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FDA (FINALLY!) ISSUES NEW REGULATIONS TO CLARIFY PHARMACEUTICAL PATENT LITIGATION: HOW TO USE PATENT "USE CODES"

By Matthew M. D'Amore, Steve Keane, and David C. Doyle



On October 6, 2016, the FDA issued a final rule implementing certain provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) governing the approval of generic drugs, including abbreviated new drug applications (ANDAs) and 505(b)(2) applications. That's right – the MMA was passed in 2003, and the FDA issued these implementing regulations 13 years later. Are they game-changing? In at least one respect, *yes*. While many of the provisions reflect FDA policies that have already been in effect but were never formalized, in one crucial area the FDA changed the game of how the NDA holder (that is, the brand) must identify and defend the method patents that cover the indications approved for its prescription drugs.

Our goal here is not to summarize every aspect of the 80 Federal Register pages of rules and commentary,[1] but instead to highlight one change to a highly litigated area involving method patents and their related FDA "use codes."[2] The new regulations become effective on December 5, 2016.

HERE IS WHAT YOU NEED TO KNOW

- NDA holders must now narrowly tailor their use codes and specify the sections and subsections (but not the specific language) of the label that relate to the use code.
- Disputes over use codes and patent listings must be brought through a new procedure that requires the challenger and the NDA holder to exchange information – but the FDA acknowledges that its solution is only "incremental" and may not ultimately resolve the dispute.
- Generics with pending ANDAs or 505(b)(2) applications do not need to provide a patent certification to untimely listed patents, and that now includes untimely use code changes.

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We discuss each of these items in more detail below.

1. **What Are "Use Codes" and How Are They Used?**

   Use codes provide the mechanism that NDA holders use to tell the FDA (and the world) how their Orange Book-listed method patents relate to their approved drug indications. Method patents (issued by the Patent & Trademark Office) claim how to use a drug substance or product; drug labels (approved by the Food & Drug Administration) describe the uses of the drug substance or product that the FDA has approved. Generics are permitted to try to "carve out" approved uses from their labels (for example, to seek approval for an unpatented indication instead of the indication covered by the method patent). Whether or not the FDA will approve the carve out depends not on the patent itself (which the FDA will not review), but on the NDA holder's 240-character description of that patent – the "use code," which is given a number and identified on the FDA's website.[3]

   Seems simple, right? But the NDA holder's patent claims do not always match the approved indication word for word, and they have some leeway in how they describe their patent claims in the use code. And out of leeway comes litigation. Several court cases have come out of the FDA's administrative "carve out" decisions.[4]

2. **How Has the FDA Changed the Use of Use Codes?**

   The FDA's new rule forces significant changes to the use code regime, ostensibly "to address overbroad or ambiguous use codes that may delay approval of generic drugs."[5] Specifically, the FDA now expressly requires that "the NDA holder's description of the patented method of use . . . must describe only the approved method(s) of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product."[6] In addition, the FDA requires that "[i]f the method(s) of use claimed by the patent does not cover an indication or other approved condition of use in its entirety, the applicant must describe only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product."[7] And, the NDA holder must "identify with specificity the section(s) and subsection(s) of the approved labeling that describes the method(s) of use claimed by the patent submitted."[8]

   The regulations seem to leave to the courts to decide what claims "could reasonably be asserted."[9] Furthermore, the FDA adopted what it calls an "incremental" solution for how it will proceed if a use code description is challenged.[10]

3. **How Can an Interested Third Party Challenge a Use Code Description?**

   Previously, if a listing was challenged by a third party, the FDA would merely request that the NDA holder confirm the correctness of the listing – without any substantive review by the FDA. Now, the FDA rules require an information exchange when a generic applicant (or other third party) disputes an Orange Book patent listing. The challenger "must first notify the Agency" of the dispute, including "a statement of dispute that describes the specific grounds for disagreement regarding the accuracy or relevance" of the patent listing.[11] The FDA will provide this notice to the NDA holder, who then has 30 days to confirm the correctness of the patent information and provide a signed verification or withdraw or amend the listing.[12]

   Where the use code is challenged, additional procedures apply. In that case, the challenger's "statement of dispute must be only a narrative description (no more than 250 words) of the person's interpretation of the scope of the patent."[13] Within 30 days, the NDA holder must then:

