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Where intellectual property and business law intersect with industry.

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Phillips Nizer has been supporting its clients and community to address the challenges of the COVID-19 pandemic. The health of our clients, contacts and friends, as well as our attorneys, our staff and their families remains our first priority. Our remote operations have allowed us to continue to serve our clients without interruption. We are here to provide legal support, address individual business needs, advice on dealing with COVID-19 issues or simply to say hello. Please email or call us anytime. We wish you and your families and colleagues good health as we navigate the days ahead together.

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Patents in the World of Coronavirus Vaccines

With the COVID-19 pandemic predicted to circulate globally for at least the next two years, researchers and scientists alike are racing to produce a vaccine at a pace that the medical world has never seen before. Now more than ever, numerous scientists and pharmaceutical professionals are working on developing treatments for the deadly illness that has claimed over 250,000 lives in just the United States over the past several months. Many legal experts believe that the declining economy as a result of COVID-19 will see the same increase in individuals seeking to patent their latest inventions similar to the boom in patent filings that followed the Great Recession of 2008. As a result of anticipated new medical discoveries, legal implications are sure to follow.

Inventors seek to patent their ideas in order to have exclusive access to the market. A patent allows an inventor to prohibit others from making, using, or selling the same invention for twenty years, thus giving the inventor the ability to sell or otherwise profit from the invention without competition from copycats during this period. In the medical field, a patent can equate to a legalized monopoly which could restrict significantly the availability of the invention.

The patenting of vaccines and medical treatments for COVID-19 raises moral and ethical implications. The main purpose of a COVID-19 vaccine is to prevent further infections and deaths resulting from one of the most infectious viruses in a century. And while the creator of one of these vaccines would want to patent it for economic gain, such a patent could pose a barrier to the public's access to the vaccine. The patent owner's exclusive rights may prevent access to critical medical therapies, such as other potential COVID-19 vaccines. Given the extent of the current global medical crisis, companies will be under pressure to sacrifice patenting their discoveries and losing out on potential financial benefits. One option companies will have is to patent their COVID-19 inventions but not enforce them. Indeed, due to the unprecedented nature of the pandemic and the urgent need for the vaccines to be distributed in mass amounts, there are ethical pushes for companies to forgo patent protection, or at least enforcement of patent rights once obtained, for the sake of greater public health.

For example, biopharmaceutical company Gilead Sciences was urged not to enforce exclusivity rights for the medical treatment Remdesivir, which would allow other countries to replicate and create generic models of the brand medication to distribute. Another company, AbbVie, gave up its intellectual property rights for its antiviral treatment, Kaletra. It no longer enforces patents relating to all formulations of Kaletra anywhere in the world.

Even if companies proceed to secure patent protection for vaccines or COVID-19 treatments, governments may have access to the vaccines or treatments via the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"). TRIPS provides a way for governments to license patented products without the permission of the owner through compulsory licensing. There are dozens of potential vaccines currently in development around the world, which could lead to access obstacles depending on the country. For example, there are researchers in the United States, Europe, Canada, and China all rushing to produce a successful vaccine. As some countries (e.g., the United States and China) are engaged in a trade war, the ability to create a viable vaccine first would enable that country to have leverage over the other. TRIPS allows for exceptions to the exclusive rights held by a patent owner and also allows for compulsory licensing by the government that can opt in to this provision. In this case, a patented vaccine may be produced without the consent of a patent owner in a national emergency, such as the current pandemic.

In the United States, the government may force patent owners to grant compulsory licenses when there is a threat to public safety. Under 28 U.S.C. Section 1498, the government has the ability to use patented inventions without permission while also paying the owner "reasonable and entire compensation." The U.S. government has invoked or threatened to invoke this right in the past when faced with a national health emergency.

In addition, under The Bayh-Dole Act of 1980, the federal government is allowed to utilize "march-in rights" by exercising exclusive licensing rights over federally funded patents. The statute also permits the government to grant additional licenses if the invention is not made available "on reasonable terms."

