roman alphabet.

“A problem can arise when someone wants to protect a trademark in a language such as Chinese, Japanese, Arabic or Russian,” says Lynn Sullivan, a member of LVM’s Chicago office. “For example, trademarks can be translated into Chinese and Japanese characters in two ways: phonetically, by sound of the mark as pronounced in English, and conceptually, i.e., according to the meaning of the word or words. Therefore, you could have several translations for the same mark that look completely different.”

A company called The Green River Tea Company, for example, could use characters

that sound like “green river” in English but that may not translate to the image the company wants to convey. Conversely, the company could choose characters that conceptually mean “a river of green.”

“It’s also important to be aware of characters’ individual meanings,” says Caroline Stevens, an associate in LVM’s Chicago office. “A character may say exactly what a company wants to say, but it can be a character with a very negative connotation in the country in which it will be used.”

Many of us have heard the anecdote that Chevrolet’s attempts to sell the “NOVA” automobile in Spanish-speaking countries were unsuccessful because, in Spanish, “No va” means “It does not go.” This anecdote may be no more than an urban legend, but it illustrates why

companies must carefully consider the meaning of their translated marks.

As a practical matter, registering all possible versions as a defensive measure would be too expensive for most companies — especially those with large portfolios. Such a defense would likely be temporary, as well, because trademarks that are not used are subject to cancellation.

“Companies must consider very carefully whether they want to translate their trademarks for certain markets,” Sullivan says.

Stevens agrees, saying, “Due to cost considerations, companies should carefully consider their trademark strategy when entering foreign markets, and after translating a mark, ensure that they and their foreign affiliates consistently use the same approved translation.”

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## Merck

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The more complex issues surrounding 271(e)(1) are related to research tools: cell lines, monoclonal antibodies, clones, methods, lab equipment and other tools scientists use in the course of developing new drugs.

Neither the Supreme Court nor the Federal Circuit addressed whether 271(e)(1) exempts the use of research tools during the FDA regulatory process. In fact, both specifically declined to consider the matter at all.

In a dissenting opinion, however, Federal Circuit Judge Randall Rader said the lack of direction means “Universities and independent

researchers will have to understand that their work on research tools is likely to amount only to a charitable (but nondeductible) gift to the pharmaceutical industry.”

That remains to be seen, as does how the courts may rule if a case specific to research tools arises. In the meantime, says Sklar, research tools and their use in drug discovery remain a gray area of the law.

“The majority opinion made it pretty clear that they were applying their decision to particular patents, and one view is that it’s limited to these facts,” he says. “But you still have to tread lightly if you want to use a certain tool. An experienced patent

attorney can help assess the risk and evaluate how to proceed.”

And, Gagala adds, it is still worthwhile for research tool developers to patent their inventions.

“I don’t think either court is interested in creating royalty-free licenses for these tools,” he says. “They could take a new look at things down the road. In the meantime, people who obtain patent rights on research tools can presume those rights will have value. If they don’t seek patents, they know for certain their inventions will have no value.”

## New rules

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require applicants to notify the Patent Office when the same applicants file multiple applications at the same time.

“That sets up a rebuttable presumption that the inventions are patentably indistinct, but you can file a rebuttal argument,” Pippenger says. “If you succeed, you get five separate cases.”

Such procedures will not always be appropriate, however, and it is important

that inventors consult legal counsel to devise their patent application strategies. The new rules take effect Nov. 1, but some of the rules also will apply to any applications filed before that if the Patent Office has not mailed a first office action on merits by that date.

## LVM Announces

LVM Chicago is pleased to announce that Elias P. Soupos has joined the firm as a patent agent.

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