IDEAS ON INTELLECTUAL PROPERTY LAW

YEAR END
2016

When is a sale not a sale?
Federal Circuit narrows on-sale bar to patents

Music to Internet service providers' ears
Appellate court extends DMCA safe harbor

Intent to infringe
Verdict goes against medical device maker

Single factor preempts likelihood of trademark confusion claim

ROUTE TO

STURM & FIX LLP

When is a sale not a sale?

Federal Circuit narrows on-sale bar to patents

The full panel of the Federal Circuit Court of Appeals, which hears all patent-related appeals, has delivered a ruling in *The Medicines Co. v. Hospira, Inc.* that's sure to be welcomed by patent holders. In a unanimous decision, the court provided guidance on what constitutes a sale for purposes of the on-sale bar to patent validity.

DRUG COMPANIES DUKE IT OUT

The Medicines Company (MedCo) held product and product-by-process patents that covered Angiomax, a drug used to prevent blood clotting. The company didn't have its own manufacturing facilities. So, in 1997, it contracted with Ben Venue Laboratories to manufacture commercial quantities of the original formula of Angiomax. The two patents at issue covered a new compounding process for the drug and the applications for the patents were filed July 27, 2008.

In late 2006, MedCo paid Ben Venue Laboratories (Ben Venue) to manufacture three batches according to the patents. The commercial-sized batches were completed October 31, November 21 and December 14. They were placed in quarantine pending approval by the Food and Drug Administration. The batches were released and made available for sale in August 2007.

In 2010, MedCo sued drug manufacturer Hospira, Inc., for patent infringement. Hospira argued that the patents were invalid under the on-sale bar, but the trial court disagreed. A three-judge panel of the Federal Circuit reversed. It held that the on-sale bar *did* apply because MedCo had "commercially exploited" the invention before the critical date (one year before the application filing date), even though the company hadn't transferred title to the commercial embodiment of the invention. The case then came up for review before the full Federal Circuit.

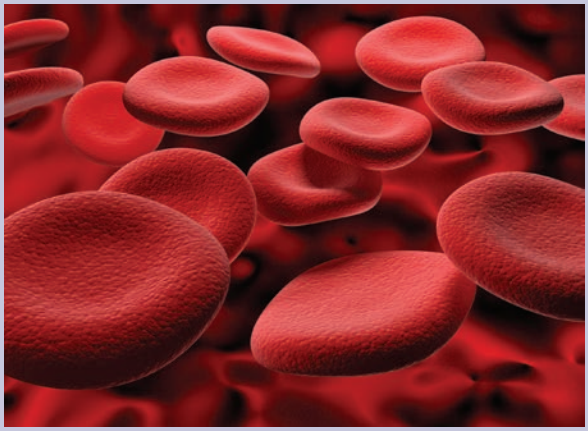
COURT FOCUSES ON FIRST PRONG

The on-sale bar applies when an invention has been "on sale" before the critical date. According to the U.S. Supreme Court, the bar applies if the invention was:

1. The subject of a commercial offer for sale, and
2. Ready for patenting.

The Federal Circuit in this case focused on the first prong of the test, concluding that transactions between MedCo and Ben Venue didn't constitute commercial sales of the patented product. Citing the Uniform Commercial Code, the court found that a commercial sale must be a sale in a commercial sense — that is, it requires a contract between parties for consideration the buyer pays or promises to

COURT REJECTS "SUPPLIER EXCEPTION"



In its ruling in *The Medicines Co. v. Hospira, Inc.* (see main article), the Federal Circuit Court of Appeals made an important clarification regarding suppliers in relation to the on-sale bar. Even though it decided that transfers between suppliers and inventors or manufacturers don't trigger the on-sale bar, the court was *not* recognizing a "supplier exception" to the bar. Such an exception would mean that a commercial sale could never occur if the inventor purchased the patented product from its supplier.

The court conceded that, when a transaction is between a supplier and inventor, it's "an important indicator that the transaction is not a commercial sale." However, the transaction isn't determinative on its own. The court explained that a transfer of product to the inventor from a supplier could constitute a commercial sale if:

- The supplier has title to the patented product or process,
- The supplier receives blanket authority to market the product or disclose the process for manufacturing it to others, or
- The transaction is a sale of product at full market value.

The focus, the Federal Circuit emphasized, must be on the commercial character of the transaction, not solely on the participants' identity.

pay the seller for the thing bought or sold. The mere sale of manufacturing services by a contract manufacturer to an inventor to create embodiments of a patented product for the inventor didn't rise to that level. And in this case, only manufacturing services were sold, not the invention itself.

