

Plan in Place to Reform U.S. Patent System

Congress has begun to consider some of the most extensive changes to U.S. patent law in the past 50 years. Earlier this summer, Rep. Lamar Smith introduced the Patent Reform Act of 2005 (H.R. 2795). The bill includes several controversial changes, including a move toward a “first-to-file priority system”; modification to the requirements for a preliminary injunction in patent infringement lawsuits; and expansion of pre-issuance publication of all pending applications and post-issuance opposition proceedings.

Most of these changes are in response to concerns about the quality of issued patents, the expense and complexity of patent litigation, harmonization of U.S. patent law with the laws of our leading trading partners, potential abuses committed by patent speculators (so-called “patent trolls”), and the particular needs of individual inventors versus those of larger corporations.

Of the changes, probably the most significant is a switch from a “first-to-invent” system to a “first-to-file” system. Priority would be given to the first application to reach the Patent Office, regardless of when the

invention was created. This provision would put U.S. patent law in line with the patent systems of most other countries, providing for greater legal certainty without the potential expense of an interference proceeding.

A second important change in the bill provides for post-grant review of patents in the USPTO. This would be in the form of an administrative proceeding within the patent office that may take place up to nine months after the patent is granted or up to six months after a notice of alleged infringement. Essentially all grounds that might be asserted to invalidate a patent in court could be asserted in such a proceeding.

The bill provides that all patent applications will be published after 18 months. Currently, only applications that have been or will be filed in other countries are required to be published. This change would prohibit applications from being held in secret until issuance, which has been a problem for businesses trying to design products that avoid pending or issued patents.

The bill includes a provision which would make it more difficult for a patent owner to obtain a preliminary injunction against an alleged infringer. H.R. 2795 would eliminate the standard practice of courts presuming that the patent owner will suffer “irreparable harm.” Instead, a court would weigh all evidence, including the extent to which a patent owner makes use of the technology claimed by the invention, to determine whether the patent owner is entitled to an injunction.

It is unclear how quickly the bill will make its way through Congress. Several hearings regarding H.R. 2795 have already been held, but change is not imminent. Some relatively minor changes to the patent system that were introduced in 1991, took 8 years to pass. Furthermore, most of the changes proposed in the bill would have no retroactive effect. The most controversial provisions would apply to patent applications or litigation filed after the passage of the Act.

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Merck KGAA v. Integra Life Sciences I presented the issue of whether the use of patented compounds in preclinical research is exempted from infringement by 35 U.S.C. § 271(e)(1) even when the results from experiments on the patented compounds are not ultimately submitted to the FDA. The relevant portion of § 271(e)(1) states “[i]t shall not be an act of infringement to . . . use . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.” In its June 13, 2005 decision, the Supreme Court expanded the scope of this exemption.

The Facts

The plaintiff, Integra Life Sciences (“Integra”), owns patents related to a tripeptide sequence Arg-Gly-Ast, known as the “RGD peptide.” The defendant, Merck KGAA (“Merck”), funded a researcher who used the patented RGD peptide in doing research on angiogenesis. Angiogenesis is a process by which new blood vessels sprout from existing vessels. It plays a role in many diseases such as solid tumor cancers. The researcher found that the RGD peptide inhibited angiogenesis. Merck then provided further funding to the researcher to identify a potential RGD peptide drug candidate. When Integra found out that Merck was funding the use of the patented RGD peptides without obtaining a license from Integra, Integra sued Merck for infringement. At trial, Merck claimed an exemption from infringement under § 271(e)(1). Instead, the jury found infringement and awarded Integra \$15 million in damages. The district

court’s interpretation of § 271(e)(1) was appealed all the way to the United States Supreme Court.

The Supreme Court Decision

The United States Supreme Court overturned the Federal Circuit’s previous interpretations of § 271(e)(1) and broadened the scope of the statute’s exemption from infringement. In the Supreme Court’s view, the Federal Circuit’s interpretation of § 271(e)(1) was too constrained. The Federal Circuit’s narrow interpretation essentially limited the exemption to only those activities related to the approval of a generic drug since this is the only activity where, at the outset, the researcher will know that the drug will be effective. Under the Supreme Court’s interpretation, Congress did not intend to limit § 271(e)(1)’s exemption to only those situations where the researcher knows with certainty that the results of the experiments will be submitted to the FDA. The Supreme Court noted that experimentation is a process of trial and error and that it is impossible to know with certainty what the experimental results will be before research begins. Therefore, some testing on patented compounds will be “reasonably related” to the submission of information under a federal law, and therefore exempt under § 271(e)(1), even though no information is actually submitted to the FDA. The Supreme Court stated that its interpretation is consistent with the expansive language that Congress put in § 271(e)(1) because Congress exempted use of all patented compounds “reasonably related” to the process for developing information for submission under *any* federal law which regulates drugs.