   - Confirm the correctness of its description or withdraw or amend it;
   - Provide a narrative description (no more than 250 words) "of the NDA holder's interpretation of the scope of the patent that explains why the existing or amended 'Use Code' describes only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted"; *and*
   - Provide a signed verification.[14]

   All of this information will go back to the challenger, and it will be posted on the FDA's website.[15] But the FDA will only amend or change the use code or Orange Book listing if it is amended or withdrawn by the NDA holder; it will not independently review or evaluate the submissions.[16]

4. **What Happens Then?**

   Good question. While the patent listing dispute procedure places more burden on the NDA holder, it ultimately may do little to reduce litigation over listing disputes, particularly for use code descriptions. The process might lead an NDA holder to amend or withdraw its use code. But if the NDA holder maintains its position, its use code stands – with the addition of the 250-word defensive statement. The FDA provides little guidance as to how it will use these statements to address carve outs. Indeed, the FDA offered but then *withdrew* a proposed rule that would defer to the ANDA or 505(b)(2) applicant's

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interpretation of the use code if the NDA holder did not respond to the notice or if the NDA holder confirmed its original description without modification.[17]

In short, the FDA is taking a "stepwise" approach.[18] It notes that "[i]f these revisions to our regulations do not adequately address the problem, we will further consider whether to finalize the proposal to review a proposed labeling carve-out for a 505(b)(2) application or ANDA with deference to the 505(b)(2) and/or ANDA applicant(s)' interpretation of the scope of the patent."[19]

Right now, it is hard to see how this rule will reduce litigation, but we'll be watching closely how the FDA, NDA holders, and use code challengers proceed once these rules are in effect.

1 Among other things, the new rules cover a range of topics ranging from restrictions on ANDA amendments and supplements to how and when generics can mail their paragraph IV notice letters.
2 If pharmaceutical patents are not up your alley, we'll forgive you if you stop reading!
3 Check them out at http://www.accessdata.fda.gov/scripts/cder/ob/results_patent.cfm.
4 *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S,* 132 S. Ct. 1670, 182 L. Ed. 2d 678 (2012); *Hospira, Inc. v. Burwell*, No. GJH-14-02662, 2014 WL 4406901 (D. Md. Sept. 5, 2014).
5 81 Fed. Reg. 69580.
6 21 C.F.R. § 314.53(b)(1).
7 *Id.* But in a small (really small) concession to NDA holders, the FDA allowed 10 more characters to describe the use code. 81 Fed. Reg. 69598 (noting increase of use code character limit from 240 characters to 250 characters). (Just to illustrate how small a change this is, we note that it takes 10 characters to write the word "characters". . . .)
8 21 C.F.R. § 314.53(b)(1).
9 81 Fed. Reg. 69581.
10 *Id.*
11 21 C.F.R. § 314.53(f)(1).
12 21 C.F.R. § 314.53(f)(1)(i)(A).
13 21 C.F.R. § 314.53(f)(1).
14 21 C.F.R. 314.53(f)(1)(i)(B).
15 21 C.F.R. § 314.53(f)(1)(iii).
16 21 C.F.R. § 314.53(f)(1)(i)(B)(1).
17 81 Fed. Reg. 69581, 69604
18 81 Fed. Reg. 69604.
19 *Id.*

COMING IN HOT!

We'd like to extend our congratulations to our colleagues on recent awards and recognitions:

- MoFo was named a Litigation Powerhouse in *Law360*'s inaugural 2016 Litigation Powerhouses series.
- MoFo was ranked by *U.S. News–Best Lawyers* "Best Law Firms" Tier 1 in Nationwide areas of Litigation-Intellectual Property, Biotechnology Law, Litigation-Patent, and Patent Law.
- *Best Lawyers* named 13 MoFo IP attorneys as recommended in the areas of Litigation: Intellectual Property, Litigation: Patent, Patent Law, Biotechnology Law, Commercial Litigation, and Bet-the-Company Litigation.
- MoFo IP Litigation partner **Chuck Barquist** was named *Best Lawyers*' 2017 Los Angeles Litigation - Patent "Lawyer of the Year."