Moreover, the court said, MedCo maintained control of the invention by keeping title to it. The passage of title is a "helpful indicator" of whether a product is on sale because it suggests when the inventor gives up its interest and control over the product. Ben Venue didn't have title to the products, nor was it free to use or sell the products or deliver them to anyone other than MedCo.

Further, stockpiling (building inventory prior to a commercial sale) by inventors that outsource manufacturing, in and of itself, doesn't trigger the on-sale bar. When stockpiling isn't accompanied by an actual sale or offer for sale, it's merely precommercial activity in preparation for future sale. The court reasoned that penalizing a company that uses third-party manufacturers would be unfair. After all, companies with in-house manufacturing capabilities aren't punished for their manufacturing activities or stockpiling.

When stockpiling isn't accompanied by an actual sale or offer for sale, it's merely precommercial activity in preparation for future sale.

The appellate court therefore affirmed the trial court's holding that the arrangements between MedCo and Ben Venue didn't trigger the on-sale bar. The court also sent the case back to the three-judge panel to consider issues on appeal that the panel

didn't need to address due to its finding that the patents were invalid under the bar.

WHAT HAPPENS NEXT?

This decision effectively exempts common manufacturing and supply arrangements from the on-sale bar. Biotechnology and pharmaceutical companies that use third-party manufacturers are likely to be the biggest beneficiaries.

One important side note: *Medicines Co.* was considered before the 2011 passage of the America Invents Act (AIA), which made significant amendments to U.S. patent law. In its decision, the court stated that it wasn't addressing whether or to what extent its analysis might differ post-AIA. ◻

Music to Internet service providers' ears

Appellate court extends DMCA safe harbor

The Second Circuit Court of Appeals recently ruled on the hotly debated issue of whether the Digital Millennium Copyright Act's (DMCA's) safe harbor provision applies to sound recordings created before 1972. That's when Congress first extended copyright protections to such recordings. With *Capitol Records, LLC v. Vimeo, LLC*, the Second Circuit is the first federal appellate court to tackle the question, and its opinion no doubt brought a huge sigh of relief from Internet service providers.

CASE RECORD

A group of record and music publishing companies sued Vimeo, Inc., a video-sharing website, alleging that Vimeo was liable for copyright infringement because of 199 videos posted on the site. The plaintiffs owned the copyrights on the recordings in those videos.

Vimeo argued that it was protected by the DMCA's safe harbor provision. The provision shields Internet service providers from liability for infringement when users upload copyrighted content to their sites and the providers are unaware of the infringement. But the DMCA does require providers to remove material if they receive notice of infringement or otherwise become aware of infringement.

The trial court found that Vimeo was protected under the DMCA for 153 of the 199 videos. But it ruled that the safe harbor didn't apply to recordings created earlier than 1972 because the provision protects only against copyright infringement liability under federal law. Pre-1972 recordings are covered by state copyright laws. Vimeo appealed the ruling.

COURT SOUNDS OFF

On appeal, the Second Circuit found that excluding older recordings would undermine Congress's purpose for passing the copyright protection law. The legislative history of the DMCA suggests that Congress intended to shield Internet service providers that comply with the rules from liability and make it economically feasible for them to provide online services.

If the provisions didn't cover pre-1972 sound recordings, service providers would have to monitor every posting to ensure it didn't contain infringing recordings or incur "potentially crushing liabilities" under state copyright laws. Both would be financially prohibitive. After all, the court noted, some of the most popular recorded music of all time was recorded before 1972, including songs by the Beatles, the Supremes, Elvis Presley, Barbra Streisand and Marvin Gaye.

So the appellate court ruled that the DMCA's safe harbor provisions *do* apply to pre-1972 recordings, even though the recordings are protected by state — not federal — copyright law.

This position contradicted statements made by the U.S. Copyright Office in a 2011 report. The court characterized the Copyright Office report's interpretation as "based in major part on a misreading of the statute." Contrary to that opinion, the appellate court said that safe harbor protection isn't limited to copyrights protected by federal law. Rather, a "literal and natural reading" of the provision leads to the conclusion that the phrase "infringement of copyright" includes infringement of state copyright laws.

NOTE OF CAUTION

It's worth noting that the appellate court decision is precedential only for those states within its territory — Connecticut, Vermont and New York. Internet service providers may not enjoy the same protections for pre-1972 sound recordings in courts in other states. ◻

Intent to infringe

Verdict goes against medical device maker

When the U.S. Supreme Court agreed that an appellate court's infringement ruling should be reconsidered, it probably seemed like good news to the medical device maker that had been found liable in the initial ruling. Alas, the new ruling that followed reconsideration also went against the company. The Federal Circuit Court of Appeals found the position in the company's defense "objectively unreasonable."