Future Roadblocks for Cyber-Pirates, Squatters

Most people surfing the Internet are familiar with web site addresses that end in .com, .edu, or .gov. These are what is known as “generic Top-Level Domains” (gTLDs). They are used to identify the nature of the entity operating the website. For example, .com websites are for commercial enterprises whereas .org sites are for non-profit organizations. However, the list of gTLDs has expanded beyond .com, .edu, and .gov and further includes .net, .aero, .biz, .coop, .info., .int and so on.

Unfortunately, as new gTLDs are introduced there are renewed opportunities for cyber-pirates and cyber-squatters -- individuals who either register websites with an address that is similar to a trademark name in order to confuse users, or those who register a Website with an address identical to a trademark name and then hold the address in ransom from the owner of the trademark. Fortunately, when the true trademark owner finds out that a cyber-pirate or cyber-squatter has attacked, they can often avoid going to court by using a formal dispute resolution procedure provided by the Internet Corporation for Assigned Names and Numbers (ICANN), the institute that oversees the website naming system. However, this procedure is only “curative” and does not prevent cyber-pirates and cyber-squatters from obtaining wrongful domain names.

A new report by the World Intellectual Property Organization (WIPO) suggests that as new gTLDs are introduced

Outline of the Decision

Thus, in the Supreme Court's view, use of patented compounds in preclinical studies is protected under the § 271(e)(1) exemption "as long as there is a reasonable basis for believing that the experiments will produce the types of information that are relevant to an investigational new drug application or a new drug application."

Integra argued that the only preclinical information of interest to the FDA is the safety of the drug in humans, and therefore that all other preclinical studies related to the drug's efficacy, mechanism of action, pharmacokinetics, and pharmacology should be outside of the scope of the exemption. The Supreme Court rejected this view by stating that the FDA's interest in information from preclinical studies is not so constrained. The Supreme Court's interpretation of § 271(e)(1) shows a clear policy of wanting to allow patented drugs to be freely used in activities related to the federal regulatory process.

A Possible Motive for the Supreme Court's Decision

The Supreme Court's holding may be a response to a growing movement in the academic community that wants "research tools" exempt from infringement so that there are fewer barriers to developing new drugs. This movement argues that the number of patents on upstream research tools creates a patent thicket in which it is too costly for researchers to license and negotiate for all of the patented tools needed in the development of a new drug or other downstream application. In a footnote to its opinion, the Supreme Court claimed it was not granting an exemption for patented research tools. The Court stated that this case was not a situation where the RGD peptides

were being used as a research tool but rather this was a situation where the defendant was studying the tool itself. The Supreme Court claimed that this decision expressed no view about whether use of patented research tools can be exempted under § 271(e)(1). However, this decision adds more fuel to the fire for those who want to expand the scope of what is exempted from infringement under § 271(e)(1).

What Does this Mean if You Own Patents on Drugs or other Compounds?

The Supreme Court's decision expands the scope of the § 271(e)(1) exemption beyond the scope of the Federal Circuit's previous interpretations. This means that some research activities which previously would have been considered infringement will now fall under the § 271(e)(1) exemption unless Congress decides to amend the statute and narrow its language. A specific situation where an activity can now be exempted, but would have previously been an infringement, is where the would-be infringer uses the patented compound in preclinical studies but does not include the experiments or the compound in submissions to the FDA. As long as there was a "reasonable basis" for believing that the experiments would produce the types of information that are relevant to a new drug application, the activity is exempted in the Supreme Court's view. Determining whether a "reasonable basis" exists will define the line between activities that are infringement and activities that are exempt. Future infringement suits and Federal Circuit decisions will have to define the contours of this line. Most certainly, the Supreme Court's decision will receive a lot of discussion.

in the future, a uniform mechanism should be in place that prevents cyber-pirates and squatters in the first place. One such mechanism that WIPO suggests is a sunrise mechanism. This procedure would provide a period of time before a new gTLD is introduced for trademark owners to get the "first shot" at a domain name before the general public does. In order to prevent abuse of this procedure, all trademarks would be verified before the domain name is given and a third party would be able to challenge the sunrise application. A sunrise mechanism was used when .biz arrived.

