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VENABLE LLP ON INTELLECTUAL PROPERTY LAW

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VENABLE LLP ON INTELLECTUAL PROPERTY LAW

U.S. patent law is both a boon and a bane to industry. The law is intended to spur genuine improvements to industry by, as President Lincoln put it, "adding the fuel of interest to the fire of genius." In this way good patents have issued for products, machines, methods, and compositions that have solved chronic problems, improved quality and reliability, saved time and resources, and combined elements in ways previously unimagined. Inventors and patent owners rightfully profit from these inventions for up to 20 years. Thereafter the monopolies end and the public has full use and enjoyment of the inventions, free of charge.

Our patent system also churns out bad patents that hurt industry. Half the 6,000 U.S. patent examiners have less than four years' experience.[i] The Patent and Trademark Office (PTO) measures examiners' performances largely on quantity, not quality.[ii] Patent examiners typically have thirty hours or less to understand an invention, assess patentability over prior art, attend to countless formalities, write reports, and respond to inventor arguments. It's no wonder many of the 150,000-plus patents issued annually are for undeserving patent claims, but patent owners can nevertheless charge infringement, forcing infringers to respect the patents or pay sometimes enormous sums to challenge validity. The threat of litigation sometimes keeps an entire industry from the benefits of a new technology that should in fairness be in the public domain.

There is a third category of patents, including one of the water treatment patents discussed below, that fall somewhere in between good patents for meritorious inventions and harmful patents for undeserving claims. They are patents for meritorious inventions that deserve protection under U.S. patent standards, but are nevertheless subject to invalidation because of inattention to the myriad of requirements and conditions underlying the patent system. These patents are the most unsatisfying for inventors, who see reasonable expectations for exclusive rights denied. They can also fail to serve the public goal of fostering innovation, since they

can leave good ideas without an investor to take the idea to market, and they can encourage unwarranted litigation expense.

We begin this paper with an overview of the two basic requirements for patentability – novelty and unobviousness. We then examine the novelty requirement by way of two recent water treatment disputes, *Wedeco UV Technologies v. Calgon Carbon Corp.*[iii] and *Clearwater Systems Corp. v. Evapco Inc.*[iv] Next we discuss important changes to the unobviousness requirement. The U.S. Supreme Court alarmed technology owners in May 2007 when it criticized lower counts for being too soft on inventors when assessing unobviousness, but recent court decisions have marginalized the Supreme Court's 2007 pronouncement in unpredictable fields like water chemistry. We close by suggesting patent management policies that can avoid outcomes like those that befell Calgon and Clearwater.

OVERVIEW OF THE NOVELTY REQUIREMENT

The water treatment patents discussed below were undone by the "novelty requirement," so it makes sense to explain that requirement first. To be patentable in the United States, an invention must be novel and unobvious.[v] The word "novel" as used in the Patent Statute bears little resemblance to a dictionary definition of the word. Instead, the Statute defines an invention as being "novel" if it is not completely taught in a *single* piece of "prior art," which is defined by law to include such things as a prior patent, publication, sale, or commercial use.[vi] It is also important to understand how the term "anticipation" is used in connection with novelty. When a single piece of prior art fully describes each and every aspect of the claimed invention, the invention is said to be "anticipated" by the piece of prior art. The invention therefore lacks novelty and is unpatentable. Conversely, if no prior art anticipates the claimed invention, the invention is novel.

When considering an inventor's entitlement to a patent, the novelty requirement is strictly applied. In the recent case of *In re Gleave,*[vii] Gleave's patent application included one set of claims directed to oligodeoxynucleotide-containing compounds,[viii] and another set directed to the *use* of those compounds to treat cancer. The examiner rejected Gleave's claims to the compounds for lack of novelty, based on a prior art reference that listed 1,400 different oligodeoxynucleotides, including those described in Gleave's compound claims. Gleave appealed but the U.S. Court of Appeals for the Federal Circuit agreed with the examiner, concluding that the single prior art reference included each compound of every claim, and that it was irrelevant that the reference lumped Gleave's compounds in with hundred of others. Fortunately for Gleave his second set of claims were method claims that recited an additional element, namely, the step of *using* the compositions to fight cancer. The examiner found these claims to be patentable because the reference did not describe the use of the compounds for that purpose.