The statute outlines four specific situations where such "march-in rights" may be invoked, including to "alleviate health or safety needs which are not reasonably satisfied by the contractor." If a COVID-19 vaccine is too expensive, and not possible for a biomedical company to make it available to a large portion of the population, then perhaps the federal government can argue it qualifies for "march-in rights" in such a situation.

It should be noted that these rights have never actually been invoked by the U.S. government to regulate drug prices. The legislators who wrote the law have stated that their intent was not for "government [to] set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional. . ."[1] It nevertheless is possible that the government could seek to invoke "march-in rights" for licensing of a COVID-19 vaccine due to the urgent and grave nature of the situation.

There also is the issue of trade secrets which, unlike patents, do not require registration with the government. A person or company seeking to protect trade secrets or other proprietary information must keep it confidential so that it is not available to the public. In this case, to protect a vaccine formula as a trade secret would mean keeping it confidential from the public and other companies so they are not able to duplicate it. Trade secret protection is used by many businesses to maintain their competitive advantages, most famously by Coca-Cola, to prevent others from deciphering its "secret sauce." In the current crisis, of course, any attempt by a company to treat the formulation of a COVID-19 vaccine as a trade secret would undoubtedly create serious ethical complications, to say nothing about the adverse public backlash likely to follow.

Despite the pressure to freely release COVID-19 vaccine formulations, the United States Patent and Trade Office ("USPTO") has maintained that it is committed to relieving certain restrictions regarding patent filings and incentivizing innovations that may help fight the battle against this pandemic. It has issued new rules that are likely to significantly decrease the time it takes to get COVID-19 related patents to issuance, i.e., COVID-19 related patents may issue

[1] Brian Farkas, *Trade Secret Basics FAQ*, NOLO, https://www.nolo.com/legal-encyclopedia/trade-secret-basics-faq.html#1743193 (last visited Nov. 1, 2020).

and be enforceable within six months,[2] whereas the typical patent process can take two years or longer. With regard to patent term extensions for human drug products awaiting FDA approval, the prohibition against filing initial patent term extension applications through the USPTO filing system was waived in late May, and the usual requirement of having two additional copies of the initial extension application also was waived. Further, the USPTO stated that it will forgo petition fees to revive patent applications that were deemed abandoned, terminated, or limited due to the effects of the virus outbreak, which relieves filers of significant fees. The guidelines described above will also make it easier for scientists, pharmacists, and inventors throughout the country to attempt to protect their latest medical innovations.

As the race to develop effective COVID-19 vaccines continues, it remains to be seen how major pharmaceutical companies decide to utilize and protect these products and other discoveries, and how the USPTO will react. In short, the current situation engenders the following question: Will the urgency of a global health crisis outweigh an inventor's right to exclusivity and the right to profit from his or her novel discoveries?

[2] 85 Fed. Reg. 28932.

Major League Baseball Grants Unprecedented COVID-19 Relief to Licensees in Good Standing by Eliminating 2020 Minimum Guarantees

When Major League Baseball Properties negotiated and consummated its licenses for the 2020 Season, COVID-19 was not a part of this country's vernacular. Minimum guarantees were determined based on detailed business plans and projected sales through multiple distribution channels, which included in-stadium and retail sales. Unlike the National Basketball Association and National Hockey League, which already had played the vast majority of their respective regular season games with fans in attendance when their seasons were suspended due to the COVID-19 pandemic, the Major League Baseball (MLB) regular season was reduced from 162 games to only 60 games. Play finally started in last week of July, but without any fans in attendance and at a time when many retail sporting goods stores across the nation were closed as a result of the pandemic. Even Fanatics, the largest of all professional sports licensees, shifted its focus from producing licensed products to producing PPEs for the country's first responders.