The WIPO has suggested another possible mechanism, the defensive registration, to prevent cyber-pirates and squatters. The major difference between a defensive registration and the sunrise mechanism is that with a defensive registration, the trademark holder does not receive the domain name to use for its own benefit. Instead, the domain name would be blocked from anyone using it, including the trademark holder.

Both of these mechanisms suggested by WIPO leave some questions unanswered, such as whether entities with "common law" trademarks could pre-register during the sunrise period, and if so, how to verify such a trademark. Also, resolving the issue of multiple parties having legitimate rights in the same word mark but in different countries, or for the same word mark but in different types of goods and services could be a problem. Additionally, ICANN, not WIPO, has the final say on what type of preventative measures, if any, should be in place in the future. However, it seems likely that ICANN will listen to WIPO's suggestions; ICANN has asked for WIPO's expert advice and has often followed their recommendations in the past.

Author or Inventor?

The differences between authorship and inventorship are subtle but important. Inventorship is legally defined where authorship is subjectively decided. The seminal case of *In Re:Katz* sets out the boundaries of the analysis. Generally one who is a co-author of a research article that discusses an invention is not necessarily an inventor of a patent on the same technology.

Authorship is granted to individuals who have assisted in research in any way. This can include lab assistants who work specifically under the direction of a researcher. They often are acknowledged on publications as co-authors. Co-authorship is primarily a form of recognition for the efforts of such people and often co-authors can include students, lab assistants, even commercial assistance, or simply those who provide components for research. This determination is largely subjective and often involves political, reciprocal, and deferential criteria based solely upon the primary author's opinions.

On the other hand, inventorship is a legal determination though it is not always definitive as to who qualifies as an 'inventor'. Individuals who have made a material contribution to any element of a claim of a patent are considered inventors and these individuals must all be listed on a patent. Failure to do so can invalidate the patent resulting in a possible loss of intellectual property rights.

The concept of "invention" includes two elements. First, there is "conception" or the mental formulation of the idea. The conception must be complete enough to enable anyone with ordinary skill in the pertinent art to "reduce the invention to practice". The second element is "reduction to practice". Reduction to practice is the actual manifestation of the invention to demonstrate how it would operate and thereby determines inventorship.

In order to be considered an inventor, an individual must have made some kind of material contribution to the conception of the invention. Simply taking part in the reduction to practice of the invention does not award the title of inventor to an individual, although it often amounts to co-authorship. If, however, the conception requires more ingenuity to reduce the invention to practice, then the person applying the additional skill has made a material contribution to the reduction to practice of the invention. Often, the conception and reduction to practice happen concurrently. In other words, if there was no preconceived idea and the invention was created in the course of actual experiments then inventorship is still assigned. This is often the case in very complex arts such as biotechnology.

As an aside, a person who suggests an idea with out a way to achieve it, is not considered an inventor.

USPTO Offers Price Break for Electronic Filing

As of July 20, the United States Trademark Office has lowered the cost of filing electronic trademark applications from \$325 to \$275 per class if certain filing requirements are met and an agreement is made to file and receive subsequent communications with the PTO electronically. Such trademark applications are known as "TEAS Plus" applications.

In order to qualify for TEAS Plus status, thereby qualifying for the lower filing fee, a trademark applicant must do more than simply meet the minimum filing requirements for obtaining a filing date. Instead, applicants must meet all of the filing requirements of Trademark Rule 2.22(a), listed at <http://www.uspto.gov/teas/eTEASupcoming.html#TEASPlus>. By providing all of this filing information up front, the trademark examiner can process the application faster and more efficiently, thereby justifying the reduction in filing fee.

One of the primary requirements for the TEAS Plus trademark application is to provide a list of goods and/or services for the application directly from the Trademark Office's "Acceptable Identification of Goods and Services Manual." While some customization of the identification of goods/services is allowed, the identification must read substantially in accordance with one of the pre-approved Trademark Office identifications. The Acceptable Identification of Goods and Services Manual is posted on the Trademark Office web site, <http://tess2.uspto.gov/netahtml/tidm.html>.

In addition, if the trademark includes a logo or design, a statement describing the logo or design must be provided to the Trademark Office at the time the application is filed. Likewise, if the mark includes color, a statement must be provided describing the placement of the color. Further, any previous registrations owned for the same mark must be identified.

For further clarification, contact your trademark attorney.