In addition to being anticipated by *literal* teachings in a prior art reference, patent claims can be *inherently* anticipated by what the reference *necessarily implies*. If for example a structure in the prior

art necessarily functions in accordance with the steps recited in an applicant's claimed process, the claim is anticipated, and this result holds true even if the inherent disclosure was neither known nor appreciated by those skilled in the art. A recent example of inherent anticipation arose in the case of *In re Omeprazole Patent Litigation*.[ix] The patent at issue claimed a method for making Prilosec that included the step of creating a separating layer by an *in situ* reaction. The alleged infringers cited a prior patent application that described a method for producing a drug similar to Prilosec.[x] The prior art did not refer to an *in situ* reaction, but when the prior art method was practiced, a separating layer would in fact form *in situ* each and every time. This consistent and therefore necessary result of the *in situ* formation of a separating layer resulted in a finding of inherent anticipation. Conversely, in the field of water treatment, the court in *Ecolochem* found that a reference ("Demmitt") showing the removal of hydrazine with a cation resin did not inherently anticipate a claim calling for the removal of hydrazine to levels of less than one part per billion, notwithstanding that it was "entirely possible and indeed likely" that the cation resin substantially completely removed the hydrazine. Because removal to levels of one ppb did not *necessarily* happen, inherent anticipation was not shown.[xi]

Congress crafted the novelty requirement not only to prevent someone from patenting technology that existed before, but also to encourage inventors to invent and to publicly disclose their inventions as soon as possible. The sooner an inventor files an application for patent, the sooner his 20-year monopoly will start to run, and the sooner the monopoly will expire and the invention will enter the public domain. This serves the goal of increasing the storehouse of public knowledge. As a result, the novelty requirement is crafted in a way that it can strip a dilatory inventor of all claims to his invention, even if he was the first to invent. Thus, an inventor cannot patent his own invention if he waits and files a patent application more than one year after he made the invention public, sold or commercially used the invention in the U.S., or offered the invention for sale in the U.S.[xii] Similarly, where two unrelated inventors independently conceive the same invention, the one who conceives second can win the right to a patent if the first inventor is not diligent in making the invention or filing an application.[xiii]

OVERVIEW OF THE UNOBVIOUSNESS REQUIREMENT

The unobviousness requirement is usually more difficult for inventors and patent owners to satisfy than the test for novelty. In determining unobviousness, teachings from different pieces of prior art, two earlier patents for example, can be *combined*, and the question becomes whether a person of ordinary skill in the art would have found it obvious to come up with the invention based on the teachings of the two patents, taken in light of all other teachings from prior art sources.[xiv]

The unobviousness requirement can also be more difficult to satisfy because of its more subjective nature – what would have been "obvious" to one person or judge may not have been "obvious" to another, especially when considering that skeptics

tend to believe they would have come up with an invention after it is disclosed to them. The statute attempts to lessen subjectivity by requiring that unobviousness be measured hypothetically through the eyes of "a person having ordinary skill" in the field of the invention, not through the eyes of a detached judge or juror. Second, the statute requires that unobviousness be assessed "at the time the invention was made," not with the use of perfect hindsight at the time of an infringement or patent dispute.

The test for unobviousness is not restricted to consideration of the differences between the invention and related technology in the prior art. The law also requires a patent examiner or court to consider non-technical evidence as to how others perceived and reacted to the invention, such as evidence of teaching away, a need in the industry that went unsolved until the invention was made, failures of others to make the invention, commercial success of the invention, acclamation for the invention by others, unexpected results, and copying of the invention by others. This kind of evidence, known generically as "objective" or "secondary" evidence, is typically created by uninterested parties, outside any adversarial context. As such it can be especially pertinent in determining unobviousness. In the field of water treatment, *Ecolochem* remains as a good example of how courts can use objective evidence to reject validity challenges based on obviousness.[xv]

Sometimes companies overlook the value of their inventions because of a misperception that patentable inventions must involve cutting-edge science or scholarly research. To the contrary, the Patent Statute was written to fulfill the objectives of Article 1, Section 8 of the U.S. Constitution, which gave Congress the power to enact laws that protect contributions to the "useful arts."[xvi] Congress exercised that power by specifying that "[p]atentability shall not be negatived by the manner in which the invention was made." This means that inventions may be unobvious and patentable even if they are made accidentally and even if they appear simple in hindsight. Mark Twain illustrated this concept when asked to name the greatest inventor of all time. His response: "Accident."