WHEN THE "PLAIN AND ORDINARY" MEANING IS NEITHER PLAIN NOR ORDINARY

By Matthew Chivvis and Dina Roumiantseva

INTRODUCTION

It is common in patent cases for the patentee to ascribe "plain and ordinary" meaning to terms in a patent claim, while the defendant often seeks a narrower construction. But what if the parties agree that "plain and ordinary" applies but then dispute what the plain and ordinary meaning should be? The Federal Circuit's decisions provide conflicting guidance on the duty to construe a term when the plain and ordinary meaning is disputed. The lack of a clear rule has allowed district courts to vary widely in how they handle claim construction in these circumstances.

PLAIN AND ORDINARY MEANING IN THE FEDERAL CIRCUIT

In *O2 Micro International Ltd. v. Beyond Innovation Technology Co.*, the Federal Circuit held that a determination that a claim term "needs no construction" or has the "plain and ordinary meaning" may be inadequate when a term

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has more than one "ordinary" meaning or when reliance on a term's "ordinary" meaning does not resolve the parties' dispute.[1] The dispute in that case concerned the term "only if"; the plaintiff argued that the limitation applied only during "steady state" operation of the current controllers at issue, while the defendant argued that the "only if" limitation applied at all times without exception.

During the claim construction hearing, the district court acknowledged the dispute over the scope of the asserted claims but declined to construe the term, stating that this term "has a well-understood definition, capable of application by both the jury and this court in considering the evidence submitted." The Federal Circuit found this decision to be in error because the "ordinary" meaning of a term did not resolve the parties' dispute. When the district court failed to adjudicate the parties' dispute regarding the proper scope of the term, the parties' arguments regarding the legal significance of the "only if" limitation were improperly submitted to the jury. The Federal Circuit noted that claim construction requires the court to determine what claim scope is appropriate in the context of the patents-in-suit, and thus courts are frequently obliged to construe "ordinary" words under *Markman*.[2] Remanding the case, the Federal Circuit concluded: "[w]hen the parties raise an actual dispute regarding the proper scope of these claims, the court, not the jury, must resolve that dispute."

On the other hand, in *Finjan, Inc. v. Secure Computing Corp.*, the Federal Circuit found that the plain and ordinary meaning was a sufficient construction despite the parties' dispute regarding the scope of the claims.[3] The term at issue was "addressed to a client" in the context of Internet communications protocols. The plaintiff argued for "plain and ordinary meaning" while the defendant proposed to define "addressed" as "containing the IP [Internet Protocol] address of the client computer," and "client" as "the computer from which the user is making a request." The district court acknowledged the parties' dispute, but ruled that the term did not require construction and the jury could be instructed to give the words in the claims their "ordinary meaning." The Federal Circuit distinguished this case from *O2 Micro*, finding that the district court resolved the dispute by rejecting the defendant's construction and by preventing the defendant's expert from repeating to the jury that the asserted claims require an IP address. Moreover, the Federal Circuit noted that Finjan was not entitled to a new trial because Finjan failed to explain on appeal how a different definition would have negated infringement.

While the Federal Circuit instructed that the dispute in *Finjan* does not constitute an "actual dispute regarding the proper scope of the claims" within the meaning of *O2 Micro*, the decision provides little guidance on when a plain and ordinary meaning construction will or will not suffice. Moreover, the Federal Circuit subsequently acknowledged that, where the parties did not define a term, the term may have more than one "plain and ordinary" meaning.[4] In *Kaneka Corp. v. Xiamen Kingdomway Group Co.*, the district court construed the term "sealed tank" to mean "a tank that is closed to prevent the entry or exit of materials."[5] The Federal Circuit reversed, agreeing with the plaintiff that the specification and disclosed embodiments showed that the "sealed tank" should be sealed to the atmosphere, but not necessarily to other materials, such as solvents. Defendants argued that because the patentee did not define the term "sealed," the term must have one plain and ordinary meaning that governs, but the Federal Circuit ruled that, following *O2 Micro*, courts should be aware that a term may have more than one "plain and ordinary" meaning and a construction that excludes all disclosed embodiments is especially disfavored.

