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Broad Claim Language May Render Patent Invalid Under Obviousness

In *BTG Int'l Ltd. v. Amneal Pharms. LLC* (Fed. Cir. May 14, 2019), the Federal Circuit affirmed the decisions of the Patent Trial and Appeal Board (PTAB) and the District Court in a consolidated appeal addressing whether generic versions of an anti-cancer drug infringed the claims of U.S. Patent No. 8,822,438 (the '438 patent) held by BTG International Ltd (BTG). The PTAB and the District Court found that the asserted claims of the '438 patent were obvious and therefore invalid. The Federal Circuit focused on one of the final written decisions of the PTAB, which it affirmed, rendering the remaining appeals moot.

Background

BTG produces Zytiga (abiraterone acetate), a CYP17 inhibitor used in conjunction with prednisone to treat refractory prostate cancer. The '438 patent discloses a method to treat cancer by administering a therapeutically effective amount of a CYP17 inhibitor and a therapeutically effective amount of an additional therapeutic anti-cancer agent or a steroid. With more specificity, independent claim 1 of the patent claims a treatment method combining a therapeutically effective amount of abiraterone acetate and a therapeutically effective amount of prednisone.

Appeal

The central issue for the Federal Circuit was whether a person having ordinary skill in the relevant art would have known that prednisone could be used as a cancer treatment. Prednisone had been part of the standard of care for treating refractory prostate cancer prior to issuance of the '438 patent, but BTG asserted that its patent required that prednisone have a direct anti-cancer effect on its own, as opposed to its well-known use of reducing side effects of co-administered cancer treatment. However, the Federal Circuit determined that the "treatment" described in the '438 patent could mean either a direct anti-cancer effect, or a palliative effect reducing toxicity of abiraterone.

The Federal Circuit's analysis began with the claim language and specification. Independent claim 1 claims a method for the treatment of prostate cancer comprising administering a therapeutically effective amount of prednisone along with abiraterone. The specification defines a "therapeutically effective amount"

of a "therapeutic agent" as an amount for treating a disease or disorder such as cancer, and states that a "therapeutic agent" may be either "an anti-cancer agent or a steroid." The Federal Circuit concluded that the use of "or" in the specification suggested that a steroid is not necessarily the same thing as an anti-cancer agent.

The Federal Circuit discussed how, if BTG intended to limit "treating" and "therapeutic agents" to "anti-cancer agents," the patent would not have identified steroids separately as agents for reducing adverse side effects of CYP17 inhibitors, nor described prednisone in the specification as a steroid without mentioning any anti-cancer effect. Thus, the Federal Circuit concluded that treatment with prednisone must logically include more than just anti-cancer effects, and should include the long-familiar use of steroids for palliation and reduction of side effects.

The Federal Circuit determined that the prosecution history also supported this conclusion. During prosecution, the examiner initially rejected claims based on a combination of prior art discussing abiraterone's anti-cancer effects and the treatment of refractory prostate cancer by co-administering prednisone to relieve the toxicity of anti-cancer drugs. The examiner subsequently allowed the claims after determining that the unexpected commercial success of abiraterone in combination with prednisone overcame the obviousness rejection. The examiner also noted that the cited art did not suggest that there would be a difference in survival rates between one cancer agent alone versus the same agent combined with prednisone.

Thus, the Federal Circuit concluded that the prosecution history was consistent with the understanding that the claimed treatment requires the combination of abiraterone with prednisone, and the claims would not have been allowable otherwise. However, the Federal Circuit agreed with the PTAB that a person having ordinary skill in the art would have had a reasonable expectation of success in combining abiraterone and prednisone because they were both considered, together and individually, promising prostate cancer treatments at the time. In particular, a combination of prior art taught that (1) patients with hormone refractory metastatic prostate cancer responded favorably to a combination of ketoconazole (a CYP17 inhibitor) and prednisone; (2) abiraterone treats prostate cancer by suppressing testosterone, and it is common to administer a supplemental glucocorticoid; (3) prednisone alone significantly reduces PSA levels, an indicator of disease activity, in patients with hormone-refractory prostate cancer.

Although administration of glucocorticoids such as prednisone had not demonstrated a survival advantage at the time the '438 patent was filed, the law only requires a reasonable expectation of success. In addition, while BTG's product did have considerable commercial success, BTG also owned a blocking patent that would have deterred others from exploring the commercial potential of abiraterone. Accordingly, the Federal Circuit rejected BTG's appeal, and held that its patent was invalid based on obviousness..

Conclusion

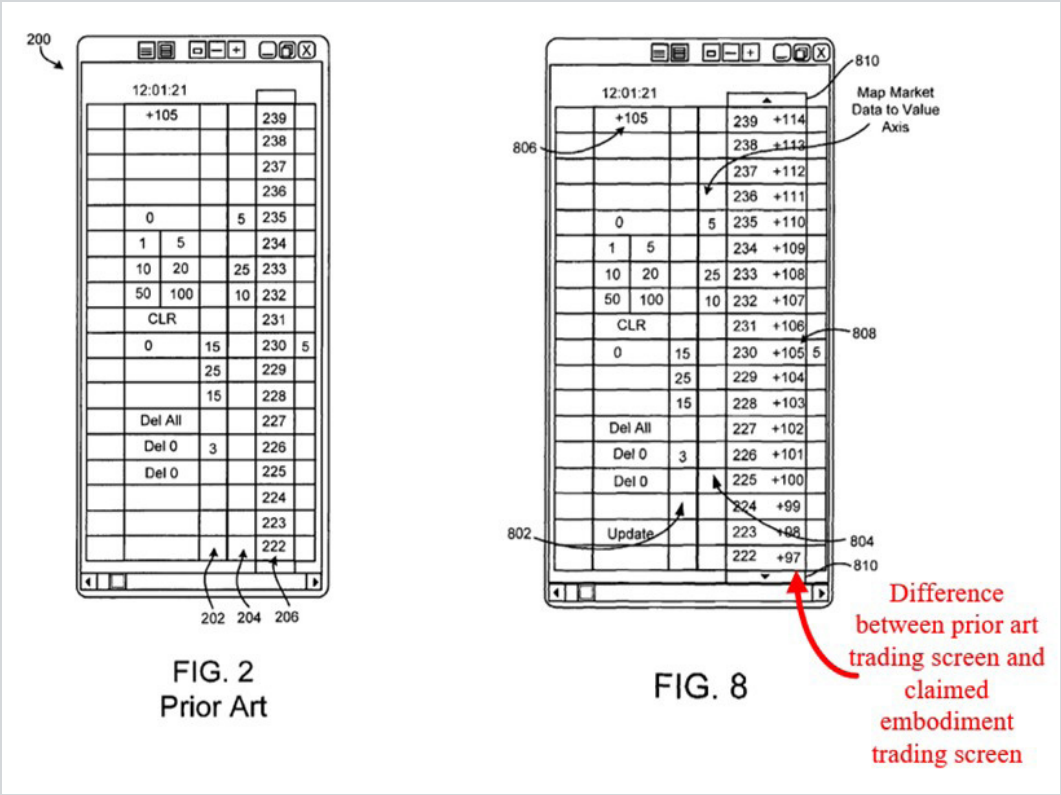
Although the '438 patent focused on prednisone's anti-cancer effects, the patent also contained broad language about prednisone's use as a steroid, and because prednisone was already being used in treating refractory prostate cancer for the traditional palliative effects associated with steroids, the asserted claims were rejected as obvious. As the Federal Circuit stated, if BTG intended to limit "treating" and "therapeutic agents" to anti-cancer agents, the claim would not have also identified prednisone as a steroid and an agent for reducing adverse effects of abiraterone. Thus, patent drafters would be wise to craft specific claims and be wary of using overly broad language in their specification.