NOVELTY AND THE DEMISE OF CALGON AND CLEARWATER PATENT CLAIMS

The novelty requirement has recently been the biggest stumbling block for patent holders in the water treatment field. The parties in *Wedeco UV Technologies v. Calgon Carbon Corp.* battled over the validity of patent claims to a method for purifying drinking water with ultraviolet light. Calgon's patents claimed methods for using low dosages of UV light to inactivate the protozoans *Cryptosporidium parvum* ("Crypto") and *Giardia muris* ("Giardia") in drinking water.[xvii] Wedeco manufactures UV water disinfection systems. It brought the lawsuit and alleged that Calgon's U.S. Patents 6,129,893 and 6,565,803 were invalid.

There had been serious outbreaks of Cryptosporidium leading up to Calgon's claimed invention.[xviii] Before Calgon filed its applications in 1998 and 1999, prior art systems had used low

dosages of UV light to disinfect bacteria and viruses in drinking water, but it was generally understood in the industry that low dosages of UV light were ineffective for inactivating protozoans. Wedeco filed this suit when Calgon claimed that its patents for UV disinfection systems covered the use of UV light to inactivate Crypto and Giardia. In seeking a declaratory judgment, Wedeco sought to have Calgon's patents declared invalid, and the patent dispute centered on whether or not Calgon's patent claims were anticipated.

Calgon argued that the prior art did not anticipate because, before its invention, no one had thought UV water treatment methods would inactivate Crypto, and no single piece of prior art specifically showed the use of UV light to inactivate protozoans in drinking water. Wedeco argued to the contrary that Calgon's patent claims were anticipated by the commercial use of UV technology at Fort Benton, Montana. The city's system was one of about 50 such systems in use in the United States in the late 90s. The system employed UV light to remove harmful contaminants from drinking water, but there was no evidence that Crypto or Giardia were present in the water supply, and that they had therefore been removed. Nevertheless, Wedeco's expert testified that the protozoans would *necessarily* have been removed *if* they were present, and Wedeco argued that the practice at Fort Benton thus inherently anticipated Calgon's claims.

The district court ruled in favor of Wedeco, finding that the Fort Benton public use inherently anticipated. The court found that the inactivation of Crypto was inherent in the use at Fort Benton, relying on experts' sworn testimony that the prior art systems would have inactivated Crypto if it had been present. According to Calgon's own expert, "Every prior UV water treatment process that inactivated bacteria necessarily inactivated Crypto." The court found this to be clear and convincing evidence that the inactivation of Crypto was the "natural result" of the operation of the UV disinfection methods stated in Calgon's claims, and thus inherent in those claims.

The court addressed Calgon's argument that, to prevail, Wedeco must have proven that Crypto was present at Fort Benton and the prior art system actually inactivated it. The court countered that inherent anticipation only requires that a prior art reference discloses a method that "naturally results" in the claimed invention. The court relied in particular on an earlier pronouncement by the U.S. Court of Appeals for the Federal Circuit in *Bristol-Myers Squibb Co. v. Ben Venue Labs* that, for process claims, "newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent."[xix]

The district court provided equitable considerations in support of its finding of inherent anticipation. It considered the unfairness to the operators of the Fort Benton facility in the event that, through natural variations in water supply, Crypto and Giardia, were introduced into the water supply, such that Fort Benton would then infringe. The court also noted Calgon's expert's opinion that Fort Benton could one day infringe, and recited the maxim "That which

would literally infringe on a patent if later in time, anticipates if earlier." The court seemed to suggest that, because Fort Benton's water supply has changed and will continue to change due to natural causes, the maxim should apply to invalidate Calgon's claims. Calgon appealed and Wedeco argued to the Federal Circuit that there was evidence that the protozoans had actually occurred in Fort Benton's system prior to the filing of Calgon's patent applications. This evidence would have strengthened Wedeco's arguments before the district court, making the inherency argument stronger. Whether or not the appellate court took this evidence into account is unknown, since it affirmed the district court's decision without explanation.

The *Calgon* case can have significant implications in water treatment, since water supplies can include hundreds and thousands of varieties of contaminants, and the toxic nature of some of these may currently be unknown. Prior art systems may already be removing some of these contaminants, albeit without the knowledge of the systems' operators. In future arguments against inherency, patent owners may be able to rely upon the language of *Bristol-Myers Squibb,* quoted above. In that case, the Federal Circuit stated that, in the case of method or process patents, inherent anticipation applies where the results are inherent *and* the process of the prior art is directed to the "same purpose" as the claimed invention. In *Calgon,* the purpose of Fort Benton's system was to remove contaminants from drinking water, and the removal of the named protozoans would have helped serve that purpose. In other cases, differences between the prior art and claimed purpose have helped avoid invalidity.[xx]

