



## The IP Beacon<sup>®</sup> The Intellectual Property Law Newsletter of Haynes and Boone, LLP

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### **Pretty Pills, Please - The FDA's Focus on Generic Drug Appearance Creates Other Concerns**

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The FDA recently issued final guidance regarding the size, shape, and other physical characteristics of generic-manufactured tablet and capsule dosage forms. The guidance noted that differences in physical characteristics of a dosage form could affect patient compliance and acceptability of medication regimens, or could lead to medication errors. The main reason for the FDA's guidance appears to be that many patients can experience difficulty swallowing tablets and capsules. But these issues can create impacts on the cost and availability of generic drugs, and may require an additional class of patents to be evaluated in clearing third-party patent rights when filing an ANDA and certain 505(b)(2) applications. For example, a larger tablet is harder to swallow than a smaller tablet, and oval tablets may be easier to swallow than round tablets. Other physical attributes that may affect a patient's ability to swallow, and thus patient compliance with a recommended dosing regimen, include coatings, weight, surface area, disintegration time, and propensity for swelling.

Accordingly, the FDA's guidance recommends that generic oral tablets and capsules intended to be swallowed intact should be of a similar size to the corresponding referenced listed drug (RLD). The FDA further recommends that tablets and capsules should have a similar shape or have a shape that has been found easier to swallow compared with the shape of the RLD. Moreover, other physical attributes of tablets and capsules should be considered in the context of their effect on ease of swallowing.

Many generic pharmaceutical enterprises have been opposed to the guidance because it proposes to eliminate an option that presently exists to design around a brand company's patents directed to physical attributes. These attributes, such as tablet or capsule sizes, shapes, weights, surface areas, and disintegration times, are alleged to be patentable. Brand companies typically file patent applications directed to compositions, formulations and methods, but will sometimes file applications claiming physical attributes of the dosage form. Generic companies have previously been able to approach this type of patent through design around to avoid infringement, such as by altering the size and/or shape of the generic dosage form while still adhering to the requirement for bioequivalence to the brand name drug. The proposed guidance would limit this option in many cases, requiring generic applicants to engage in a typically more costly process to

invalidate such patents directed to physical attributes.

U.S. Patent No. 8,383,152 (the “’152 patent”) is an example of a patent that claims a very specific shape of the dosage form. The ’152 patent is not listed in the Orange Book at present, but it claims dosage forms having different breaking strengths along different axes of the dosage form. Many of the dependent claims recite a particular shape of the dosage form. For example, claim 2 recites a shape having a longitudinal axis and two opposite longitudinal edges, a transversal axis perpendicular to the longitudinal axis and two opposite transversal edges, a front side, an opposite back side and a circumferential rim between the front and back side.

The front side and/or the back side include a basis area, and include at least one bulge that extends above the basis area. The “at least one bulge” is present at and/or adjacent to at least a section of one or both longitudinal edges and/or at and/or adjacent to at least a section of one or both transversal edges and/or between both longitudinal edges and both transversal edges. Figures 1A and 1B illustrate one embodiment of the shape.

Figure 1A

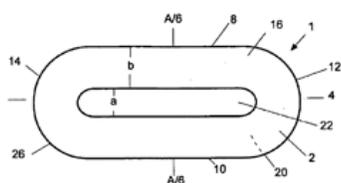
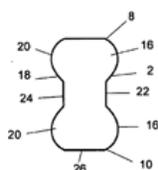


Figure 1B



To the extent that this patent ever lists for a product in the Orange Book, the ability to design around may be impacted by the FDA’s guidance. We would note, however, that the FDA guidance permits design around options that are expected to be easier to swallow.

Another physical attribute claimed as patentable by some brand companies is weight of the active pharmaceutical ingredient (API) relative to the dosage form. For example, U.S. Patent No. 6,294,197 (“the ’197 patent”) is listed in the Orange Book for several Novartis valsartan products. The ’197 patent claims a

dosage form that includes an API present in an amount of more than 35 percent by weight based on the total weight of the dosage form. One way generics might attempt to get around this claim is to include a larger amount of pharmaceutical excipients so that the amount of API is less than 35 percent by weight of the dosage form, while still ensuring bioequivalence to the FDA’s specifications. This, however, tends to lead to a larger dosage form, which is now discouraged by the FDA.

Yet another attribute brand companies pursue is coatings. U.S. Publication No. 2013/0034605 (“the ’605 publication”) attempted to claim extended-release paliperidone compositions with various coatings. For example, claim 1, as published, recited a paliperidone core with a coating that includes a seal coating layer, a controlled release coating layer, a pH dependent polymer coating layer, and an optional overcoating layer. The ’605 publication was abandoned after the first Office Action. Another example is U.S. Publication No. 2010/0330180 (“the ’180 publication”), which tried to claim a process and tablet that included a specific coating layer coated with an anti-static agent. The anti-static agent was recited as being selected from the group consisting of kaolin, magnesium trisilicate, starch, microcrystalline cellulose, bentonite, silicon dioxide, cellulose, stearic acid, sodium stearyl fumarate, and glycerol behenate. The ’180 publication was abandoned after the first Office Action and an Examiner interview.