Patent Eligibility of GUI-Related Claims in Light of the Federal Circuit's Recent Decision in *Trading Techs. Int'l. v. IBG LLC*

Vera Suarez

In *Trading Techs. Int'l. v. IBG LLC*, the Federal Circuit affirmed the Patent Trial and Appeal Board's decision that the claims in a GUI-related patent, U.S. Patent No. 7,783,556 to Singer et al. (the '556 patent), were ineligible under 35 U.S.C. § 101.[1] Generally, the '556 patent relates to displaying a trading screen on a graphical user interface (GUI).[2] The trading screen displays market information to a trader and also places orders for a trade from the trader.[3] Using the *Alice* framework, the Federal Circuit determined that the claims were "directed to" an abstract idea at step one of the *Alice* framework, and that there were no additional elements that transformed the claims into a patent eligible application at step two of the *Alice* framework.[4] At first glance, this decision might be disappointing to inventors of GUI-related technology. However, a review of the '556 patent reveals support for this decision, which still leaves room for patent eligible GUI-related claims.

Referring to step one of the *Alice* framework, the Federal Circuit in *Trading Techs*. evaluated the "focus of the claimed advance over the prior art" to determine if the claims were directed to excluded subject matter.[5] To accomplish this, the Federal Circuit relied on the detailed review of the prior art in the '556 patent itself. The only difference between the trading screen provided in the prior art and that of the claimed embodiment was that the claimed embodiment added price derivative values to one of the columns.[6] This is best illustrated by the side-by-side comparison of Figure 2 and Figure 8 of the '556 patent, reproduced below:



Other than the addition of the price derivative values in the right-hand column shown in Figure 8, there are no other significant differences between the claimed embodiment illustrated in Figure 8 and the prior art trading screen illustrated in Figure 2.

Any claim limitations that went beyond the display of derivative values were found either not to constitute a patentable improvement, or to be identical to the prior art.[7] For example, claim limitations relating to how the values were calculated were classified as "nothing more than 'mere automation of manual processes using generic computers,'"[8] while claim limitations relating to placing an order using the screen were characterized as identical to the prior art[9] and, thus, did not provide an advance over the prior art.

After comparing the claimed embodiment and the prior art, the Federal Circuit stated that the claims "focused on providing information to traders in a way that helps them process information more quickly, '556 patent at 2:26-39, not on improving computers or technology."[10] The court also noted that the claims failed because "arranging information along an axis does not improve the functioning of the computer, make it operate more efficiently, or solve any technological problem", and concluded that the claims were directed to an abstract idea under step one of the *Alice* framework.[11]

The Federal Circuit's analysis of step two of the *Alice* framework was shorter. The court again noted that adding price derivative values to the screen was the only difference between the screens provided in the prior art and the claimed invention.[12] The specification of the '556 patent even acknowledged that one of ordinary skill in the art would recognize that there were many possibilities to calculate these price derivative values.[13] Moreover, displaying these values on the screen—even if never done before—did not provide "significantly more" under step two of the *Alice* framework because the use of the abstract idea to which a claim is directed cannot supply the inventive concept that renders the claim eligible under that step.[14] As such, the claims also failed step two of the *Alice* framework and were thus ineligible under 35 U.S.C. §101.[15]

Considering the similarities between the prior art and the claimed embodiment, the Federal Circuit's decision appears reasonable, and should not deter inventors from pursuing patent protection for GUI-related inventions. However, inventors considering filing GUI-related applications should consider including an advancement over the prior art that can **also** be tied to one to or more of the following improvements: 1) improving the functioning of the computer; 2) making the computer operate more efficiently; and 3) solving a technical problem, as well as including an explanation in those applications as to why the advancement results in one or more of the three above-listed improvements.

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1 *Trading Technologies Int'l, Inc. v. IBG LLC, et al.*, No. 2017-2323, slip op. at 11 (Fed. Cir. April 30, 2019).

2 The '556 patent at Abstract.

3 The '556 patent at col. 11 ll. 60-col. 12 ll. 3.

4 *Id.* at 10.

5 *Id.* at 8.

6 *Id.*; see the '556 patent.

7 *Trading Techs. Int'l. v. IBG LLC*, at 8-9.

8 *Id.*

9 *Id.*

10 *Id.* at 9.

11 *Id.*

12 *Id.*

13 *Id.*

14 *Id.*

15 *Id.*

Supreme Court Settles Split: Trademark License Rejection Under Bankruptcy Code Does Not Extinguish Licensee's Rights



Randall Colson | Ian Peck | Katharyn Zagorin

On May 20, 2019, the Supreme Court settled a circuit split concerning whether a debtor's rejection of a trademark license under § 365 of the Bankruptcy Code "deprives the licensee of its rights to use the trademark." In a decision written by Justice Kagan, the Supreme Court held that while a debtor-licensor's rejection of a trademark license results in a pre-petition breach, it does not constitute a rescission of the contract, and thus the licensee may retain the rights granted to it under the license.

