ADDITIONAL DEVELOPMENTS—PATENT LAW

IN RE NUIJTEN

500 F.3d 1346 (Fed. Cir. 2007).

The United States Court of Appeals for the Federal Circuit held, by a vote of two to one, that applicant Petrus Nuijten's claims directed toward a signal embedded with supplemental data did not claim patentable subject matter. The case, along with its companion *In re Comiskey*, 499 F.3d 1365 (Fed. Cir. 2007), represents the Federal Circuit's retreat from previously more liberal patent eligibility rules.

The Patent and Trademark Office examiner allowed Nuijten's other claims on the process of adding low-distortion watermarks to signals, on a device that performs the process, and on a storage medium for holding the resulting signals. But the examiner rejected Nuijten's claims directed toward the signals themselves as outside the scope of patentable subject matter under 35 U.S.C. § 101. The Board of Patent Appeals and Interferences affirmed. Thus, the sole claims on appeal before the Federal Circuit covered the encoded signals themselves. The court affirmed the rejection on the basis that a transitory, propagating signal like Nuijten's was not a process, machine, manufacture, or composition of matter and therefore did not constitute patentable subject matter under § 101.

Section 101 provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter" may obtain a patent. The four categories define the "exclusive reach" of patentable subject matter. Thus, explained the court, if a claim covers material not found in any of the four statutory categories, that claim falls outside the scope of §101 even if the subject matter is otherwise new and useful.

The court considered each statutory category in turn. First, the court found that the disputed claims were not process claims, despite the required recitation of acts in the claims, because such claims were directed toward the signal—the ultimate product—and not the process. Next, the court held that the claims did not meet the statutory definition of a "machine," because signals did not possess the concrete structure consisting of mechanical devices and parts required under the Supreme Court's definition of "machine." Nuijten also failed to persuade the court that the claimed signals fell within the category of "manufacture," because the court remained unconvinced that a signal comprised tangible articles or commodities. The Federal Circuit did not reach the issue of whether the signals constituted compositions of matter because the parties did not contest the PTO's determination that they did not.

IN RE COMISKEY

499 F.3d 1365 (Fed. Cir. 2007)

The United States Court of Appeals for the Federal Circuit held that appellant Comiskey's claims directed toward a method for mandatory arbitration resolution regarding unilateral and contractual documents did not constitute patentable subject matter.

The Patent and Trademark Office had rejected Comiskey's claims as obvious in light of prior art under 35 U.S.C. §103(a), and the Board of Patent Appeals and Interferences affirmed. On appeal, the Federal Circuit did not reach the ground relied on by the Board because it held that many of the claims were barred as failing to state patentable subject matter under 35 U.S.C. §101.

Section 101 provides that a patent may be obtained for "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement thereof." Despite the broad range of patentable subject matter under § 101, courts have long recognized that certain categories—phenomena of nature, mental processes, and abstract intellectual ideas—are not patentable. Accordingly, the Federal Circuit rejected Comiskey's claims directed toward the process of resolving a legal dispute between two parties by the decision of a human arbitrator. The court reasoned that the claims sought to patent a mental process—the use of human intelligence in and of itself. The court stated that "mental processes—or processes of human thinking—standing alone are not patentable even if they have practical application."

The Federal Circuit noted, however, that a claim reciting an abstract concept can state patentable subject matter if it is tied to a particular machine, or involves another class of statutory subject matter such as a machine, manufacture or composition of matter. Thus, the Federal Circuit remanded consideration of Comiskey's claims that recited patentable subject matter to the PTO for determination of whether the additional limitation of modern computers and communications devices to otherwise unpatentable mental processes would have been obvious. The court stated that remanding these claims was appropriate because had the Board relied on the new § 101 ground for rejection in the first instance, and Comiskey would have had the opportunity to amend his application in response to that rejection under 37 C.F.R. §41.50(b).

PFIZER, INC. V. APOTEX, INC.