Ultimately, the FDA guidance may aid a subclass of patients swallow their medications (while also providing additional motivation for making certain design choices regarding particular patent-seeking approaches potentially obvious). But this limits a non-infringement paragraph IV certification option on patents directed to physical attributes, and resolves the costly Hatch-Waxman/ANDA disputes that more often arise after invalidity certifications, appears to overlook the likely increased generic drug costs when physical attribute patents are listed in the Orange Book or exist as unlisted roadblocks to marketing. Indeed, if health-care consumers, insurers, and budget-conscious governments are concerned about generic drug pricing (which affects ultimate access to the medication) and shortages, this proposed guidance is not likely to help resolve such ongoing problems in the drug supply chain.

Please feel free to contact the authors to learn more about the patent issues involved in launching an ANDA or 505(b)(2) product when designing around or avoiding brand company patents. The FDA Guidance may be found here (<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm377938.pdf>).

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## High Court Addresses the Effect of Opinions on Charges of Inducement of Infringement

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On May 26, 2015, the Supreme Court held that an ultimately incorrect, but good faith belief in invalidity of a patent is not a defense to a claim for induced infringement in *Commil USA, LLC v. Cisco Systems, Inc.*<sup>1</sup> However, in cases where the asserted claims are held invalid, an invalidity holding still operates as a defense because where a patent “is shown to be invalid, there is no patent to be infringed.”<sup>2</sup> This article explores the practical impact of *Commil* on opinion practice.

In the underlying case, *Commil* sued Cisco for direct infringement and induced infringement of *Commil*'s patent for implementing short-range wireless networks. After two jury trials, the United States Court of Appeals for the Federal Circuit stated that a good faith belief that the asserted patent was invalid would serve to negate the intent requirement that the alleged infringer acted with intent to induce the infringement.<sup>3</sup> The Supreme Court disagreed.

Referencing the statute,<sup>4</sup> the Court emphasized the dichotomy between invalidity and infringement and held that “because infringement and invalidity are separate issues under the statute,<sup>5</sup> a belief regarding invalidity cannot negate the scienter required under §271(b),” the portion of the statute that governs induced infringement.<sup>6</sup> The Court, however, agreed with the

dissent that an invalid patent cannot be infringed:

To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed.<sup>7</sup>

Despite this interplay between invalidity and infringement, the Court explained that these were “distinct issues, bearing different burdens, different presumptions, and different evidence,” and that “the allocation of burden to persuade on these questions, and the timing for the presentations of the relevant arguments, are concerns of central relevance to the orderly administration of the patent system.”<sup>8</sup> The Court further explained that an accused infringer “may prevail either by successfully attacking the validity of the patent or by successfully defending the charge of infringement.”<sup>9</sup>

### Application of *Commil*

It is common practice for a company to seek opinion letters regarding the issues of non-infringement and invalidity of patents. After arming itself with an opinion, some feel free to practice the invention at issue. *Commil*, however, notes some distinctions between the two types of opinions and indicates that each has its own strengths and weaknesses.

As the Supreme Court noted, inducement requires both that the defendant in a patent suit knew of the patent and that it knew the induced acts would constitute infringement, *i.e.*, “active inducement” is required by the statute.<sup>10</sup> In other words, the earlier *Global-Tech* requirement of knowledge that the acts are inducing required scienter and, more specifically, required a showing that the “defendant knew the acts were infringing.”<sup>11</sup> Under this standard, a person who has a reliable non-infringement opinion prior to institution of the activities in suit would have a good faith belief that the acts were not infringing and would thus lack the scienter required for the statute. Such a defense would rely on a good faith belief, however, such a belief may be tested or changed over time.

In contrast, the Supreme Court drew a distinction as to why a good faith belief of non-infringement would insulate an alleged infringer from induced

infringement while a good faith belief of invalidity would not. In sum, the Court stated that a good faith belief of invalidity does not operate to imply that a patent is not infringed; rather, the alleged inducer would believe that, because the patent is invalid, liability would not exist, and infringement would thus be irrelevant. Or, stated another way, “invalidity is not a defense to infringement; it is a defense to liability.”<sup>12</sup>

So what does this mean for companies attempting to determine whether they are free to operate amidst a variety of patents that others might assert? The Court essentially indicated that as long as a good faith belief of indirect infringement is held by the company accused of infringement by inducement, the company lacks the knowledge required for inducement. Thus, a patent clearance and a reasonable, although ultimately incorrect, opinion addressing non-infringement of process or method patent claims may insulate the alleged infringer from liability for induced infringement, as long as the good faith belief is held. The quality of the non-infringement opinion in this instance is significant and must be viewed as credible even though it was ultimately opposite the finding of infringement.