Section 365 of the Bankruptcy Code permits a debtor filing for Chapter 11 protection to "reject any executory contract" subject to court approval. However, the bankruptcy code provides some protections for licensees of "intellectual property." Under § 365(n)(1), "if the rejected contract is one 'under which the debtor is a licensor of a right to intellectual property,' the licensee may elect to 'retain its rights…to such intellectual property." However, the relevant statutory definition of "intellectual property" does not include trademarks, leading to a long-standing question regarding the effect of a debtor-licensor's rejection of a trademark license.

Here, Tempnology, LLC, which manufactured exercise apparel under the name COOLCORE, granted a non-exclusive license to Mission Product Holdings, Inc. to use the COOLCORE marks. Several years later, Tempnology filed for Chapter 11 bankruptcy and rejected the license agreement. While both parties agreed that the rejection allowed Tempnology to stop performing under the contract and entitled Mission to a pre-petition claim for damages (both non-controversial propositions under bankruptcy law), Tempnology asserted that the rejection also terminated Mission's rights to use the licensed marks. Tempnology obtained a declaratory judgment from the United States Bankruptcy Court for the District of New Hampshire confirming that its rejection of the license agreement terminated Mission's rights. Thereafter, the United States Bankruptcy Appellate Panel of the First Circuit reversed, holding that rejection does not eliminate the licensee's contractual rights, just as the breach of an agreement outside of bankruptcy does not extinguish the rights of the non-breaching party—a holding consistent with Seventh Circuit case law (*Sunbeam Products, Inc. v. Chicago American Manufacturing, LLC*, 686 F.3d 372 (7th Cir. 2012)). Tempnology appealed, and the Court of Appeals for the First Circuit overturned the Bankruptcy Appellate Panel's decision. Because trademark licensors must exercise quality control over goods bearing the licensed marks in order to maintain their trademark rights, the First Circuit concluded that allowing the licensee to use the mark post-rejection would frustrate the statute's intent to "release the debtor's estate from burdensome obligations."

The Supreme Court reversed the First Circuit's decision and adopted the Seventh Circuit's rejection-as-breach approach, holding that "[r]ejection of a contract—any contract—in bankruptcy operates not as a rescission but as a breach." While "[t]he debtor can stop performing its remaining obligations under the agreement…. the debtor cannot rescind the license already conveyed." In short, the Supreme Court found that a "debtor-licensor's rejection cannot revoke the trademark license," and the licensee can continue to use the trademarks as permitted by the agreement.

While the Supreme Court has now provided trademark licensors and licensees with long-awaited certainty that a debtor-licensor's rejection of a trademark license does not constitute termination of the licensed rights, the practical effect of this holding remains to be seen. For example, a trademark license could require the licensee to obtain the licensor's approval before selling a licensed product. If the debtor-licensor fails to respond to the licensee's request for approval, the licensee may be unable to use the licensed mark. As highlighted in Justice Sotomayor's concurring opinion, special contractual terms, like this example, or state law could determine whether a particular licensee's rights practically survive the debtor's breach.

Paul Dietze, Elizabeth Crompton in *Law360*: FDA's Risk Evaluation Guidance Brings Clarity, Not Solutions

Paul Dietze, Ph.D.

Elizabeth Crompton, Ph.D.

This April, the U.S. Food and Drug Administration issued final guidance clarifying how the FDA applies the factors in section 505-1 of the Federal Food, Drug and Cosmetic Act[1] to determine whether a risk evaluation and mitigation strategy is necessary to ensure that the benefits of a drug outweigh its risks.

Section 505-1 of the FD&C Act was created as part of the Food and Drug Administration Amendments Act of 2007. A REMS is a required risk management plan to ensure that the benefits of a drug outweigh its risks.

To approve a drug, the FDA must determine that the drug is safe and effective for its labeled indications under its labeled conditions of use.[2] The REMS guidance notes that "FDA's determination that a drug is safe, however, does not suggest an absence of risk" and that "a drug is considered safe if it has an appropriate benefit-risk balance."[3]

A major factor in assessing benefits vs. risks is management of those risks, including both risk assessment and risk minimization. This is an iterative process that involves: "(1) assessing a drug's benefit-risk balance, (2) developing and implementing tools to minimize the drug's risks while preserving its benefits, (3) evaluating tool effectiveness and reassessing the benefit-risk balance, and (4) making adjustments, as appropriate, to risk minimization tools to further improve the benefit-risk balance."[4]

The process continues throughout a drug's life cycle, as the results of risk assessment inform the sponsor's decisions regarding risk minimization.[5]

Risk mitigation is intended to preserve a drug's benefits while simultaneously reducing the risks as much as possible.[6] Although routine risk mitigation measures, such as providing health care providers with risk information through FDA-approved prescribing information, are sufficient to preserve benefits for most drugs while minimizing risks, additional interventions beyond the FDA-approved labeling may be necessary to ensure that the drug's benefits outweigh its risks.[7]

In such a situation, the FDA may determine that a REMS is necessary to ensure an appropriate benefit-risk balance. The FDA can require a REMS at any time, from before a new drug is approved to after approval.[8] If a REMS cannot mitigate the risks associated with a drug such that the benefit would exceed the risks, the FDA will not approve the drug.[9]

If the FDA determines that a REMS is required as part of the risk management plan, the FDA may require one or more REMS elements such as a medication guide, a patient package insert and/or a communication plan.[10] In certain situations in which a drug has been shown to be effective but is associated with a specific serious risk that would weigh against approval, the FDA may further require that the REMS includes elements to assure safe use, or ETASU, to mitigate the risk.[11]

The ETASU can include one or more of the following requirements:

- Health care providers who prescribe the drug have particular training or experience, or are specially certified
- Pharmacies, practitioners, or health care settings that dispense the drug are specially certified
- The drug be dispensed to patients only in certain health care settings, such as hospitals
- The drug be dispensed to patients with evidence or other documentation of safe use conditions, such as laboratory test results
- Each patient using the drug be subject to monitoring
- Each patient using the drug be enrolled in a registry[12]