Third-party uses and disclosures are not the only concerns innovators must keep in mind. Materials developed *in house* can also serve as prior art in the anticipation analysis. In *Clearwater Systems Corp. v. Evapco Inc.,* Clearwater's U.S. Patent 6,641,739 was for a method of using a burst of magnetic flux to oxidize liquid and thereby treat microorganisms in the liquid. Evapco asserted that a patent already owned by Clearwater, U.S. Patent 6,063,267 for a device that used the method claimed in the '739 patent, inherently anticipated the method claims. The court agreed, observing that the description contained in the '267 patent inherently anticipated the method because, according to the method patent, when the device of the '267 patent is used, the oxygen-bearing oxidizing agent of the '739 claim is always produced. Because of this, the court held that the agent was inherently present in the '267 patent, and that the '739 patent was therefore invalid due to anticipation. It did not matter that the '739 patent may have embellished upon the disclosure that originally appeared in the '267 patent, since "[d]iscovery of a previously unappreciated property of a prior art composition, or a scientific explanation for the prior art's function, cannot be the basis for a valid patent.[xxi] Because each element of the '739 patent was expressly or inherently present in the '267 patent when practiced, the '739 patent claims were invalid.

Similarly in *Zenon Environmental Inc. v. United States Filter Corp.*,[xxii] anticipation was based on one of Zenon's earlier patents. Zenon owned U.S. Patent 6,620,319 for a microfiltration system that included a "multiplicity of vertical fibers," a pair of headers, and

"permeate collection means held peripherally in fluid tight engagement with each header so to collect permeate from the ends of the fibers." The system used a gas distribution system to clean the fibers in the engagement, and the '319 patent was the sixth patent to issue from a series of connected applications that were filed by the same assignee. Zenon sued US Filter for infringing various patents, including the '319 patent. Both parties conceded during trial that each and every claim of the '319 patent was included in an earlier patent filed by Zenon, U.S. Patent 5,639,373, and Zenon contended that the patents it obtained between the '373 patent and the '319 patent incorporated by reference the gas distribution system claimed in the '373 patent. By incorporating the gas distribution system by reference in the connecting patents, Zenon attempted to use those connecting patents as stepping stones to relate the '319 patent back to the '373 patent so that Zenon could claim an early filing date. Unfortunately for Zenon, the court ruled that the intervening patents did not incorporate by reference the gas distribution system. As a result the court held that the '319 patent was invalid because the '373 patent disclosed each and every element of the '319 patent, thereby invalidated by anticipation.

THE EBB AND FLOW OF OBVIOUSNESS CRITERIA: *KSR* (2007) TO *PROCTER & GAMBLE* (2009)

The U.S. Supreme Court roiled patent owners with the issuance of its May 2007 decision in *KSR*.[xxiii] The case struck at the heart of the U.S. Patent Statute by purporting to raise the standard for unobviousness. In its wake the allowance rate for U.S. patent applications dropped to 44% in 2008, the lowest rate in over 30 years, and district court decisions invalidating patents increased as well. But recent decisions of the U.S. Court of Appeals for the Federal Circuit have largely eliminated *KSR's* impact in unpredictable fields such as water treatment.

***KSR* RAISED THE UNOBVIOUSNESS STANDARD:** For many years prior to May of 2007, the U.S. Court of Appeals for the Federal Circuit (the appellate court responsible for all patent appeals) had accepted a relatively wide range of evidence and arguments in support of unobviousness. Several press accounts generally critical of allegedly lax patentability standards circulated in 2005 and 2006, however, and against that backdrop the Supreme Court issued its *KSR* decision in May 2007, overturning a decision below by the Federal Circuit. The Supreme Court's decision curtailed inventors' arguments and generally increased the inventor's burden of proving that his invention was worthy of a patent. The following is a summary of the Supreme Court's most significant holdings in *KSR*:

1. ***The TSM test.*** The Federal Circuit had for many years prior to 2007 relied on the so-called "TSM test" to assess obviousness. The test generally required that, to successfully defeat an inventor's patent claim, an examiner or patent challenger establish that there was something in the prior art that taught, suggested, or motivated one skilled in the art to make the claimed invention. In *KSR*, the Federal Circuit had held that the district court had not applied the

TSM test strictly enough, since it failed to make findings as to the specific understanding or principle that would have motivated one with no knowledge of the invention to make the invention. On review, the Supreme Court rejected the Federal Circuit's rigid application of the test and concluded that a patent can be found invalid even when the TSM test is not satisfied.