What then is the place for invalidity opinions with regard to process and methods patents, *i.e.*, the patents most likely to lead to inducement of infringement claims? Those opinions have the same stature as before the Federal Circuit’s *Commil* opinion. While merely having a good faith belief in the invalidity of a patent will not insulate an alleged infringer from liability for inducement, an ultimate finding of invalidity, whether through prior or concurrent clearance via a Patent Trial and Appeals Board challenge or a declaratory judgment or other patent litigation, will also lead to a finding of non-liability. A reliable invalidity opinion or analysis is often the first step a company can take to determine the likelihood of invalidity, and is a basis for making appropriate business decisions and can function as a map to a successful PTAB challenge or district court litigation.

Ultimately, while companies running freedom-to-operate analyses would surely appreciate the additional defense denied them by the Supreme Court in *Commil*, the Court’s holding underscores

the continued importance of obtaining invalidity and non-infringement opinions. Of significance is that the opinions are of high quality, provide the company the support it needs to make decisions, and is ultimately found by a court or the United States Patent and Trademark Office to be correct, *i.e.*, the patent in question is invalid or not infringed.

<sup>1</sup> 575 U.S. \_\_\_\_ (2015).  
<sup>2</sup> *Id.* at \_\_\_\_ (slip op., at 11).  
<sup>3</sup> *Commil USA LLC v. Cisco Sys. Inc.*, 720 F.3d 1361, 1368 (Fed. Cir. 2013).  
<sup>4</sup> 35 U.S.C. §282(a).  
<sup>5</sup> “Part III of the Act deals with ‘Patents and Protection of Patent Rights,’ including the right to be free from infringement. §§ 251-329. Part II, entitled ‘Patentability of Inventions and Grants of Patents,’ defines what constitutes a valid patent. §§101-212.” *Commil*, 575 U.S. at \_\_\_\_ (slip op., at 10).  
<sup>6</sup> 35 U.S.C. §271 (b) provides: “Whoever actively induces infringement of a patent shall be liable as an infringer.”  
<sup>7</sup> *Commil*, 575 U.S. at \_\_\_\_ (slip op., at 11).  
<sup>8</sup> *Id.*  
<sup>9</sup> *Id.* at \_\_\_\_ (slip op., at 10).  
<sup>10</sup> *Id.* at \_\_\_\_ (slip op., at 5) (citing to *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068 (2011)).  
<sup>11</sup> *Id.* at \_\_\_\_ (slip op., at 9).  
<sup>12</sup> *Id.* at \_\_\_\_ (slip op., at 11).

## The U.S. Supreme Court Declined to Review *Oracle v. Google*, but the Billion-Dollar Case is Just Booting Up

David Harper, Jason Bloom, Stephanie Sivinski



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On June 29, 2015, the Supreme Court denied Google’s petition for certiorari,

refusing to review the long-running battle over the scope of software copyright protection. The suit began almost five years ago when Oracle sued Google for infringing Oracle’s copyright on portions of the popular Java software that allowed Java to communicate with other programs. After licensing negotiations over the software failed, Google copied portions of the Java code for use in its Android operating system. While Google independently

recreated much of the implementing code, it allegedly copied Java's declaring code that provided the taxonomy system Java used to name routinely-used functions. For example, the declaring code "java.lang.Math.max(1,2)" refers to a method for returning the greater of two numbers.

A jury found that Google infringed Oracle's copyright, but was unable to return a verdict on whether Google's copying was fair use. The district court, however, found that Oracle's declaring code, including its organization and structure, was a system or method of operation excluded from copyright protection under Section 102(b) of the Copyright Act. Oracle appealed the district court's decision that the declaring code was not copyright eligible. On appeal, the United States Court of Appeals for the Federal Circuit<sup>1</sup> reversed the district court, finding that Section 102(b) merely codifies the idea/expression dichotomy that is the foundation of copyright protection. An idea itself is not copyrightable, but the expression of that idea is. In the Federal Circuit's view, Oracle's Java declaring code was expression and deserved copyright protection.

Google then asked the Supreme Court to review the decision, arguing that courts were "deeply divided" about how to apply Section 102(b). The Supreme Court asked the United States Solicitor General's office for input. Historically, the Supreme Court has deferred to the Solicitor General's judgment about whether certiorari should be granted, and this case was no different. The Solicitor General urged the Supreme Court not to take the case because the Federal Circuit had correctly decided it. The Solicitor analogized declaring code to a book that explained how to build a bicycle. While the expression embodies a method, the expression of that method itself is copyrightable. The Court denied certiorari.

While many in the software industry were disappointed in the Court's refusal to clarify this aspect of software copyright law, the case is not over. On remand, the trial court will determine whether Google's use of the declaring code constituted fair use and will determine damages. With potentially a billion dollars at stake, there are still important issues to be resolved in the case. The extent of copyrightability for different aspects of software may still be uncertain,

but this decision will likely have a far-reaching impact as industry and society increasingly rely on the interoperability between computing devices, software applications, and software services, particularly in mobile and cloud computing.

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<sup>1</sup> The Federal Circuit had appellate jurisdiction over the case because Oracle brought claims for patent infringement in the district court litigation. Neither side appealed the district court's disposition of the patent-related claims, and because the issues that were ultimately appealed involved only copyrights, the Federal Circuit applied Ninth Circuit law.