480 F.3d 1348 (Fed. Cir. 2007)

In one of its first post-*KSR* obviousness decisions, the Court of Appeals for the Federal Circuit held obvious claims 1-3 of plaintiff Pfizer Inc.'s U.S. Patent No. 4,879,303 ("the '303 patent"). In so doing, the Federal Circuit affirmed the allocation of the burden of proof and evidentiary standard facing challengers as to obviousness. It also clarified the application of the teaching-suggest-motivation test to combination and chemical patents, especially as to the effects of a reasonable expectation of success and of unexpected results.

Pfizer filed suit alleging that defendant Apotex infringed the '303 patent by seeking approval from the Food and Drug Administration to commercially sell amlodipine besylate tablets. Apotex counterclaimed for a declaratory judgments that Pfizer's '303 patent was invalid on obviousness and novelty grounds. The U.S. District Court for the Northern District of Illinois entered judgment for Pfizer and ruled against Apotex on its counterclaim for declaratory judgments. Apotex appealed.

Pfizer had obtained a prior patent claiming certain dihydropyridine compounds and their pharmaceutically-acceptable acid addition salts, including maleate. Despite structural differences between the newly-claimed amlodipine besylate and the prior art amlodipine maleate, the Federal Circuit held that the district court erred in finding nonobviousness. First, the court scolded the district court for having held that the examiner's initial rejection of Pfizer's application, standing alone, constituted a prima facie showing of obviousness. According to the Federal Circuit, that determination "reflect[ed] a serious misconception regarding the proper burden of proof each party bears in patent litigation." Rather, the court explained, an examiner's rejection provides "at most only one factual consideration the court must consider" in assessing obviousness.

Next, the Federal Circuit explained that the party claiming obviousness must demonstrate by clear and convincing evidence: (1) that the prior art would have taught, motivated, or suggested to a skilled artisan to combine its elements to come up with the claimed invention and (2) that the artisan would have had a reasonable expectation of success. The court found that the prior art taken as a whole and the nature of the problem addressed by the relevant prior art both would have encouraged a skilled artisan to produce amlodipine besylate. The Federal Circuit pointed to trial evidence that when Pfizer researchers encountered trouble with the prior art amlodipine maleate, they created a list of chemical alternatives, including besylate, that they expected would remedy the problems. The court found that although the researchers could not guarantee that they would be able to make the alternative salts, mere unpredictability as to whether a salt would form or what its properties would be did not negate obviousness so long as there was a reasonable expectation of success.

The court then laid out the rule that unexpected results can defeat a prima facie case of obviousness, but that "obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art" if the skilled artisan would nevertheless have harbored reasonable probability of success. Under this rule, the allegedly unexpected properties of drug stability and processing efficiencies of amlodipine besylate over amlodipine maleate did not rise to a level of significance sufficient to defeat Pfizer's obviousness problems. According to the court, Pfizer failed to present persuasive evidence that the properties of amlodipine besylate were actually unexpected by skilled artisans. The mere

fact that Pfizer researchers had to perform some experiments to verify their expectation was of "no consequence" to obviousness analysis.

Finally, the Federal Circuit rejected Pfizer's contention that it was merely "obvious to try" rather than obvious to make the claimed combination. The court stressed that the distinction among the claimed and the prior art salts involved only one variable parameter (not many), that one skilled in the art would have noted that the FDA had previously approved the use of the claimed salts, and that Pfizer had to perform only "routine testing" to verify the success of the salt it selected. The court explained that Pfizer's "routine testing" served as mere verification of its reasonable expectation of success rather than demonstrating any true discovery.

Over spirited dissents from Judges Newman, Lourie, and Rader, the Federal Circuit refused to rehear the case *en banc*.

VODA V. CORDIS CORP.

476 F. 3d 887 (Fed. Cir. 2007)

The United States Court of Appeals for the Federal Circuit held that a district court could not exercise supplemental jurisdiction over Voda's foreign patent claims.