Consequently, many MLB licensees consulted with sports lawyers to ascertain whether or not they could receive relief from their contractual minimum guarantee obligations for the 2020 baseball season as a result of a "force majeure" or Act of God.

To MLB's credit, it acted swiftly to provide licensees with relief. On April 2, 2020, all MLB U.S. licensees received a memorandum from Dennis Nolan, MLB's Global Senior VP, Consumer Products, that read in relevant part: "Our next priority after playing games again is to make sure we are doing all we can to support our long-term partners. With that in mind, we are prepared to offer each licensee that is currently in good standing with MLB the opportunity to demonstrate that your sales of MLB license products have been harmed as a direct result of the COVID-19 crisis."

During the month of April, licensees received a form to fill out to demonstrate the impact of COVID-19 on their actual and projected sales. The form also allowed each licensee to provide a narrative about how the pandemic otherwise impacted its business. The data collected was then reviewed by the licensee's MLB account representative along with executives at Major League Baseball Properties.

Those licensees that were able to demonstrate significant harm to their sales and business as a result of the COVID-19 pandemic were then provided a proposed amendment to their license agreements offering to eliminate all 2020 minimum guaranteed compensation obligations, provided that such licensees continued to pay royalties on actual sales and met certain other conditions. In exchange, MLB sought some legal protections for itself. For example, the proposed amendment made clear that such relief from guaranteed compensation was each licensee's exclusive remedy with respect to COVID-19 and that, with the sole exception of the licensee satisfying mandatory payments on outstanding loans to its existing secured lenders, its obligation to pay fees to Major League Baseball Properties based on the sale of licensed products in

2020 would receive priority over all obligations of the licensee to third parties.

By taking early action, MLB allayed the concerns of its licensing partners without having to engage in prolonged negotiations or litigation over the force majeure clause or the enforceability of its license agreements. That said, MLB has made it clear that new licenses for the 2021 season would not contain waivers of guaranteed compensation and that such waivers should not be expected.

Tiffany v. Costco Part II

On August 17, 2020, the Second Circuit Court of Appeals finally ruled on one of the most anticipated intellectual property cases of the year in *Tiffany & Co. et al. v. Costco Wholesale Corp.*, which overturned Tiffany's $21 million award against Costco.[3]

In a previous newsletter, we reviewed this dispute which started eight years ago over Costco's use of the "Tiffany" trademark on diamond engagement rings. To recap, in the fall of 2012, Costco displayed signs bearing the terms "Tiffany set", "Tiffany setting" and "Tiffany style" alongside pictures of jewelry. Alerted by a customer, Tiffany sent Costco a cease and desist letter to remove the advertising. Despite Costco's compliance, Tiffany moved forward with a suit. Ultimately, the Southern District of New York found Costco liable for both trademark infringement and counterfeiting, on summary judgment. Tiffany was awarded $21 million in treble damages.

The Second Circuit reversed the District Court's multi-million dollar ruling, stating that there were still issues of triable fact that should have been placed before a jury. In its 42-page decision, the Second Circuit warned against making factual determinations at the summary judgment stage. The Court reasoned that finding a likelihood of confusion between the Costco and Tiffany rings was not automatic because it was possible for a juror to find that Costco's use of the term "Tiffany" was a generic use of the word to describe a particular stone setting. Many anticipated that Tiffany's win in the District Court would be overturned because of this descriptive fair use argument.

The Second Circuit also held that knowledge is required to be found liable for counterfeiting.[4] In advance of the Second

[3] *Tiffany and Co. et al. v. Costco Wholesale Corp.*, 2nd Circuit Court of Appeals, No. 17-2798.

[4] 15 U.S.C. §1117, Trademark Counterfeiting Act of 1984.