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## U.S. Federal Courts Now Must Be Bound by TTAB Decisions to a Greater Extent

David A. Bell, Mike A. McArthur



David A. Bell Mike A. McArthur

In a monumental decision, today the United States Supreme Court ruled that Trademark Trial and Appeal Board ("TTAB") decisions carry preclusive effect in subsequent

federal district court decisions so long as the ordinary elements of issue preclusion are met. The ruling implicates that, where use is the "paramount" issue in a court case, a TTAB decision that at least peripherally contemplates marketplace use will have preclusive effect. Moreover, the Court's ruling expands the significance of TTAB proceedings, and likely will raise the costs of such administrative proceedings as a whole. At the same time, the decision will likely result in judicial economies of scale – taking away the "2 bites at the apple" approach utilized in many trademark disputes.

### Background Facts and Procedural History

The Court's decision of *B&B Hardware, Inc. v. Hargis Indus., Inc.*, 575 U.S. \_\_\_\_, No. 13-352 (2015), marks the most recent stage of an eighteen-year trademark dispute between B&B Hardware, Inc. ("B&B") and Hargis Industries, Inc. ("Hargis"). As the Court noted, the facts "could fill a long, unhappy book," but an understanding of the procedural history certainly helps to make sense of the Court's decision.

B&B applied to register the mark SEALTIGHT for fasteners, and more specifically self-sealing ones for use in the aerospace industry. Hargis subsequently applied to register the mark SEALTITE for fasteners, and more specifically self-piercing and self-drilling screws for use in building construction. The parties' legal feud then began. B&B sued Hargis for trademark infringement. The jury ruled against B&B on the ground that it lacked a distinctive and enforceable trademark.

B&B next took the battle to the TTAB, by opposing Hargis's trademark application before the TTAB. Ultimately, the TTAB ruled that Hargis could not register SEALTITE because the mark was too similar to B&B's SEALTIGHT mark. The jury next issued its decision in the court proceeding, finding that the marks were not confusingly similar. B&B sought judgment in its favor despite the verdict, arguing that the TTAB decision precluded the court's litigation on the issue. The district court disagreed.

The Eighth Circuit affirmed in relevant part, refusing to give preclusive effect to the TTAB decision and declining to instruct the lower court to give deference to the TTAB's decision. The appellate court reasoned that the likelihood of confusion issues decided by the TTAB were not the same as those presented to the district court, particularly as to the weight afforded the evidence of actual use.

### **The Court's Decision**

The Supreme Court overruled the Eighth Circuit in a 7-2 decision authored by Justice Samuel Alito, ruling that decisions by the TTAB can have a preclusive effect on district courts as long as the "ordinary elements of issue preclusion" are met. As discussed below, the Court addressed three related questions to reach its ultimate conclusion.

### **Administrative Decisions Can Bind Courts**

The Court first answered whether an administrative decision can ever have a preclusive effect on an Article III court, holding that it can. As noted by the Court, issue preclusion is appropriate *"when an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment ... whether on the same or a different claim."* The Court held that if Congress

grants an agency the power to adjudicate a category of disputes without a clear intention against issue preclusion, the agency's decisions can bind district courts.

The constitutionality of such a holding under Article III has never been addressed by the Court, and Justice Alito expressly reserved that question for a later day.

### **The Lanham Act Does Not Forbid Issue Preclusion**

Next, the Court searched for but found no clear reason that Congress - in creating the Lanham Act (the federal trademark statute) - would not want TTAB decisions to carry preclusive effect. According to Justice Alito, the text and form of the Lanham Act do not forbid the application of issue preclusion. The Court reasoned that if a party had to extinguish its rights with the TTAB before bringing an infringement suit, TTAB proceedings may devolve into a formality and issue preclusion thus would not be appropriate. Contrastingly, the registration process is not a streamlined agency formality in the Court's eyes, but instead is a robust procedure subject to de novo review by district courts. As a result, *Congress did not expressly intend issue preclusion to not apply to TTAB decisions.*

### **TTAB Decisions Can Carry Preclusive Effect on Courts**

The Court then addressed whether there is a reason that no TTAB decision could ever meet the ordinary elements of issue preclusion. Although not every registration decision will deserve preclusive effect, the Court concluded that it is possible that some will, and that this is the more important point.

A critical inquiry for issue preclusion is whether the two tribunals address the same issue. In other words, *are the likelihood of confusion standards for registration and infringement the same? The Court's answer is yes.* As one justification, the language of the registration and infringement provisions of the Lanham Act "is essentially the same," each using "likely to cause confusion" with inconsequential spacing variations. Additionally, district court judges apply a single likelihood of confusion standard when adjudicating infringement and registration disputes in the same proceedings. Issue preclusion thus can apply to TTAB decisions when the mark owner makes

actual use of its mark in materially the same way as listed in the registration application. On the other hand, if the mark owner makes a materially different use of the mark than that applied for, the TTAB would not be deciding the same issue and preclusion should not apply. The Court also states that use of different factors by the TTAB and courts is of no relevance.