DEVICE MAKER CHARGES INFRINGEMENT

NuVasive, Inc., holds a patent on a method for detecting the presence of and measuring the distance to a nerve during surgery. Its device uses a series of electrical pulses that gradually increase in strength until a pulse reaches sufficient strength to elicit a nerve response. The stimulus signal stops immediately after the response is detected (the patent's "stopping limitation").

When Warsaw Orthopedic, Inc., and Medtronic Sofamor Danek USA (collectively, MSD) sued NuVasive for patent infringement, NuVasive counterclaimed, accusing MSD of infringing its patent. In March 2015, the appeals court affirmed a trial court's verdict that MSD infringed the NuVasive

patent, holding that users of MSD's device (doctors) directly infringed the patent and that MSD induced this infringement.

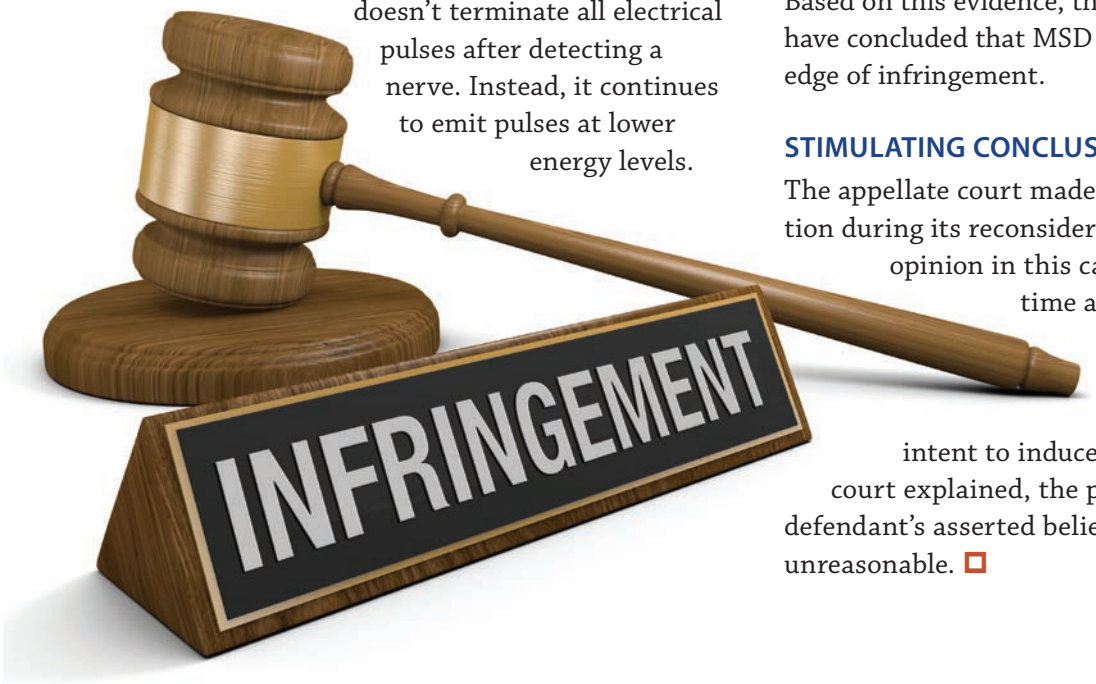
COMMIL PROMPTS RECONSIDERATION

Three months later, the Supreme Court decided *Commil USA, LLC v. Cisco Systems, Inc.* In that case, it held that proof of induced infringement requires not only knowledge of the patent but also proof that the defendant knew the induced acts were infringing. According to the Federal Circuit, the ruling also necessarily reaffirmed that willful blindness can satisfy the knowledge requirement, even in the absence of actual knowledge.

The *Commil* decision prompted MSD to ask the Supreme Court to vacate the appellate court's ruling. MSD contended that NuVasive had failed to prove that MSD had the requisite knowledge to induce infringement. The Supreme Court sent the case back to the appellate court for reconsideration.

COURT SIGNALS ITS SKEPTICISM

On reconsideration, the appellate court focused on whether the jury had enough evidence to infer that MSD knew — or was willfully blind to the fact — that doctors' use of its device infringed NuVasive's patent. MSD asserted that the patent's stopping limitation required a complete termination of any and all electrical pulses. Therefore, MSD argued, its device didn't infringe the patent because the device doesn't terminate all electrical pulses after detecting a nerve. Instead, it continues to emit pulses at lower energy levels.