Jan Voda, a doctor from Oklahoma, filed a suit in the Western District of Oklahoma against Cordis, a U.S. company with several foreign affiliates, for infringement of his U.S. patent on a medical device. Voda subsequently sought to amend his complaint to add foreign patent infringement claims. The district court granted Voda leave to amend, basing its subject matter jurisdiction over Voda's foreign patent claims on 28 U.S.C. § 1367, which provides for supplemental jurisdiction. Cordis filed an interlocutory appeal from the district court's decision.

The Federal Circuit could have decided that the district court lacked subject matter jurisdiction over Voda's foreign patent claims on the basis of either 28 U.S.C. § 1367(a) or § 1367(c). Under § 1367(a), there would be no supplemental jurisdiction unless Voda's foreign patent claims were "part of the same case or controversy" as his U.S. patent claims. The court emphasized that the test with respect to this issue remains whether the claims involved a "common nucleus of operative fact," as set forth in *United Mine Workers of America v. Gibbs*, and that language in *Gibbs* concerning whether a district court would "ordinarily be expected to try [the claims] all in one judicial proceeding," did not constitute a separate operative test. However, the Federal Circuit declined to decide whether § 1367(a) authorized supplemental jurisdiction since it decided that the district court erred under § 1367(c).

Under § 1367(c), the exercise of supplemental jurisdiction is within the district court's discretion, not a plaintiff's right. A district court should consider and weigh the values of comity, judicial economy, convenience, and fairness in deciding whether to exercise supplemental jurisdiction. The Federal Circuit found that the district court had conducted no such analysis, as required by § 1367(c). After considering these factors values and the treaty obligations of the United States, the Federal Circuit held that the district court abused its discretion in deciding to exercise supplemental jurisdiction.

The Federal Circuit first noted that international treaties, like the Paris Convention, Patent Cooperation Treaty, and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) do not contemplate one jurisdiction adjudicating the patents of another. The Federal Circuit held that the risk that exercising supplemental jurisdiction over foreign patent claims would violate U.S. treaty obligations was an "exceptional circumstance" that warranted declining jurisdiction under § 1367(c). The court further stated that exercising supplemental jurisdiction in this case would undermine comity, the "spirit of cooperation" in which a domestic court should approach the resolution of cases that involve laws of other sovereigns. The court held that judicial economy weighed against exercising jurisdiction because a U.S. district court would expend more resources in the case than a foreign court better versed in the foreign patent regime. Convenience also favored declining jurisdiction, the court stated. Finally, the court suggested that exercising supplemental jurisdiction could be fundamentally unfair to the alleged infringer if, assuming U.S. courts cannot inquire into the validity of plaintiff's foreign patents, the case is decided just on infringement grounds.

COMPULSORY LICENSES IN THAILAND AND BRAZIL

Under World Trade Organization (WTO) rules, Thailand issued compulsory licenses for several patented medicines, including efavirenz, a pivotal HIV medicine patented by Merck & Co, Inc. Brazil soon followed, issuing a compulsory license on the same drug, making it the second emerging economy to aggressively seek a reduction in the cost of patented medicines. A compulsory license allows a government to purchase a patented product or process from rival sources without the consent of the patent owner. This option is intended to cut treatment costs. While most countries uphold it under international law, the practice has sparked an international debate as to the appropriate balance between access to life-saving drugs and encouraging innovation in the pharmaceutical field.

Between November 2006 and January 2007, Thailand's Ministry of Heath issued compulsory licenses for two antiretroviral drugs used for treating human immunodeficiency virus (HIV) (efavirenz and lopinavir/ritonavir) and a heart medication (clopidogrel). The licenses represent the climax of years of failed negotiations with the patent holders. Each drug was issued for government use at a royalty rate of 0.5 percent. Thailand exercised its authority to issue government-use compulsory licenses according to Article 51 of the Thai Patent Act.