Materiality is a crucial consideration. Issue preclusion can still apply even if there are minor variations between actual use and the applied for use.

In court proceedings bearing on a mark's use, often much more attention is placed on marketplace factors, consumer base, advertising channels and formats, and other such use issues than a TTAB proceeding would hear. The Court's decision hardly addresses these differences. Also downplayed are the differences in TTAB and court procedure, as well as the higher significance that the TTAB places on marks' appearance and sound.

Nonetheless, the Court importantly states that, *if the TTAB does not consider the marketplace usage of the parties' marks (at all), then the TTAB's decision will have no preclusive effect in a court proceeding where actual use is "the paramount issue."*

### **The Court Also Addresses a Circuit Split**

The decision today aligns fairly closely with the law of the Third and Seventh Circuits, which have given TTAB rulings preclusive effect when facts and analyses in the parallel cases lined up sufficiently. The Second Circuit has done so in cases where the TTAB contemplated the marketplace fully. Other Circuits, such as the Fifth and the Eleventh, have refused to give TTAB decisions preclusive effect, yet nonetheless have given some deference to TTAB decisions.

### **A Noteworthy Dissent**

Justice Thomas, joined by Justice Scalia, issued a dissent that is nearly as lengthy as the majority opinion. Among other issues discussed, the dissent rejects the presumption of administrative preclusion, and specifically finds that the TTAB is not a court of competent jurisdiction as a tribunal must be for issue preclusion to apply. Further, the dissent finds that TTAB registration decisions were never meant to be

decisive in later infringement suits.

### **Implications of the Court's Majority Opinion**

*The Court's reasoning extends to issues beyond likelihood of confusion between two marks.* So long as the standards used by the TTAB and courts "are not fundamentally different," issue preclusion should apply. Expect the Court's decision to be applied to priority, descriptiveness, abandonment, acquired distinctiveness, and other issues determined by the TTAB.

*Moreover, the TTAB may be less inclined to quickly suspend proceedings* when a court action is filed. In fact, district court litigation – at least in its early stages, or if a concurrently running TTAB proceeding is in its later stages – may be stayed so that the TTAB can issue its decision, which the court will follow.

*TTAB proceedings are likely to become more costly and involve more extensive discovery and motion practice as the Court's decision increased the stakes for brand owners.* Infringement lawsuits in district courts have traditionally carried greater consequences than TTAB proceedings because only courts can issue remedies of damages, attorneys' fees, court costs, and injunctions. But in cases where a TTAB decision will be dispositive at the district court level, parties will be more willing to vigorously dispute likelihood of confusion and other issues before the TTAB. As a result of extra discovery and increased motion practice, TTAB proceedings will advance slowly at more expense to the parties.

*These effects may make it more likely that trademark owners forum shop and circumvent the TTAB altogether.* On the other hand, even after TTAB proceedings conclude, where additional facts arise, careful lawyering might allow a party to present a new issue on appeal so as to avoid issue preclusion.

Of course, the Court's decision raises several new questions, as well. Among these include:

- What is the standard for determining whether actual use in the marketplace is significant enough to be "paramount" in a court proceeding such that preclusion might not apply?

- If the situation is not right for issue preclusion, can a federal court nonetheless find that a TTAB holding is persuasive, or should the court give the TTAB decision no evidentiary weight?

## District Court Rejects Plaintiff's Narrow Construction of the Term "User" in the DMCA's Safe Harbor Sec 512

Pierre Grosdidier



Pierre Grosdidier

The Internet is inundated with user-uploaded text, pictures, music, and videos, many of which are subject to copyright protection. This material appears to be available—*gratis*—at the click of a mouse on various media hosting websites owned and managed by online service providers (“**OSPs**”), e.g., YouTube. This online *divertissement* may be a violation of copyright law when the copyright owners do not grant permission to display their material. Each instance of infringing material may also be a breach of contract because the OSPs’ terms of use invariably forbid users from uploading copyrighted material absent permission from the rightful owners.

In *BWP Media USA Inc., v. Clarity Digital Group, LLC*, the court addressed the issue of who is a “user” under the Digital Millennium Copyright Act’s (“**DMCA**”) safe harbor provision, 17 U.S.C. § 512. No. 14-cv-00467, 2015 WL 1538366, at \*6 (D. Colo. Mar. 31, 2015). The significance of this decision is that OSPs can benefit from § 512 even when their own employees upload infringing copyrighted material on the OSP’s websites. An OSP’s liability for the posting of infringing material by its employees, at least in the District of Colorado, will likely turn on § 512(c)(1)(A), i.e., on whether the OSP knew or should have known of the infringement and what it did about it, not on the definition or scope of the term “user.” But even though § 512 imposes no obligation on OSPs to police their users, OSPs might be well advised to be alert to “facts or circumstances from which [their employees’] infringing activity is apparent,” and to act “expeditiously” when such activity is discovered.<sup>1</sup>