A REMS that includes an ETASU may also include an "implementation system to enable the applicant to monitor, evaluate, and improve the implementation of the elements," such as, for example, the development of a REMS-specific web site or call center to facilitate enrollment and the establishment of electronic

databases of certified health care settings.[13] In general, all REMS should include one or more overall goals, which, in the case of a REMS with ETASU should be directed to the specific risk the ETASU are designed to mitigate.[14]

If the FDA determines that a REMS is needed, the FDA will consider the goals of the proposed REMS to address the risks and what specific REMS elements could help meet those goals.[15] The REMS should be "designed to meet the relevant goals, not unduly impede patient access to the drug, and minimize the burden on the health care delivery system to the extent practicable."[16]

The REMS must also include a timetable for submission of assessments of the REMS, which usually will occur at 18 months, 3 years and 7 years after the REMS is approved.[17]

The REMS guidance explains that determining whether a REMS is necessary for a particular drug is "a complex drug-specific inquiry, reflecting an analysis of multiple, interrelated factors and of how those factors apply in a particular case. In conducting this analysis, the FDA considers whether (based on premarketing or postmarketing risk assessments) there is a particular risk or risks associated with the use of the drug that, on balance, outweigh its benefits and whether additional interventions beyond FDA-approved labeling are necessary to ensure that the drug's benefits outweigh its risks."[18]

When determining if a REMS is needed, the FDA considers information from a variety of sources, including, for example, the FDA's internal and external experts; input on relevant issues from other centers in the FDA, other government agencies, advisory committee meetings, the Drug Safety Oversight Board, literature, and professional societies.[19]

For approved drugs the FDA also considers information from post-approval clinical trials and other postapproval studies, including post-approval adverse event reports and active surveillance.[20]

In considering whether to require a REMS and what type of REMS should be required, the FDA considers the following six factors, as required by Section 505-1(a)(1) of the FD&C Act:

- The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug
- The expected benefit of the drug with respect to the disease or condition
- The seriousness of the disease or condition that is to be treated with the drug
- Whether the drug is a new molecular entity
- The expected or actual duration of treatment with the drug
- The estimated size of the population likely to use the drug[21]

All six factors are considered together, and no single factor is determinative as to whether a REMS is necessary.[22]

The REMS guidance discusses the application of each factor.[23]

The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug. "The more serious a drug's known or potential associated risks relative to its benefits, the more likely it is that a REMS will be necessary."[24]

The REMS guidance then provides examples. For example, for a drug that is associated with an adverse event that is reversible or preventable, the REMS may require monitoring the patient through laboratory studies to determine if the adverse event is present.[25]

On the other hand, a drug that is associated with an adverse event that is irreversible (e.g., that causes a permanent disability or persistent incapacity) may require a REMS that mandates a prescriber training and patient counseling on the associated risks and the drug's benefit-risk calculations so as to "facilitate informed patient and prescriber decisions about treatment with the drug."[26]

The FDA will also consider the frequency and severity of adverse events associated with the use of a drug.[27]

A high frequency of adverse events can necessitate a REMS, as can an infrequent adverse event, if the adverse event is particularly severe.[28] As part of its evaluation of whether a REMS is needed, the FDA also considers additional factors, including: availability of information about managing the risk; implementation of risk management measures; the specialties of the health care providers who prescribe, dispense, and administer the drug; health care professional familiarity with approaches to mitigate the risk; the health care setting(s) in which the drug is used or is likely to be used; and, for drugs used in an outpatient setting, the degree to which patients can be expected to reliably recognize symptoms as being associated with a drug and to take necessary actions to address adverse events.[29]

The Expected Benefit of the Drug with Respect to the Disease or Condition

In evaluating a drug's benefit, the FDA considers information about the drug's effectiveness, the seriousness of the disease or condition treated, whether it fills an unmet medical need and whether it can cure the disease or alleviate its symptoms.[30] For new dosage forms, the FDA may also consider "the extent to which the new dosage forms enhance convenience of administration and/or improve adherence to prescribed regimens, and whether new formulations or delivery mechanisms may extend treatment to patient populations who were formerly unable to use the drug."[31]

The drug's benefits, however, are balanced against the risks associated with its use.[32] As an example, the REMS guidance notes that, although a once-a-month dosage form may offer benefit in that it is more convenient and leads to better patient compliance, it may have a different risk profile that would warrant a REMS.[33]

The Seriousness of the Disease or Condition That is to be Treated with the Drug

The FDA also considers the seriousness of a disease or a condition.[34] "[T]he more serious the disease or condition to be treated, the greater the potential benefit of the drug's measured effect in the benefit-risk assessment."[35] However, even for drugs intended to treat serious or life-threatening diseases or conditions, an associated risk may be sufficiently severe, irreversible or long to warrant a REMS.[36]

Whether the drug is a new molecular entity. For new molecular entities or certain biological license applications, information about the drug may be limited and, thus, there can be greater uncertainty about risks associated with its use.[37] When safety information about a NME or BLA indicates a serious risk and there are uncertainties about the nature of the serious risk, a REMS may be required to assure that the benefits of the drug outweigh its risks.[38]

The Expected or Actual Duration of Treatment With the Drug

A REMS may be necessary when long-term therapy with a drug appears to increase the likelihood of a serious adverse event.[39] Such a REMS would likely limit the duration of treatment or ensure that patients on long-term treatment are monitored for the adverse event.[40]

A REMS could also be necessary for a drug with a relatively short duration of treatment.[41] For example, if a drug is associated with an adverse event immediately after administration, a REMS may limit administration to a setting where the patient can be monitored so that the adverse event, if it were to occur, can be properly managed.[42]

Likewise, a REMS may require specialized training for drugs that are can have adverse effects if improperly administered.[[43]] In cases where adverse events can occur after drug treatment has ended, a REMS may be required to ensure proper monitoring of patients for a sufficient time after treatment has concluded.[44]

The Estimated Size of the Population Likely to Use the Drug

The FDA will consider whether the expected patients are likely to use the drug for unapproved uses, and what are the risks associated with those unapproved uses.[45] A REMS can be designed to ensure that a drug's use is limited to its approved indication.[46]

After discussing the six factors identified in section 505-1(a)(1) of the FD&C Act, the REMS guidance then identifies burdens on the health care delivery system and patient access relating to REMS.[47] The REMS

guidance states that "FDA understands that REMS, particularly those with ETASU, may impose some measure of burden on patients and/or health care providers," and the FDA considers these factors when deciding whether a REMS is necessary.[48]