2. ***Scope of the relevant prior art.*** The Supreme Court criticized the Federal Circuit's assessment of the scope of the prior art. It surmised that the Federal Circuit's narrow conception of the obviousness inquiry, resulting from its flawed application of the TSM test, was related to the Federal Circuit's overly narrow view that courts and patent examiners should look only to the problem the inventor was attempting to solve and only to prior art addressing that problem. The Supreme Court said:

> Common sense teaches . . . that familiar items may have obvious uses beyond their primary purposes, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle.[xxiv]

This statement encourages patent examiners and courts to look at a broader range of prior art teachings, and in some cases the broader consideration of prior art has prevented the issuance of patents and led to invalidity findings.

3. ***Obvious to try.*** The Supreme Court disapproved of the Federal Circuit's treatment of the so-called "obvious to try" exception to obviousness, whereby the Federal Circuit had reasoned that teachings in the prior art were merely evidence that one skilled in the art would have found the claimed invention obvious to try, and not necessarily obvious. According to the Supreme Court:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. . . . [and the resulting discovery] is likely the product not of innovation but of ordinary skill and common sense.[xxv]

This statement has led to the disallowance or invalidity of patent claims where a prior art reference, while not teaching the new invention per se, has significantly narrowed a range of possibilities from which the invention could be selected and tested.

4. ***Combinations and unpredictable results.*** The Supreme Court's decision states that a claimed combination of "familiar elements" according to known methods is "likely to be obvious" if it does not yield unpredictable results, but it stops short of requiring a showing of unpredictability any time elements of a claimed combination are found in the

prior art. However, when the claimed invention involves a "simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement," the Supreme Court said that a court "must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions."[xxvi]

The Supreme Court's rejection of the TSM test as a requirement for showing obviousness was the most significant aspect of *KSR*. Where previously an applicant or patentee could sometimes rely solely on the TSM test to defend against an obviousness challenge based on prior art, some examiners and courts thereafter required the applicant or patentee to affirmatively show why the combination of teachings would not have been obvious. The impact of *KSR* was limited in part by the fact that many patent examiners and courts had already been applying the unobviousness test more stringently, and some of the Supreme Court's anti-patent pronouncements in *KSR* were contradicted by the Court's pro-patent pronouncements in the same decision. But *KSR* has an anti-patent tone, and the tone alone has caused greater scrutiny of arguments for patentability, and consequent expense in obtaining and defending patents.

PROCTER & GAMBLE LOWERS THE STANDARD IN UNPREDICTABLE ARTS: The Federal Circuit has rebelled against the anti-patent implications of KSR when considering unobviousness in unpredictable chemical and pharmaceutical arts, and this trend recently culminated in *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc*.[xxvii] In *Procter & Gamble* the Federal Circuit constricted the impact of *KSR* by endorsing, and indeed even suggesting a renewed requirement for, the TSM test in unpredictable arts. Teva had challenged P&G's patent claims for the compound risedronate, the active ingredient of P&G's osteoporosis drug Actonel.[xxviii] Risedronate is a member of a group of compounds referred to as bisphosphonates. Bisphosphonates were known to be active in inhibiting bone resorption, but clinical problems had prevented their commercialization. P&G conducted a significant amount of experimentation involving hundreds of different bisphosphonate compounds, but could not predict the efficacy or toxicity of the new compounds. Eventually, P&G's researchers identified risedronate as a promising drug candidate.[xxix]

The prior art reference asserted by Teva neither claimed nor disclosed risedronate, but instead claimed an intermittent dosing method for treating osteoporosis. The prior art reference "addressed the central problem seen in bisphosphonates at the time, namely that they inhibited bone mineralization, by teaching the use of a cyclic administrative regimen to achieve a separation of the benign effect of anti-resorption from the unwanted side effect of anti-mineralization in patients." The reference listed thirty-six polyphosphonate molecules as treatment candidates and eight preferred compounds for intermittent dosing, including 2-pyr EHDP, which Teva contended was so structurally similar to risedronate as to render P&G's patent invalid for obviousness. The

district court disagreed, finding that the prior art reference would not have led a person of ordinary skill in the art to identify 2-pyr EHDP as the lead compound, and that, in light of the extremely unpredictable nature of bisphosphonates at the time of the invention, a person of ordinary skill would not have been motivated to make the specific molecular modifications to make risedronate. Based on the unexpected results of risedronate's potency and toxicity the district court rejected Teva's invalidity challenge, and Teva appealed.