Despite the fact that infringing material resides on their servers, OSPs are largely immune from civil liability thanks to the DMCA’s § 512. This provision, also known as the Online Copyright Infringement Liability Limitation Act (“**OCILLA**”), shields qualifying OSPs from “infringement of copyright by reason of the storage at the direction of a user . . .”<sup>2</sup> OCILLA grants OSPs immunity for when users upload unauthorized copyrighted material—provided the OSPs follow certain rules. One of these rules is that the OSPs do not have knowledge of the users’ infringing activity.<sup>3</sup>

One source of ambiguity is that OCILLA does not define the term “user.” In *BWP*, the court defined a “user” as “a person or entity who avails itself of the service provider’s system or network to store material.” Significantly, this definition includes OSP employees who are also users of their employer’s hosting websites, which implies that OSPs can benefit from § 512’s safe harbor even when their own employees upload infringing copyrighted material.

Clarity Digital Group, the defendant in *BWP*, operated [www.examiner.com](http://www.examiner.com), a news website. Examiner.com staff initially vetted contributing authors, referred to as “Examiners,” and provided them with some content and editorial supervision, the exact extent of which was disputed. Examiners received some financial compensation for their contributions but otherwise remained independent contractors. The Examiners’ contract expressly prohibited them from including unauthorized copyrighted material in their posts, and warned that repeat violators could be terminated.

The plaintiffs claimed, and Clarity admitted, that the Examiner website “displayed 75 of plaintiffs’ copyrighted photographs without permission.” Plaintiffs first sent Clarity a take-down notice in July 2013, and then sued in February 2014 alleging various copyright infringement claims. In both instances, Clarity timely removed all the infringing photographs. Clarity sought summary judgment, arguing that it was entitled to immunity from plaintiffs’ claims under the DMCA’s safe harbor § 512(c) because Examiners, i.e., “users,” had posted the infringing photographs acting independently of, and unbeknown to, Examiner.com staff.

The plaintiffs argued, *inter alia*, that the court should

construe the term “user” narrowly to exclude an OSP’s “owner[s], employee[s] and/or agent[s].” The plaintiffs acknowledged that the issue was one of first impression, but argued that the “case law dictate[d] that the word ‘user’ [wa]s a legal term of art for purposes of applying the safe harbor provision of the DMCA.”<sup>4</sup> The plaintiffs further argued that, under the facts of the case, the Examiners were agents of the defendant and that, “[a]gents of an [O]SP are not users under the DMCA.”<sup>5</sup> Simply stated, plaintiffs sought to defeat Examiner.com’s safe harbor defense by excluding OSPs and their agents as “users” and by arguing that Examiners were the OSPs’ agents.

The court rejected the plaintiffs’ arguments and adopted the plain-language and dictionary-based definition of the term “user” stated above. The court first cautioned that plaintiffs could not use the term “user” to “distinguish between storage at the direction of the [OSP] and storage at the direction of third parties” because the DMCA already made this distinction without recourse to the term. Indeed, the DMCA’s §§ 512(a)(1) and (b)(1)(A) speak of “person[s] other than the service provider.” That the DMCA distinguishes between OSPs and third-parties without recourse to the term “user” “caution[ed] against plaintiff’s [sic] interpretation.”

The court also noted that § 512(c)(1)’s language did not support a distinction between service providers and third parties, as plaintiffs argued. Subsections 512(c)(1)(A)–(C) already incorporated the sort of OSP conduct that plaintiffs complained about. OSPs that breach these subsections cannot expect to qualify for the DMCA’s safe harbor provision. OSPs cannot claim safe harbor protection for their own storage of infringing material, for example. Likewise, OSPs cannot claim protection from profit-making activities that they have “the right and ability to control.” The court held that plaintiffs’ narrow reading of the term “user,” therefore, would be redundant in light of §§ 512(c)(1)(A)–(C), and contrary to the rule that courts should avoid statutory interpretations that make other provisions in the same statute unnecessary.<sup>6</sup>

The court remained unpersuaded by the cases cited by the plaintiffs. In *Capitol Records, LLC v. Vimeo, LLC*, for example, Vimeo employees uploaded infringing videos to Vimeo’s website.<sup>7</sup> In that case, the court

held that a triable issue existed regarding whether the employees were acting as §512(c) “users” or in their capacity as Vimeo employees (by implication, Vimeo could be charged with knowledge or awareness of the uploads under § 512(c)(1)(A)). Moreover, *Vimeo* was distinguishable because the alleged wrongdoers in that case were Vimeo employees, whereas Examiners were not defendant’s employees. Other cited cases fared no better in the court’s eyes, and none, the court noted, construed the term “user.”

For the above-stated reasons, the court adopted its plain-language definition of “users,” and held that the Examiners qualified as such. This result did not end the court’s inquiry, however. OCILLA’s safe harbor protection extends “only to content uploaded ‘at the direction of a user.’”<sup>8</sup> The question was, therefore, whether the infringing pictures were uploaded at the direction of the Examiners, or at the direction of the defendant. Finding that the plaintiffs had adduced no evidence sufficient to support “a genuine dispute of material fact” as to this and other issues in dispute, the court granted defendant’s motion for summary judgment.