Similarly, in May of 2007, Brazil announced it had issued a compulsory license for efavirenz. In the years leading up to the decision, the Brazilian government had successfully threatened to issue compulsory licenses against other pharmaceutical firms in order to negotiate lower prices of antiretroviral drugs. The compulsory license issued against Merck resulted from a breakdown in negotiations and was the first time Brazil actually carried out its threat. The government relied on the public interest provision of the Brazilian Industrial Property Law to grant the license. Accordingly, the license must be for non-commercial use, non-exclusive production, and for a fixed period of time, although it may be extended and will remain in force for as long as the public interest exists.

The Thai and Brazilian governments argue the compulsory licenses are lawful not only under their domestic laws, but also under the WTO's Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS), as affirmed by the Doha Declaration on the TRIPS Agreement and Public Health. Under paragraph 5b of the Doha Declaration, each member state is free to determine the grounds upon which compulsory licenses are granted. For national emergencies, other circumstances of extreme urgency, or public non-commercial use, negotiation of a voluntary license can be bypassed to save time, though the patent owner is still owed royalties. Thailand and Brazil both contend that they have valid public health reasons and are producing the drugs for permissible public non-commercial use.

While the countries' compliance with the TRIPS agreement is by and large uncontested, there is concern that it sets a precedent for the way in which developing countries manage their public health problems and access to patented medicines. While health and human rights activists view compulsory licensing as a victory in the fight for access to affordable medicines, the pharmaceutical industry warns that it could have a chilling effect on drug development. Critics of compulsory licensing argue that the expropriation of intellectual property will discourage industry from undertaking risky research on diseases affecting the developing world.

NANOTECHNOLOGY

Nanotechnology holds the potential to revolutionize a wide range of fields—from pharmaceuticals to consumer products to computing—but also presents significant regulatory and intellectual property challenges. Nanotechnology studies materials at the level of molecules, measured in nanometers, one-billionth of a meter. There are fundamental differences between the physical, chemical and biological features of molecules at the nanoscale compared to the properties of individual atoms or molecules. Working at the nanoscale gives rise to new ways of manipulating compounds for therapeutic and other commercial applications. However, nanotechnology comes with new questions with respect to health and safety regulation and intellectual property management.

Possible uses of nanotechnology are difficult to predict at this early stage. Nonetheless, nanotechnology has generated great excitement in biotechnology and other industries. Early scientific applications of nanotechnology in biotechnology include: (1) more predictable drug toxicity based on surface-level characteristics such as charge or particle positioning of nanoscale molecular materials; (2) more efficient drug delivery mechanisms through nanoscale manipulations; and (3) better controlled drug absorption through nanoscale manipulations. Other applications beyond biotechnology include better product development for sunscreen, cosmetics, paint, and disinfectant manufacturers.

In July 2007, the U.S. Food and Drug Administration (FDA) Nanotechnology Task Force issued a report on regulating nanotechnology. The FDA refused to adopt a comprehensive definition of nanotechnology or nanoscale materials given the relative novelty of the field and the difficulty of predicting the scope of uses. The FDA stressed the importance of careful regulation of nanotechnology given possible molecular unpredictability of nanoscale materials.

In particular, the FDA emphasized challenges posed by nanotechnology inventions as "combination products" given that nanotechnology inventions will likely have application in a variety of contexts including biotechnology, food processing, and cosmetics. The FDA recommended increasing nanotech expertise for agency staff and recruitment of nanotech specialists to help with regulatory review.

Industry is fast embracing the promise of nanotechnology. Many companies have rushed to patent a variety of nanotechnology inventions. Law firms with strong intellectual property practices have developed specialized nanotechnology practices to help with prosecuting nanotechnology patents.

Nonetheless, the rush to patent at such an early scientific stage could present roadblocks to development and innovation. In particular, scholars have expressed concern that patenting "building block" technologies will create a "patent thicket" that could hinder development and commercialization of nanotechnology in fields ranging from biotechnology to electrical engineering.

Going forward, it is important for regulators and industry members alike to monitor the proliferation of nanotechnology in the marketplace, the promise of nanotechnology for advancement of science and industry, and the effects of patenting practices upon development of this new and exciting field.