The Federal Circuit summarized the pertinent parts of the U.S. Patent Statute on appeal, and suggested anew that a patent challenger must show a teaching, suggestion, or motivation to combine:

> A party seeking to invalidate a patent based on obviousness *must* demonstrate by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so. (Emphasis added.)[xxx]

The Federal Circuit attempted to resolve the apparent contradiction between this statement and the Supreme Court's decision in *KSR* by saying the Supreme Court found the "teaching, suggestion or motivation" test to provide helpful insight as long as it is not applied rigidly, and then went on to say that, notwithstanding *KSR,* "it remains *necessary* to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound." (Emphasis added.)[xxxi]

The Federal Circuit observed that there were structural similarities between risedronate and 2-pyr EHDP. Both are positional isomers since they each contain the same atoms arranged in different ways. But to successfully argue that a new compound is obvious, the Federal Circuit said "it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound."[xxxii] After reciting an expert opinion that the physical-chemical, biological and therapeutic characteristics of one bisphosphonate could not be predicted by the characteristics of others and unexpected results of P&G testing, the Federal Circuit concluded that Teva failed to make a prima facie case of obviousness under the TSM test, saying the district court did not err when it found that Teva failed to establish sufficient motivation for a person of ordinary skill to synthesize and test risedronate.

The Federal Circuit also considered Teva's challenge to unobviousness on grounds that the prior art made it "obvious to try" risedronate as part of routine testing. The appellate court noted the Supreme Court's warning in *KSR* against granting patents for unworthy advances and then observed, notwithstanding, that researchers can only "vary all parameters or try each of numerous possible choices until one possibly arrive[s] at a successful result,

where the prior art [gives] either no indication of which parameters [are] critical or no direction as to which of many possible choices is likely to be successful," and that, in such cases, "courts should not succumb to hindsight claims of obviousness."[xxxiii] The Federal Circuit also held that patents are not to be barred just because it was obvious "to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it."[xxxiv] The Federal Circuit concluded that there was no credible evidence that P&G's structural modification was routine.

Because Teva established no prima facie case of unobviousness, the Federal Circuit found considered objective evidence in the nature of teaching away, a long-felt but unsolved need in the industry, failures of others to make the invention, commercial success, acclaim for the invention, copying by others, and unexpected results, and decided that the objective evidence was sufficient to overcome the invalidity challenge. For extra measure, however, the Court held that, even if Teva had established a prima facie case of obviousness, P&G had established sufficient evidence of unexpected results as to rebut such a showing, and that a finding of unobviousness was also supported by risedronate's commercial success and its satisfaction of a long-felt unmet need.

PUTTING RECENT DEVELOPMENTS TO WORK: EFFECTIVE PATENT MANAGEMENT AND ACCURATE ASSESSMENTS

Lessons can be learned from the cases discussed above. The advantage of hindsight shows that Calgon could have better assessed the prior art, and in particular, the possibility that a prior art reference teaching the use of ultraviolet light could have inadvertently though necessarily removed the protozoans of Calgon's patent claims. Had this inherent prior art teaching been realized earlier on, some or all of the subsequent expense of developing and protecting the invention may have been avoided. In the *Clearwater* case, a better informed research department could have realized in advance that they were creating prior art that would be used against them to destroy their investment in the invention claimed. The failure of patent claims to water treatment technology points up the need to develop sound policies for managing technology and assessing patent rights. Such policies should include the following components:

CONDUCT IP AUDIT OF COMPANY AND ITS COMPETITORS: In 1978, about 80% of a typical company's assets were tangible (buildings, equipment, and the like) and 20% were intangible, including patents and trademarks, according to a study by the American Intellectual Property Law Association. By 2000, this relationship reversed, with almost 80% of a typical company's assets being intangible. It is increasingly important to take stock of technology assets as a first step in knowing what needs to be maintained and may be exploited. An IP audit also examines and evaluates strengths and weaknesses of the procedures used to identify, develop, and manage important technology. A company's own personnel may be sufficiently knowledgeable to conduct the audit, but attorney input is recommended and can shield the

results from future disclosure under the attorney-client privilege.

IDENTIFY GOOD IDEAS, DECIDE IF PATENT IS WARRANTED, FOLLOW THROUGH: Too often valuable ideas are not appreciated until after patenting opportunities have expired. Establish a committee that meets on a monthly or quarterly basis to discuss any new idea, how exclusive patent rights in the idea might benefit the company, and the steps that will be taken to ensure follow-through. Important dates should be docketed, including the absolute deadline for filing a patent within one year of any sale, offer for sale, public disclosure, or commercial use of the invention. Sometimes it makes sense to protect ideas as trade secrets rather than as patents, and in this case follow-through may take the form of ensuring that sufficient safeguards are in place in maintain secrecy of the information.

