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The Short-Sighted Attack on Patent Eligibility of Healthcare Related Patents

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Editorial

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On March 20, 2012, the Supreme Court of the United States unanimously decided the case of *Mayo Collaborative Svc. v. Prometheus Labs.* At issue was a patent, held by Prometheus that taught doctors how to adjust the amount of thiopurine (a drug used for treatment of a variety of autoimmune diseases) administered to a patient. In an opinion by Justice Breyer, the Court held Prometheus's invention to not be patent eligible and invalidated the patent. Though I believe that the reasoning the Court employed was erroneous and highly problematic (of which more later), the decision could have been viewed as a small problem if it were not part of a sustained, and worldwide attack on the scope of patent eligibility for inventions in general and healthcare and biologic inventions in particular. This assault on the availability of patents for inventions in some of the most complex and labor-intensive areas of science bodes poorly for the future advances in these fields, and therefore for the availability of new breakthrough diagnostics and treatments for the patients.

In *Prometheus*, the inventors discovered the (high) levels of thiopurine in the body which would be toxic to the patient and the (low) levels which would be ineffective for the treatment of the disease, and they patented a method for the proper use of the drug which consisted of three steps: administering the drug, measuring the level of the drug in the body, and then adjusting the levels of the drug to get them within the therapeutic range. In striking down the patent, the Supreme Court concluded that Prometheus was claiming a process reciting the law of nature and that that is not patent eligible. To be

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fair, no one disagreed with the proposition that the fact that thiopurine is only effective at certain dosages and is toxic at higher levels is a "law of nature." But then again, that is not what the patent claimed. Instead, the patent claimed an application of that law of nature to the treatment of certain diseases. The Court did not consider this difference to be significant as it concluded that the steps of administering drugs and ways of monitoring their levels are well known. What is important to understand though, is that the Court did not reject the patents for lack of novelty, but rather for failure to claim patent-eligible subject matter. The problem with this approach is that it melds together completely separate inquiries – that of the eligible subject matter and that of novelty. The distinctness of these categories is evident from the structure of the Patent Act, which has a separate section for each requirement.

Not only did the Court misread the statute as a matter of statutory construction, but it effectively put into doubt all method-of-treatment patents. After all, such patents all rely on laws of nature. The only reason certain drugs and biologics work is because they exploit natural phenomena to achieve their purpose. If that is the road that the Court intends to travel, then potential profits from pharmaceutical research (and therefore incentive to conduct such research) will be greatly diminished.

The Supreme Court expressed its belief that having a more stringent patent eligibility requirement will likely benefit the public, because physicians will be better able "to provide sound medical care." This view, expressed by a number of medical associations that have submitted briefs to the Court, has been gaining currency not only in the U.S., but worldwide, reversing the previous trend for a more inclusive patent eligibility regime. It is worth remembering that for quite some time, patents on pharmaceutical compounds were not available in a number of countries, including developed countries like Japan, Switzerland, Italy, Finland, Greece, Iceland, Monaco, Norway, Portugal, and Spain. The reason behind this exclusion was the same moral concern that animated the *Prometheus* Court, i.e., the availability of needed drugs to the public. Yet, in the 30 years that the developed countries have permitted patenting pharmaceuticals, we have developed more and better drugs that have prolonged lives and alleviated suffering for countless individuals. The fear that allowing exclusive rights to drugs will preclude access has turned out to be unfounded. Yet, the *Prometheus* decision is just one episode of the multi-front attack on pharmaceutical and biologic patents.

Recently, litigants and activists in a number of countries have attacked patents on DNA and other genetic materials. The American Civil Liberties Union filed suit to declare DNA to be per se patent ineligible. Bills to accomplish the same result have been introduced in Congress. Similar bills have been introduced in Australia. European geneticists have issued similar calls. Along the same lines, a number of countries simply disregard patent rights by issuing compulsory licenses on valuable drugs. (A compulsory license, after all, is little different from refusal to grant exclusive rights in the

first place). While that approach may be excused and even welcomed in the face of a public health emergency, it is exceedingly hard to justify for drugs like Viagra or Plavix. Yet countries have issued compulsory licenses for both of those drugs.

All of these actions have popular appeal. The public prefers cheaper drugs and tests to the more expensive ones. Thus judicial, executive, and legislative actions that prevent anyone from charging monopoly rents by precluding the availability of exclusive rights are likely to be met with cheers. However, this is very shortsighted. Limiting of patent rights today may lower the cost and increase availability of drugs and tests already on the market, but that approach will also simultaneously lower incentives for further innovation. Fewer treatments and diagnostics will be developed (and they will be developed more slowly) as a result. In essence, limiting patent eligibility for medical products benefits the present generation at the expense of the future ones. If we are to hope that medicine will make as large strides in the next 30 years as it made in the past 30, courts, legislatures, and the public must be convinced that limiting the scope of patent eligibility is precisely the wrong way to go.

Articles

Thomas Hoeren and Silviya Yankova***

The Liability of Internet Intermediaries – The German Perspective

A. Introduction

The principles concerning the liability of Internet intermediaries in Germany are primarily based on case law. Specific and to some extent divergent liability criteria have been developed not only within all concerned legal areas but regarding almost all different types of service providers as well. This makes it a demanding and challenging task for a legal practitioner to acquire a general idea of the main liability conception on the one hand and to stay well-informed and up-to-date with the new court practice tendencies concerning all various legal aspects of the matter on the other. This article aims to outline the main legal application areas of liability arising from the

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