OCILLA embodies a tension for copyright law, separate from its attempt to strike a balance between the interests of copyright owners and those of OSPs by preserving both sides’ interests and incentivizing their cooperation.<sup>9</sup> As another court in the Southern District of New York reaffirmed, the DMCA’s safe harbor § 512 should be narrowly construed, as should all immunities from liability.<sup>10</sup> This principle might arguably support a narrow construction of the term “user.”

But Congress made clear its intent to shield qualifying OSPs from liability for their user’s copyright infringement when it drafted the DMCA. As the Ninth Circuit Court of Appeals noted in *dicta*,

Congress explicitly stated in three different reports that the DMCA was intended to protect qualifying service providers from liability for all monetary relief for direct, vicarious and contributory infringement.<sup>11</sup>

Moreover, § 512 imposes no obligation on OSPs to police their users or ferret out instances of copyright

infringement. Instead, Congress placed the burden on copyright owners to identify instances of infringement and to give notice to the OSPs. A tension exists, therefore, between § 512's language and legislative history, which unambiguously supports the OSPs' immunity, and copyright case law in general, which would seem to circumscribe this immunity. *BWP* is a district court's most recent attempt to address this tension. It is unlikely to be the last—the *BWP* plaintiffs have filed a notice of appeal.

<sup>1</sup> 517 U.S.C. § 512(c)(1)(A).

<sup>2</sup> *Id.* § 512(c)(1).

<sup>3</sup> *Id.* § 512(c)(1)(A).

<sup>4</sup> Plaintiffs' Opposition to Defendant's Motion for Summary Judgment at 9, *BWP Media USA Inc., v. Clarity Digital Group, LLC*, No. 14-cv-00467 (D. Colo. Feb. 17, 2015) (Pacer Docket No. 63).

<sup>5</sup> *Id.* at 16.

<sup>6</sup> *BWP*, 2015 WL 1538366, at \*7 (citing *Freytag v. Comm'r*, 501 U.S. 868, 877 (1991) ("[our] cases consistently have expressed 'a deep reluctance to interpret a statutory provision so as to render superfluous other provisions in the same enactment.'").

<sup>7</sup> 972 F. Supp. 2d 500, 517-18 (S.D.N.Y. 2013), *reconsideration granted*, 972 F. Supp. 2d 537 (S.D.N.Y. 2013).

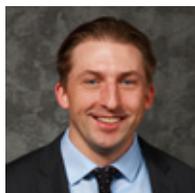
<sup>8</sup> *BWP*, 2015 WL 1538366, at \*8 (emphasis in original).

<sup>9</sup> *Capital Records, Inc. v. MP3Tunes, LLC*, 821 F. Supp. 2d 627, 636 (S.D.N.Y., 2011).

<sup>10</sup> *Id.* (citing *United States v. Texas*, 507 U.S. 529, 534 (1993); *Fame Publ'g Co. v. Ala. Custom Tape, Inc.*, 507 F.2d 667, 670 (5th Cir.1975) (narrowly construing a statutory exception to copyright owners' exclusive rights)).

<sup>11</sup> *BWP*, 2015 WL 1538366, at \*5 (citing *UMG Recordings v. Shelter Capital Partners LLC*, 718 F.3d 1006, 1028 (9th Cir.2013) (emphasis and quotations omitted)).

## Haynes and Boone Adds Denver IP Capabilities with Addition of Experienced Denver Practitioner Robert Ziemian



Robert Ziemian

**Robert Ziemian**, a seasoned intellectual property lawyer with deep experience obtaining and enforcing patents and trademarks on a global basis, has joined the newly established Haynes and Boone, LLP Denver office.

"Denver has emerged as a leading source of IP innovation and products and we want to be able

to service this vital part of the local and national economy. Robert's capabilities to help our existing clients on a broad range of patent prosecution services across multiple venues will prove invaluable in the years to come," said Denver Administrative Partner **Patrick L. Hughes**. "His experience and medical products focus make him an ideal fit for our nationally recognized IP practice."

Ziemian has focused his practice on prosecuting, enforcing and licensing patents in the areas of chemical engineering and industrial process flow, automotive technologies, medical devices, wireless, consumer electronics, telecom, e-commerce, targeted marketing, software and electronic gaming. In 2009 he was part of a patent litigation team that successfully settled a major patent infringement action for \$70 million, which was one of the top ten IP wins that year.

His experience focuses on a holistic perspective in patent portfolio-building that includes filing and prosecuting patents, analyzing existing assets and identifying and acquiring new assets. He has previously worked with a team of top-level scientists and engineers in order to identify and acquire value patents in a variety of fields, including semiconductors, optics, software, telecom, wireless, e-commerce, electronic gaming, social networking, and electronics. His past work experiences include positions at entities such as TPL, Inc., Bose, the Navy Office of General Counsel, MWH Global, and Woods Hole Oceanographic Institute.