ASSESS PRIOR ART AND MARKETPLACE BEFORE COMMITTING FUNDS: Because the development, marketing, and protection of an invention can be expensive, it is important to objectively assess prior art and the likelihood that the marketplace will yield profits that will make the investment worthwhile. When the business plan relies heavily on defensible patent protection, a reasonable search for and assessment of prior art can become paramount in importance, along with the need to disclose known prior art information to the examiner. Competitors are likely to look for and find reasonably accessible prior art if patents are enforced against them, as was the case in *Calgon*.

EDUCATE EMPLOYEES ON PATENT BASICS: Employees need to know the basics of patent law so that they (a) do not overlook valuable ideas that may be patentable, or over-invest in ideas that are not patentable, (b) maintain new ideas in confidence and report them to management, and do not unnecessarily create prior art that can be used against them**,** (c) establish a verifiable record of the conception and development of new ideas, in case needed to show inventorship, (d) understand and observe the one-year deadline for filing applications, and observe diligence when developing patentable ideas, and (e) avoid making decisions that would result in the infringement of competitors' patents.

MAKE SURE TECHNOLOGY-RELATED PAPER WORK IS IN ORDER: Important agreements for a technology-owning company include (a) incoming employee agreements that put employees on notice of the company's ownership of ideas conceived and developed while employed, (b) reminders to exiting employees as to the commitments they made when they were hired, and (c) written procedures, redistributed on a periodic basis, for storing and accessing trade secret information, and for sharing it as needed with third parties.

PROMOTE INNOVATION WITH INCENTIVE PROGRAM: Most employees expect that ideas conceived and developed on company time are owned by the company. This is helpful for managing employees' expectations, but it may also serve to de-incentivize innovation. An increasing number of companies consider programs that recognize innovation with monetary rewards for ideas that are deemed worthy of patenting, or that become

embodied in successful products or methods, or that generate licensing income.

PUT TECHNOLOGY TO WORK: Patent owners can exploit the economic value of their patents in several ways, depending on the quality of the technology, the scope of the patent claims, the objectives of the patent owner and its competitors, and the financial condition of the market. Patents that are not being used to make money in one way might make money if used in another. The owner may use its patents to:

1. Gain an advantage by being the sole provider of a better product or service.
2. Gain an advantage by reducing costs and increasing efficiencies.
3. Deter potential competitors from entering a market, or encouraging them to leave.
4. Obtain royalty income by licensing competitors, using the income to better compete.
5. Obtain royalty income by licensing use in non-competing markets or fields of use.
6. Gain leverage in cross-licensing - a license is granted for a valuable license in return.
7. Demonstrate the company's innovation and technological know-how to customers.
8. Increase assets to attract investors, preferred lenders, or merger partners.
9. Defend against infringement charges by others who may be cross-infringing.
10. Sue infringers for damages (lost profits/reasonable royalties), costs, and injunction.
11. Sue willful infringers and also claim increased damages and attorneys' fees.

CONCLUSION

U.S. Patent Law is not set in stone, but is constantly changed and refined by Congress and the courts. Recent decisions on water treatment patents help illustrate the operation of patent law and the importance of the doctrine of anticipation. Innovators are advised to stay current with these developments and put systems in place to maximize the value of their technology. *KSR* presented challenges to inventors in unpredictable arts such as water treatment. But due in part to the ambiguous and self-conflicting nature of *KSR*, the U.S. Court of Appeals for the Federal Circuit has been able to restrict and contain *KSR's* impact where technology is by nature unpredictable.

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[i] The USPTO hired 1,193 new patent examiners In Fiscal Year 2006 (year ending September 30, 2006), 1,215 new examiners in fiscal 2007, and 1,211 in fiscal year 2008. See: USPTO Performance and Accountability Report Fiscal Year 2007 and 2008, United States Patent and Trademark Office.

[ii] Examiners receive one credit each time they complete a "First Office Action" and one each time they allow or finally reject an application.

[iii] *Wedeco UV Technologies v. Calgon Carbon Corp.,* No. 01-924, 2006 WL 1867201 (D.N.J., June 30, 2006), *aff'd,* 223 Fed.Appx. 982.