In particular, some of the factors the FDA considers include existing REMS elements for other drugs with similar risks; whether the REMS under consideration can be designed to be compatible with already-existing drug distribution, procurement and dispensing systems; access to healthcare for patients for whom the drug is indicated and whether the REMS may impose additional access difficulties; and the consequences of potential treatment interruption or delays, particularly where patients have serious or life-threatening conditions and/or have difficulty accessing health care.[49]

The REMS guidance further notes that the selection of REMS elements and tools can be influenced by the extent to which they have already been used in clinical trials to evaluate the drug's safety and efficacy and by regulatory precedent for addressing similar risks.[50]

The REMS guidance concludes: "FDA also encourages sponsors to submit REMS proposals that are compatible with established distribution, procurement, and dispensing systems. Following approval of a REMS, FDA continues to evaluate the impact of the REMS on patient access and the health care delivery system."[51]

Although REMS are an important means for minimizing the risk associated with drugs, REMS programs have come under scrutiny, including by outgoing FDA Commissioner Scott Gottlieb for delaying entry of generics into the marketplace.

As noted in an April 4, 2019, FDA statement entitled "FDA In Brief: FDA affirms its commitment to efficient adoption of Risk Evaluation and Mitigation Strategy plans and to making sure they do not impede generic drug development," Gottlieb, discussing the REMS guidance, stated that "[w]hile REMS are a critical tool designed to reinforce medication use behaviors and actions that support the safe use of that medication, some companies also try to game the system and use REMS to delay the entry of generics."[52]

The FDA statement noted: "In some cases, branded sponsors have refused to sell samples of brand products with REMS with ETASU impacting distribution of the drug to potential generic competitors. Generic drug developers need the samples of the brand drug to develop their generic product and to conduct testing to show that their product is bioequivalent to the brand drug for FDA approval. The FDA cannot stand idly by and allow companies to abuse the system, frustrating generic drug manufacturers and ultimately keeping patients from accessing lower cost generic drugs."[53]

Although the REMS guidance does not address this abuse, the FDA statement noted that in May 2018, the FDA "made available a list of companies that have potentially been blocking access to the samples of their branded products" and that the FDA will continue to update this list "to help deter companies from using REMS as an excuse."[54]

Congress has also been interested in abuses of the REMS system to hinder generic competition. Both the House and the Senate are again considering the CREATES Act, which aims "[t]o promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products."[55]

Congress stated that REMS abuses include the practice of using REMS distribution restrictions "as reasons to not sell quantities of a covered product to generic product developers, causing barriers and delays in getting generic products on the market."[56] Among other things, the CREATES Act would allow a generic or biosimilar pharmaceutical manufacturer to sue the brand sponsor if the brand sponsor refuses to sell them the samples needed to develop a generic or biosimilar version of the brand drug.[57]

The FDA's REMS guidance provides useful information to pharmaceutical manufacturers about the basis for adopting a REMS and the considerations involved. However, the REMS guidance itself does not affect any of the potential abuses in which Congress seems so interested. Whether the CREATES Act gains any traction and causes change is yet to be determined.

First published by *Law360* on April 26, 2019.

[1] 21 U.S.C. § 355-1

[2] REMS Guidance at 4.

[3] *Id.*

[4] *Id.*

[5] *Id.*

[6] *Id.* at 4.

[7] *Id.*

[8] *Id.* at 3.

[9] *Id.* at 5.

[10] *Id.* at 2.

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] *Id.* at 3.

[15] *Id.* at 5.

[16] *Id.*

[17] *Id.* at 3.

[18] *Id.* at 4.

[19] *Id.* at 4-5.

[20] *Id.* at 5.

[21] *Id.* at 5.

[22] *Id.*

[23] *Id.* at 5-9.

[24] *Id.* at 6.

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] *Id.* at 7.

[30] *Id.*

[31] *Id.*

[32] *Id.*

[33] Id.

[34] *Id.* at 8.

[35] *Id.*

[36] *Id.*

[37] *Id.*

[38] *Id.*

[39] *Id.* at 9.

[40] *Id.*

[41] *Id.*

[42] *Id.*

[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] *Id.*

[47] *Id.*

[48] *Id.*

[49] *Id.*

[50] *Id.* at 10.

[51] *Id.*

[52] FDA Statement.

[53] *Id.*

[54] *Id.*

[55] CREATES Act of 2019, S. 340, H.R. 965, 116th Cong.

[56] *Id.* at § 2(6).

[57] *Id.* at § 3(b)(1).

Patent Eligibility Used as the Federal Circuit's Shuttlecock in Weekly Badminton Match

Chad Hammerlind

In the months following the release by the USPTO of The 2019 Revised Patent Subject Matter Eligibility Guidance (2019 Revised Guidance), anecdotal evidence shows a noticeable uptick in the number of patent ineligibility rejections that have been withdrawn by Examiners at the USPTO, which is promising for applicants and inventors filing patents in technology areas that have been gridlocked since the Supreme Court decision in *Alice Corp. v. CLS Bank International, 573 U.S. 208, 134 S. Ct. 2347 (2014)*. While the trend at the USPTO appears to be improving in favor of applicants, a division continues to exist in the Court of Appeals for the Federal Circuit (CAFC). Recently, two different panels of the CAFC made apparently contradictory decisions on patent eligibility within a week of each other that. Sample claims from each case are reproduced below:

Case #1:

1. A computer-automated method of hierarchical event monitoring and analysis within an enterprise network comprising:

   deploying a plurality of network monitors in the enterprise network;

   detecting, by the network monitors, suspicious network activity based on analysis of network traffic data selected from one or more of the following categories: {network packet data transfer commands, network packet data transfer errors, network packet data volume, network connection requests, network connection denials, error codes included in a network packet, network connection acknowledgements, and network packets indicative of well-known network-service protocols};

   generating, by the monitors, reports of said suspicious activity; and

   automatically receiving and integrating the reports of suspicious activity, by one or more hierarchical monitors.

Case #2:

1. An apparatus, comprising:

    a control device to turn electric supply on and off to enable and disable charge transfer for electric vehicles;

    a transceiver to communicate requests for charge transfer with a remote server and receive communications from the remote server via a data control unit that is connected to the remote server through a wide area network; and

    a controller, coupled with the control device and the transceiver, to cause the control device to turn the electric supply on based on communication from the remote server.