Circuit's decision, trademark practitioners and brand owners expressed concern that upholding Tiffany's victory would lower the liability threshold for counterfeiting, where the damage awards exceed those for trademark infringement. Such brand owners were worried that if they engaged in inadvertent copying, they would be vulnerable to counterfeiting claims. However, the Second Circuit's ruling distinguished unintentional copies from counterfeit goods because some form of knowledge or the "intent to deceive" is necessary for counterfeiting.[5]

Tiffany & Co. et al. v. Costco Wholesale Corp. has now been remanded back to the U.S. District Court in Manhattan for a new trial. Tiffany's attorneys released a statement that they remain confident that they will secure another victory during the retrial. One thing remains clear: the retrial of this intellectual property battle is highly anticipated by both brand owners and their lawyers.

Editorial contributions made by:

Candace R. Arrington, Isabel Malmazada, Monica P. McCabe, Tod M. Melgar, Edward H. Schauder and **Andrew J. Tunick**

Phillips Nizer IP Practice News

The firm welcomed **Tod M. Melgar**, **Gerard A. Haddad** and **Jason Plotkin** to the firm. Mr. Melgar leads the firm's patent litigation and prosecution practice as a partner in the New York office. He has litigated a wide variety of patent, trade secret, copyright and trademark disputes in federal district and appellate courts, as well as argued patent issues before the U.S. Patent Trial and Appeal Board. He has worked for top high tech industry companies, including hardware and software, medical device, cellular and digital transmission systems, LEDs and lasers. A registered patent attorney, Mr. Melgar has prepared and prosecuted hundreds of patent and trademark applications, and provided general counseling to clients on patent portfolio development, intellectual property due diligence, licensing and enforcement of rights issues.

Mr. Haddad focuses his practice on intellectual property litigation and counseling, and has litigated patents in the fields of computer software and hardware, medical devices, pharmaceuticals and telecommunications.

[5] *Tiffany and Co. et al. v. Costco Wholesale Corp.*, at 23.

He joined the firm as Counsel in the patent litigation practice.

Mr. Plotkin is a registered Patent Attorney. His practice focuses on all aspects of patent prosecution and litigation, with a focus on electronics and software technologies. He joined the firm as an associate in the patent litigation practice.

Committees and Appointments

Patrick J. Burke was appointed to the New York State Bar Association's Technology & the Law Committee.

Monica P. McCabe was selected to Co-chair the American Bar Associate Women in Dispute Resolution Program Committee.

Tod M. Melgar was appointed to the New York Intellectual Property Law Association, Law Firm Management Committee.

Edward H. Schauder was appointed to the New York City Bar Association Sports Law Committee.

Recognitions and Awards

Helene M. Freeman was recognized by *Billboard Magazine* as a 2020 Top Music Lawyer. Ms. Freeman and her co-counsel successfully defended Led Zeppelin against the claim brought by a trustee of the estate of deceased Spirit songwriter Randy Wolfe that "Stairway to Heaven" infringed on the copyright of the Spirit instrumental "Taurus." In March, the Ninth Circuit Court of Appeals affirmed a trial court's earlier decision of no copyright infringement. Significantly, the appeals court rejected the "inverse ratio rule," which declared that the higher the degree of access to a work, the lower the bar for proving substantial similarity. In September, the United States Supreme Court refused to hear the appeal.

Eleven Phillips Nizer attorneys were recognized by Best Lawyers, including **Alan Behr**, **Helene M. Freeman** and **Marc A. Landis**. Additionally, our **Copyright** and **Trademark** Law practices were recognized in the national and New York City metro tiers.

Seventeen Phillips Nizer attorneys were selected as 2020 New York Metro Super Lawyers, including **Alan Behr** and **Monica P. McCabe** (Intellectual Property), **George R. Fearon** and **Helene M. Freeman** (Entertainment & Sports), **Marc A. Landis** (Real Estate), **Edward H. Schauder** (Corporate/Business), and **Martin B. Wasser** (Environmental).

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Special thanks to our summer associate, **Isabel Malmazada** for her contributions to this newsletter.