[iv] *Clearwater Systems Corp. v. Evapco Inc.*, No. 3:05cv507, 2009 WL 68204 (D.Conn. Jan. 8, 2009).

[v] The novelty requirement appears in Section 102 of the Patent Statute (35 U.S.C. § 102), and the unobviousness requirement appears in Section 103 (35 U.S.C. § 103).
[vi] Section 102 generally permits a patent unless the invention had previously been patented in the U.S. or abroad, described in a publication in the U.S. or abroad, known or used by others in the U.S., in public use or on sale in the U.S., described in a pending patent application that later issued as a U.S. patent, or made in the U.S. by another who did not "abandon, suppress, or conceal" the invention.
[vii] *In re Gleave*, 560 F.3d 1331 (Fed. Cir. 2009).
[viii] Claim 1 was deemed to be representative of the composition claims: "1. Bispecific antisense oligodeoxynucleotide, wherein substantially all of the oligodeoxynucleotide is complementary to a portion of a gene encoding human IGFBP-2 and substantially all of the oligodeoxynucleotide is also complementary to a gene encoding human IGFBP-5, and wherein the oligodeoxynucleotide is of sufficient length to act as an antisense inhibitor of human IGFBP-2 and human IGFBP-5." *Id.* at 1333.
[ix] *In re Omeprazole Patent Litigation,* 483 F.3d 1364, 1367 (Fed. Cir. 2007).
[x] *Id.* at 1368.
[xi] *Ecolochem, Inc. v. Southern California Edison Company,* 863 F.Supp. 1165 (C.D. Ca. 1994), *rev'd on other grounds,* 91 F.3d 169 (Fed. Cir. 1996).
[xii] 35 U.S.C. § 102(b).
[xiii] 35 U.S.C. § 102(g).
[xiv] Section 103 states: "A patent may not be obtained though the invention is not identically disclosed or described as set forth in Section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."
[xv] *Ecolochem, Inc. v. Southern California Edison Company,* 227 F.3d 1361 (Fed. Cir. 2000), *cert. den.,* 121 S.Ct. 1607. Ecolochem obtained patent protection on its DEOX® Process for removing dissolved oxygen from water. The process was commercially successful, was copied by others, and helped solve a persistent corrosion problem. The court ruled that Ecolochem was entitled to recover increased damages with interest, as well as attorneys' fees due to the willful nature of the infringement.
[xvi] Article 1, Section 8 gives Congress the power "To promote the … useful Arts, by securing for limited Times to … Inventors the exclusive Right to their respective … Discoveries."
[xvii] Claim 1 of Calgon's '893 patent is representative and reads: "A method for the prevention of cryptosporidium oocysts comprising irradiating water with a continuous broad band of ultraviolet light in doses of from about 10 mJ/cm2 to about 175 mJ/cm 2."
[xviii] In 1993, for example, a Cryptosporidium outbreak in Wisconsin caused an estimated 403,000 people to become ill, and was believed responsible for more than 100 deaths. Corso P, Kramer M, Blair K, Addiss D, Davis J, Haddix A (2003). "Cost of illness in the 1993 waterborne Cryptosporidium outbreak, Milwaukee, Wisconsin". Emerg Infect Dis 9 (4): 426–31. ww.ncbi.nlm.nih.gov/pubmed/12702221.
[xix] *Bristol-Myers Squibb Co. v. Ben Venue Labs. ,* 246 F.3d 1368 at 1375 (Fed. Cir. 2001).
[xx] In *Ecolochem,* one of the patent claims called for the removal of hydrazine with cation resin to a level of less than one part per billion. A prior art reference showed the use of a cation resin to remove hydrazine from water, but the hydrazine was removed so that it would not interfere with a specific chemical reaction downstream, as opposed to hydrazine removal to facilitate use in boiler equipment.
[xxi] *Id.* (internal citations omitted).
[xxii] *Zenon Environmental Inc. v. United States Filter Corp., 506 F.3d 1370, 1372 (Fed. Cir. 2007).*
[xxiii] *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007),
[xxiv] *Id.* at 420.
[xxv] *Id.* at 421.
[xxvi] *Id.* at 417.
[xxvii] *Procter & Gamble Co. v. Teva Pharmaceuticals USA Inc.*, 566 F.3d 989 (Fed. Cir. 2009).
[xxviii] *Id.* at 993-994.
[xxix] *Id.* at 993.
[xxx] *Id.* at 994.
[xxxi] *Id.*
[xxxii] *Id.* at 996.
[xxxiii] *Id.* at 996-97.
[xxxiv] *Id.* at 997.