With the Haynes and Boone IP practice now encompassing about 20 percent of the firm, Ziemian said the resources available to his clients will also be vastly expanded.

"It is clear that Haynes and Boone is deeply invested in IP work at all levels," Ziemian said. "Beyond that, the firm seems to care a lot about its regional offices, which includes an important California component. I could not pass up the chance to help launch these capabilities here in Colorado."

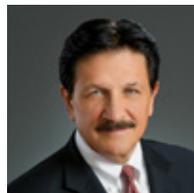
The arrival of Ziemian comes on the heels of the recent announcement that the Denver office has expanded its energy, natural resources and

environmental litigation capabilities with the addition of longtime Denver practitioner **John D. Fognani** and his colleague **Mike Hegarty**.



Mike Hegarty

The Denver growth comes on the heels of a significant expansion of the firm's Greater China cross-border practice, which added a six-member team of lawyers, including two seasoned partners – one in Shanghai and the other in Houston. Complementing this effort is the growth of the firm's 20-year-old Mexico City office in anticipation of the opportunities for regional oil and gas companies as a result of the historic energy and infrastructure reforms in Mexico.



John D. Fognani

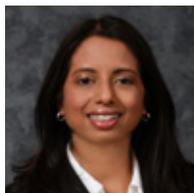
And, having had the opportunity to try cases with John in the past, I have seen his excellence in the courtroom. I am excited to have the opportunity to work with them again at Haynes and Boone."

Said **David Harper**, leader of the firm's Intellectual Property Litigation Section: "We are very fortunate that Whitney and John have agreed to lend their considerable talents to our growing generic pharmaceutical practice in Washington. Both of these professionals are very experienced dealing with the complex IP issues involved in bringing generic drugs to the marketplace. They will be an effective complement to Kyle and his existing team."

**Remily** has more than 15 years of experience as a lawyer and registered patent agent. Her practice focuses on transactional work in the pharmaceutical field with a particular focus on rendering patent opinions (including the provision of detailed statements and notice letters) and conducting other forms of due diligence and landscape analyses.

### Haynes and Boone Adds Pharmaceutical Patent Practitioners Whitney Remily and John Bateman to Washington, D.C. Office

The Washington, D.C. office of Haynes and Boone, LLP proudly announces the expansion of its Hatch-Waxman/ANDA Practice Group with the addition of **Whitney Remily** and **John Bateman**.



Whitney Remily

Both come to Haynes and Boone as partners from the Washington, D.C. office of Kenyon & Kenyon LLP, an intellectual property law firm.

Washington Partner **Kyle Musgrove**, who previously worked with Remily and Bateman at Kenyon, said the new acquisitions are talented lawyers who bring with them pharmaceutical experience that will help grow the firm's already robust Hatch-Waxman practice.



John Bateman

She has significant experience with various patent matters relating to filings of Abbreviated New Drug Applications by generic drug manufacturers. In this context, she has handled more than 500 opinion matters, including issues relating to FDA exclusivity, new chemical entities, importation of active ingredients, synthetic intermediates, polymorphs, approved and off-label indications, finished formulations/compositions and drug products.

Her practice also includes experience negotiating licenses, preparing and prosecuting patent applications (including patent term extensions) and counseling in litigation arising under the Hatch-Waxman Act. And, in addition to pharmaceuticals, she has substantial experience in other technical areas including organic and inorganic chemistry, agrochemicals, cosmetics, diagnostics, polymers, food products, nutritional supplements, cigarettes, fine chemicals and medical devices.

Whitney previously worked at Merck & Co. as a synthetic organic chemist, where she was involved in the synthesis and development of pharmaceutical compounds.

"These additions will allow us to serve our clients even better," Musgrove said. "Whitney has a history of developing arguments that will hold up in litigation.

**Bateman** has more than 20 years of experience litigating patent disputes, including serving as lead counsel at trial and on appeal. His practice focuses on matters involving pharmaceuticals, medical devices, biotechnology and agrochemicals, with a special emphasis on representing generic companies in Hatch-Waxman cases. He has worked with a wide variety of generic pharmaceutical clients, including companies based in the United States, India, Europe and Israel.

He has obtained favorable judgments for such clients after trial and on appeal, clearing the way for them to bring their products to market. For example, Bateman and Musgrove represented an ANDA applicant at trial and on appeal in a case in which a patent covering a drug with sales of over \$1 billion a year was found invalid and not infringed.

He said he is looking forward to joining Haynes and Boone for several reasons. “Haynes and Boone has an outstanding pharmaceuticals practice, with great clients and skilled attorneys, and I feel lucky to be a part of it,” Bateman said. “And the firm’s recognized experience in inter partes review proceedings will be of tremendous benefit to the companies I work with, as such proceedings have become an integral component of litigation strategy in Hatch-Waxman matters.

“Plus, both Whitney and I were struck by the cooperative environment and genuine enthusiasm Haynes and Boone lawyers have for their firm. That really stood out.”

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



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