2. The apparatus of claim 1, further comprising an electrical coupler to make a connection with an electric vehicle, wherein the control device is to turn electric supply on and off by switching the electric coupler on and off.

At first glance, one might expect both of these claims to result in similar patent eligibility outcomes under 35 USC § 101. The claims for Case #1 are directed to using network traffic data to identify and report suspicious activity on a network, while the claims for Case # 2 are directed to using network communications to enable and disable charge transfer at a charge station for electric vehicles. However, the claims in one of the cases were found to patent eligible, while the claims in the other case were found to be patent ineligible. Without being given any information other than the recited subject matter, the claims of Case #2 would appear to be most logical choice for patent eligibility due to their recitation of the multiple physical components and the use of communications from a server in order to provide improvements to a charge station for electric vehicles, while the claim of Case #1 appear more abstract due to their recitation of the analyzing of network traffic data and generating and compiling reports of suspicious activity. However, the above analysis would be wrong, as the CAFC ruled that the claims in Case #1 were patent eligible in *SRI International, Inc., v. Cisco Systems, Inc.*, No. 2017-2223 (Fed. Cir. March 20, 2019) (*SRI v. Cisco*), while the claims in Case #2 were patent ineligible in *ChargePoint, Inc., v. SemaConnect, Inc.*, No. 2018-1739 (Fed. Cir. March 28, 2019) (*ChargePoint v. SemaConnect*). As a result, patent practitioners and applicants may feel like they are throwing darts when trying to determine whether claims are patent eligible, as the CAFC judges appear to be so split on the issue of patent eligibility that determining how claims will be interpreted by the CAFC has become virtually unpredictable, particularly in view of *ChargePoint v. SemaConnect*, as discussed below.

In *SRI v. Cisco*, the CAFC affirmed a district court's decision to deny a motion by Cisco, Inc. (Cisco) for summary judgment of patent ineligibility under § 101. At the time of the invention at issue in this appeal, hacker attacks on computer networks were detectable when the number of login attempts to a computer in the computer network exceeded a threshold. However, hackers had discovered that the network could be attacked by attempting to log in to multiple computers in the network, while limiting the number of login attempts per computer below the threshold, which made the attack difficult to detect by administrators looking at a single computer within the network. SRI International, Inc (SRI) developed a computer-automated method of hierarchical event monitoring and analysis within an enterprise network to solve this issue, and claimed that method in U.S. Patent Nos. 6,585,203 (the '203 patent) and 6,711,615 (the '615 patent), which describe a plurality of network monitors that detect suspicious network activity based on analysis of network traffic data, and generate reports of the suspicious activity that are then integrated with other reports of other network monitors by a hierarchical monitor.

SRI sued Cisco for infringement of the '615 patent and '203 patent. Cisco then moved for summary judgment, arguing that the claims were both patent ineligible and anticipated. The district court denied Cisco's motions, and the jury found that the claims were valid and willfully infringed by several of Cisco's products. On appeal, Cisco argued that it was improper for the district court to deny Cisco's motion for summary judgment of patent ineligibility because the claims were directed to an abstract idea. Specifically, Cisco argued that the claims were analogous to those in *Electric Power Group, LLC v. Alstom S.A.*, 830 F. 3d 1350 (Fed. Cir. 2016) (*Electric Power)* by being

directed to generic steps required to collect and analyze data while not providing an improvement to any computer functionality. Judge O'Malley and Judge Stoll disagreed and distinguished the claims of the '615 patent and '203 patent from those in *Electric Power*, stating: "The *Electric Power* claims were drawn to using computers as tools to solve a power grid problem, rather than improving the functionality of computers and computer networks themselves. *Id.* at 1354. We conclude that the claims are more like the patent-eligible claims in *DDR Holdings*. In *DDR*, we emphasized that the claims were direct to more than an abstract idea that merely required a 'computer network operating in its normal, expected manner,' 773 F.3d at 1258. Here, the claims actually prevent the normal, expected operation of a conventional computer network. Like the claims in *DDR*, the claimed technology 'overrides the routine and non-conventional sequence of events' by detecting suspicious network activity, generating reports of suspicious activity, and receiving and integrating the reports using one or more hierarchical monitors. *Id.*" *SRI v. Cisco* at p. 10.

The majority also analogize the claims in the '615 patent and '203 patent to those in *Enfish, LLC v. Microsoft Corp.*, 822F.3d 1327 (Fed. Cir. 2016), stating that the claims were not directed to abstract ideas that use computers as tools for automating a conventional idea, but rather providing improvements to the technical functioning of a computer network by reciting a specific method for improving computer network security. Like in *Enfish*, the majority used teachings from the specification to support their argument that the claims were directed to an improvement in computer networks: "The specification bolsters our conclusion that the claims are directed to a technological solution to a technological problem....The specification explains that the claimed invention is directed to solving these weaknesses in conventional networks and provides 'a framework for the recognition of more global threats to interdomain connectivity, including coordinated attempts to infiltrate or destroy connectivity across an entire network enterprise.' [the '615 patent] at col. 3 ll. 44-48." *SRI v. Cisco* p. 9. Thus, the majority agreed with the district court, and found that the claims were not directed to a patent ineligible concept under step one of the *Alice* analysis.

Judge Lourie dissented and stated that the claims were "hardily distinguishable from Electric Power." *SRI v. Cisco* p. 3 (Lourie, dissenting). He argued that "[t]he detecting of the suspicious activity is based on 'analysis' of traffic data, but the claims add nothing concerning specific means for doing so. The claims only recite the moving of information. The computer is used as a tool, and no improvement in computer technology is shown or claimed. There is no specific technique described for improving computer network security." *Id.* He goes on to criticize the majority's use of the specification, stating that "the majority opinion quotes from and paraphrases language from the specification that only recites results, not means for accomplishing them. *See, e.g., Majority Op.* at 9. The claims as written, however, do not recite a specific way of enabling a computer to monitor network activity. As we noted in Electric Powe, result-focused, functional claims that effectively cover any solution to an identified problem, like those at issue here, frequently run afoul of *Alice*. 830 F.3d at 1356." *Id.* at p. 4.