The appellate court found this position "objectively unreasonable." It concluded that the stopping limitation requires stopping a particular kind of signal — "said stimulus signal," or the signal that elicited a response from the nerve being probed. This doesn't require stopping any and all electrical signals emitted by the device. According to the court, neither the language in the patent nor its prosecution history supported MSD's position that the patent required complete termination of all electrical stimulus pulses.

> The ruling reaffirmed that willful blindness can satisfy the knowledge requirement, even in the absence of actual knowledge.

And the original jury heard undisputed evidence that, immediately after nerve stimulation, MSD's device reduced the strength of the electrical stimulus pulses it emitted to a level that wasn't capable of stimulating the nerve that had provided the response. In other words, the court said, the "said stimulus signal" emitted by the device stopped immediately after the nerve response was detected.

MSD's knowledge of the patent was also undisputed. Based on this evidence, the jury could reasonably have concluded that MSD had the requisite knowledge of infringement.

STIMULATING CONCLUSION

The appellate court made an important clarification during its reconsideration. It stated that its opinion in this case didn't mean that any time a defendant's products are found to directly infringe, the plaintiff has sufficiently established an intent to induce infringement. Rather, the court explained, the plaintiff can show that a defendant's asserted belief in noninfringement was unreasonable. ◻

Single factor preempts likelihood of trademark confusion claim

When a trademark or potential trademark is challenged, courts and the Trademark Trial and Appeal Board (TTAB) generally turn to the so-called *DuPont* factors to determine whether a likelihood of confusion exists between two marks. Courts don't necessarily consider all 13 factors and, in fact, a single factor can settle the matter. This was the case in *Oakville Hills Cellar, Inc. v. Georgallis Holdings,* decided by the Federal Circuit Court of Appeals.

REGISTRATION FILING UNCORKS OPPOSITION

Georgallis Holdings, LLC, filed to register the mark MAYARI for use on wine. Oakville Hills Cellar, Inc., opposed the registration, claiming that the mark would likely cause confusion with its previously registered and used mark MAYA, also for wine.

When the TTAB evaluated 10 *DuPont* factors and concluded that confusion wasn't likely, it dismissed the opposition. Oakville Hills appealed.

RULING STEMS FROM SINGLE FACTOR

On review, the appellate court found that the TTAB didn't err by balancing 10 relevant *DuPont* factors and determining that a single factor — similarity of the marks — would settle the issue of likelihood of confusion. The court explained that a single factor may be conclusive when that factor is the *dis*similarity of marks.

Oakville disputed the TTAB's finding of insufficient similarity between the marks. Among other things, it argued that MAYA dominates both marks and that the suffix "RI" in MAYARI was of "minor import" as a distinguishing element. It further argued that the board shouldn't have found that MAYARI has no meaning and that a consumer wouldn't view MAYARI as MAYA plus "RI."

The court disagreed. It pointed out that, in determining similarity or dissimilarity, marks must be compared in their entireties, which include appearance, sound, meaning and commercial impression. There was no reason to think that, even if consumers dissected MAYARI into separate components, the dissection would be "MAYA-RI," not "MAY-ARI" or "MA-YARI." The court also found no evidence that the marks would be pronounced alike or that MAYARI has recognized meaning to U.S. consumers. It therefore upheld the TTAB's dismissal of Oakville's opposition.

TIP TO REMEMBER

While a single *DuPont* factor might settle a likelihood of confusion question, it's important to remember that the factor itself might take into account multiple factors. As *Oakville* shows, when "similarity of the marks" has been singled out, a court or the TTAB will consider appearance, sound, meaning *and* commercial impression. ◻

Expertise you can rely on

When you need legal services relating to patents, trademarks, copyrights or other intellectual property, call the experienced professionals at Sturm & Fix LLP. Since our firm's founding in 1962, we have focused exclusively on helping clients protect and defend their intellectual property rights. We serve a wide spectrum of U.S. and international clients in the areas of patent, trademark, copyright, trade secret and unfair competition law. Our services include application preparation, prosecution, licensing, litigation and counsel on intellectual property matters.

Our skilled attorneys have a broad range of experience and expertise that enables them to effectively communicate with and serve clients in all areas of science and technology, including:

- Agricultural Engineering
- Animal Science
- Biomedical Engineering
- Chemical Engineering
- Civil Engineering
- Food Technology
- Mechanical Engineering
- Pharmaceuticals
- Physics

We welcome the opportunity to discuss your needs and to put our expertise to work for you. Please call us today and let us know how we can be of service.

Sturm & Fix LLP
Suite 1552 • 666 Walnut Street • Des Moines, IOWA 50309-3971
Telephone (515) 288-9589 • Telefax (515) 288-4860

Partners

Michael O. Sturm

Richard L. Fix

STURM &FIX LLP

www.hsllp.com