The decision in *SRI v. Cisco* was another win for patent applicants, and seemed to be consistent with the 2019 Revised Guidance, aligning and harmonizing the CAFC and the USPTO in a manner that offered predictability as to what subject matter is patent eligible. that all changed a week later with the decision in *ChargePoint v. SemaConnect*.

In *ChargePoint v. SemaConnect*, the CAFC affirmed a district court's decision of patent ineligibility under 35 U.S.C. § 101. At the time of the invention at issue in this appeal, charging systems for electric vehicles (EVs) were installed for personal use at homes, as well as for use by customers at businesses such as restaurants, apartments, and shopping centers, raising various concerns for regulating the use of the charging stations. For example, utility companies often have supply and demand issues associated with low demand during certain times of the day and high demand at other times of the day, and often regulate electricity delivered to customers based on a preplanned load prioritization scheme. Furthermore, while EVs draw electricity from the electric grid, EVs can also supply electricity to the electric grid via energy stored in their batteries during peak demand hours, referred to as V2G. However, prior to the inventions in this case, there was no way for businesses and utility

companies to remotely control the flow of electricity at individual charging stations, and ChargePoint, Inc.'s (ChargePoint) inventors created "improved" charging stations that could operate on a network and be managed from a central location. ChargePoint claimed an apparatus that provided the functionality discussed above in U.S. Patent No. 8,138,715 (the '715 patent). Three other patents that shared the same specification as the '715 patent were also at issue including U.S. Patent Nos. 8,432,131 (the '131 patent), 8,450,967 (the '967 patent), and 7,956,570 (the '570 patent), all of which generally describe electric vehicle charging stations that connect to a network, local power grids, and electric vehicles.

ChargePoint sued SemaConnect, Inc. (SemaConnect) for patent infringement and filed a motion for emergency injunctive relief. The district court denied injunctive relief and ordered expedited briefing on SemaConnect's Rule 12(b)(6) motion based on 35 U.S.C. § 101, which the district court granted with prejudice, holding each asserted claim ineligible for patenting under § 101. On appeal at the CAFC, and during their analysis of the '715 patent at step one of the *Mayo*/*Alice* inquiry that determines whether the claims are directed to excluded subject matter, the CAFC discussed that there were various tools that the court could use to determine whether the claim is directed to ineligible subject matter. Specifically, the court stated, "we have found the specification helpful in illuminating what a claim is 'directed to….' [and] as part of our 'directed to' analysis, we also consider whether a claim is truly focused on an abstract idea (or other ineligible matter), whose use the patent law does not authorize anyone to preempt." *ChargePoint v. SemaConnect* pp. 7-8. The court identified that claim 1 of the '715 patent "involves an abstract idea—namely, the abstract idea of communicating requests to a remote server and receiving communications from that server, i.e., communication over a network." *Id.* p. 9. However, the court correctly reasoned that identifying an abstract idea was not sufficient to determine whether the claim as a whole is directed to the abstract idea.

With these tools in mind, the court turned to the specification of the '715 patent to understand the problem facing the inventors, as well as what the specification describes as the invention. The court found that the problem identified by the specification was that "'[t]here is a need for a communication network which facilitates finding the recharging facility, controlling the facility, and paying for the electricity consumed.' '715 patent col. 1 ll.35-38. The specification went on to discuss that '[t]here is a need for an efficient communication network for managing peak load leveling using Demand Response and V2G." *Id.* col. 2 ll. 8-10. Looking to future needs, the specification anticipated that 'there will be a need for a system for collection of taxes and consumption information.' *Id.* col. 2 ll. 18-20." *Id.* at p. 11. Thus, the court determined "that the problem perceived by the patentee was a lack of a communication network for these charging stations, which limited the ability to efficiently operate them from a business perspective." *Id.* Moreover, the court noted that "the specification never suggests that the charging station itself is improved from a technical perspective, or that it would operate differently than it otherwise could." *Id.* 12.

However, the court did not find the claims to be directed to an abstract idea based on the specification alone, and rather also analyzed the claim language to determine whether that claim language would preempt the building blocks of science and technology and found that the claim language would "preempt the use of any networked charging stations." *Id.* at 13. The court discussed cases such as *O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1853) and *Wyeth v. Stone*, 30 F. Cas. 73 (C.C.CD. Mass. 1840) (No. 18,107) and concluded, with limited analysis of the claim language, that "the broad claim language would cover any mechanism for implementing network communication on a charging station, thus preempting the entire industry's ability to use networked charging stations." *Id.* Thus, because the specification indicated that the focus of the claims was directed to the abstract idea of network communication for device interaction, and because the claims preempted networked charging stations, the court found the claims of the '715 patent were "directed to the abstract idea of communication over a network to interact with a device, applied in the context of charging stations." *Mayo*/*Alice*. p. 16.

With respect to the claims of the '131 patent, '967 patent, and the '570 patent, the court found those claims directed to the same abstract idea for similar reasons. Some of those claims described the control

device modifying the application of charge transfer based on communications received as part of a demand response system, and in looking at the specification, the court determined that the demand response system was merely an abstract concept of a familiar business choice, and thus the specification merely recited improvements to a business practice rather than a technical improvement.

Briefly turning to the second step of the *Mayo*/*Alice* analysis, the court concluded that the only possible inventive concept in the eight asserted claims was the abstract idea itself without significantly more. The court reasoned that "the alleged 'inventive concept' that solves problems identified in the field is that the charging stations are network-controlled. But network control is the abstract idea itself, and 'a claimed invention's use of the ineligible concept to which it is directed cannot supply the inventive concept that renders the invention 'significantly more' than that ineligible concept.' BSG Tech, 899 F.3d at 1290." *Mayo*/*Alice*. at p. 23. Thus, the claims were found patent ineligible.

A review of the court's analysis in *ChargePoint v. SemaConnect* identifies illogical and inconsistent positions. For instance, the court concluded that the need for an efficient communication network for managing peak load leveling using Demand Response and V2G was a business problem but did not take into account that managing peak load on a power grid has technological benefits as well. For example, if there is too much demand for electricity at a given time, the power grid may experience adverse effects such as brownouts and failure, while if there is too little demand, electricity is wasted. The '715 patent explicitly states "Electricity grids have periods of high demand where the demand may approach or even exceed the electricity supply. Conversely, there are periods of low demand which coincide with high electricity production." Col. 1, ll. 39-42. As such, the specification itself implies that the inventors contemplated that their invention could be used to make the electrical grid more efficient, in addition to the business advantages described in the specification.

With respect to the preemption analysis, the claims of the '715 patent state:

> ...a control device to turn electric supply on and off to enable and disable charge transfer for electric vehicles
>
> a transceiver to communicate requests for charge transfer with a remote server and receive communications from the remote server via a data control unit that is connected to the remote server through a wide area network
>
> a controller, coupled with the control device and the transceiver, to cause the control device to turn the electric supply on based on communication from the remote server. (Emphasis added).

The court states that "the claim language here would cover any mechanism for implementing network communication on a charging station, thus preempting the entire industry's ability to use network charging stations." *Id.* at 15. However, the court conveniently omits that the communications are used to enable and disable charge transfer using a control device, a transceiver, and a controller, providing a system that arguably does not preempt all networked charging stations. For example, the court identified from the Applicant's specification that "'there will be a need for a system for collections of taxes and consumption information'", *Id.* at 11 (citing the '715 patent at col. 2 ll.18-20), and independent claim 1 of the '715 patent does not preempt the use of a networked charging station that transfers consumption information. Nor would claim 1 cover a system that reports error information over the network, provides sensor information over the network, streams video over the network to the network charging station, and/or performs countless different uses via a network connection. Furthermore, the combination of the network, the control device, the transceiver, and the controller do not preempt enabling and disabling electrical flow at the charging station, which is really what claim 1 of the '715 patent is directed to.

In addition, the use of *O'Reilly v. Morse* and *Wyeth v. Stone* seemed peculiar in the courts preemption analysis, as the claims at issue appear very different than the one claim that was at issue in *O'Reilly v. Morse*, which was directed to using electromagnetism for making any markings at a distance and was found patent ineligible (while claims using electromagnetism and the various components were found patent eligible.) Furthermore, the claim in *Wyeth v. Stone* was directed to cutting ice by means of any power other than human power. In contrast, the claims of the '715 patent appear to be more similar to those in *Diamond v. Diehr*, 450 U.S. 175 (1981) (*Diehr*), which were directed to using a mathematical formula in a rubbing curing process. As stated by the Court in *Diehr*, "When a claim containing a mathematical formula implements or applies the formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (e. g., transforming or reducing an article to a different state or thing), then the claim satisfies § 101's requirements." *Id.* at 176. In the claims of the '715 patent, the communications received by the transceiver from the server via the network are used by the controller and the control device to physically switch the flow of electricity on or off, which would appear to replace a manual switch in a conventional charging station.

In any case, one takeaway from both of these cases is that the CAFC is relying heavily on the teachings of the specification when making its determination on patent eligibility. If the drafters of the '715 patent were aware of how patent law would change in the years following the filing of this application, they may have made an attempt to describe the technical improvements that this invention provides for a power grid and/or a charging station which, from the CAFC's opinion in *ChargePoint v. SemaConnect*, may have resulted in a different outcome for these claims. Thus, these cases reinforce that it is important to thoroughly describe the technical improvements in the specification while avoiding any discussion of business improvements realized via the invention.

Haynes and Boone Lawyers Featured in 2019 *IAM Patent 1000* Directory

Intellectual Asset Management (IAM) Patent 1000 has recognized Haynes and Boone and 11 lawyers in the 2019 edition of the independently researched legal directory: Randall Brown, Tom Chen, Randall Colson, David McCombs, Greg Michelson, C. Kyle Musgrove, David O'Brien, Phillip Philbin, Mark Tidwell, Jeffrey Wolfson, and Phil Woo.

The IAM Patent 1000 spotlights firms and individuals deemed by peers and clients as outstanding in the patent practice. IAM interviewed more than 1,800 patent lawyers and in-house counsel over five months to decide which firms and lawyers to include in the directory.

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After a hearing on the merits handled by Haynes and Boone, an administrative law judge of the U.S. International Trade Commission (ITC) has determined that ACON Laboratories, Inc. and ACON Biotech (Hangzhou) Co. infringed two of PTS Diagnostics' key patents.

Partners Kenneth Parker and Robert Ziemian led the trial team that obtained the victory for PTS Diagnostics. The team also included Haynes and Boone lawyers Charlie Jones, Michael Karson, Richard Rochford, Tiffany Cooke, Aaron Taggart, Eva Zhao, and Winnie Wong.

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IP QUIZ

Trademark Trivia
Is there a likelihood of confusion?

Attempted registration:

For alcoholic beverages except beer.

and

Registered mark:

SURLY

For beer and bar and restaurant services.

According to the U.S. Trademark Trial and Appeal Board, the answer is YES.

The Board sustained an opposition brought by Surly Brewing Company, finding that there was a likelihood of confusion between the applicant's mark, SURLY PENGUIN and design for alcoholic beverages except beer, and opposer's mark, SURLY for beer and for bar and restaurant services.

First, the Board held that the opposer's mark is inherently strong, as it is an arbitrary term for beer or bar and restaurant services. The Board also found that the opposer's mark is commercially strong because of its many media references, substantial sales and advertising expenses, and promotional activities. This allowed a broad scope of protection and weighed in favor of a likelihood of confusion.

Regarding the similarity of the marks, the Board held that consumers familiar with the opposer's SURLY marks may view the SURLY PENGUIN mark as a new mark for a line of SURLY alcoholic beverages. Both marks share the word SURLY, which conveys a similar connotation and commercial impression, especially as the opposer's label features a scowling man and the applicant's logo features a scowling penguin.

As to the similarities of the goods, the Board found that beer and alcoholic beverages except beer are related, in light of the strength of the opposer's mark, based on evidence showing more than fifty other entities producing beer and other alcoholic beverages under the same mark, 48 third-party registrations for both applicant's and the opposer's goods, and other evidence.

Lastly, the Board found that the opposer's beer and the applicant's alcoholic beverages are offered in some of the same channels of trade to some of the same classes of consumers. As such, the Board sustained the opposition.

Surly Brewing Company v. Christopher Olshan, Opposition No. 91230831 (April 26, 2019) [not precedential].

If you have any questions, please visit the Haynes and Boone Intellectual Property Law page of our website.

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