Most recently, the Federal Circuit revisited *O2 Micro* in finding that a plain and ordinary meaning construction was insufficient to overturn a $13 million infringement verdict in *Eon Corp. IP Holdings v. Silver Spring Networks, Inc.*[6] The crucial question in *Eon* was whether the terms "portable" and "mobile" should be construed to cover fixed or stationary products, such as Silver Spring's smart electricity meters, in the context of claims directed to networks for two-way interactive communications. The Federal Circuit found that while "a court need not attempt the impossible task of resolving all questions of meaning with absolute, univocal finality," the district court erred in rejecting Silver Spring's proposed definition in favor of plain and ordinary meaning, thereby leaving the question of claim scope for the jury. The Federal Circuit further noted that while the district court acknowledged the importance of context in determining claim scope (finding the terms' meanings clear "in the context of the claims" and precluding the parties from interpreting the terms "in a manner inconsistent with this opinion"), the district court's error lay in failing to provide the necessary context to the jury. The Federal Circuit then construed the claim terms in view of the specification and held that no remand was necessary because no reasonable jury could have found that Silver Spring's electric utility meters infringe.

Notably, Judge Prost, who also authored the *O2 Micro* opinion, wrote for the majority in *Eon*. Judge Bryson dissented, arguing that the accused meters would qualify as mobile and portable under the ordinary meaning of those terms, "capable of being easily and conveniently transported," and that the majority went too far in adopting Silver Spring's proposed limitation "and *designed to operate without a fixed location*." Judge Bryson pointed to video and photograph evidence demonstrating that the power meters are smaller than a volleyball and are easily installed by hand into a socket with no tools needed. In

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Judge Bryson's view, the fact that the meters were secured with a retaining ring and bolt only supported the jury's finding that the meters were portable or mobile, as these precautions were put in place to prevent the meters from being moved. He also noted that the close parallelism of all of the dictionary definitions indicated that there is only one plain and ordinary meaning of the terms "mobile" and "portable" and, therefore, the district court's instruction that the jury should give those terms their plain and ordinary meaning properly resolved the parties' dispute. Thus, it appears that the adequacy of "plain and ordinary" meaning construction remains a contested subject within the Federal Circuit.

DIFFERENT DIRECTIONS ON PLAIN AND ORDINARY MEANING IN DISTRICT COURTS

The lack of clear direction from the Federal Circuit has caused district courts to pursue different directions in claim construction. The Northern District of California has tended to construe even "ordinary" terms when a dispute regarding the claim scope is presented by the parties, while the Eastern District of Texas has tended to find that no construction is necessary or that a "plain and ordinary" meaning construction will suffice.

For example, in *TVIIM, LLC v. McAfee, Inc.*, the parties disputed the scope of the term "vulnerability" in the context of computer security, and both parties purported to propose a "plain and ordinary" meaning of the term.[7] The plaintiff, however, argued that the ordinary meaning should be a "'pre-existing security problem,' defined as a 'mistake' or 'defect' in software" while the defendant argued that the meaning should be "any exploitable weakness in a computer system." The Northern District of California found that the parties fundamentally disputed the meaning and scope of the term, and proceeded with a review of the specification and intrinsic history to conclude that the plain and ordinary meaning should not be limited to only "pre-existing" security problems.

In another case, the Northern District of California found that a "plain and ordinary" meaning must be supplemented by the meaning intended in the specification.[8] In *NobelBiz, Inc. v. LiveVox, Inc.*, the parties disputed the term "replacement telephone number," and the plaintiff sought the "ordinary" meaning while the defendant proposed "a telephone number that is put in the place of the originator's telephone number." The court noted that plaintiff's additional argument that the number is "selected" not "replaced" was inapposite and ignored the nature of the term entirely. The court also noted that the defendant's inclusion of the clause "put in the place of" was too limiting and not supported by the specification. Thus, the court settled that the plain and ordinary meaning should be "a telephone number that substitutes for an original telephone number."

In contrast, in *Queen's University at Kingston v. Samsung Electronics Co.*, the Eastern District of Texas held that a dispute regarding the scope of a claim term "boils down to the application of commonly understood words to particular fact situations" and concluded that questions of fact should be left for the finder of fact rather than for the court.[9] One of the terms in dispute was "wherein the operation that is modulated is initiated by the device" in the context of human-device communications. The plaintiff argued that no construction is needed, while the defendant proposed "wherein the operation that is modulated is initiated by the device based on an information event and without explicit or implicit user input." The court observed that the invention was directed to device-initiated interactions or communications, and that the patentee's statements during prosecution constituted a disclaimer of direct user input. Yet the court concluded that the prosecution history disclaimer did not confine the meaning of "initiated by the device" so as to exclude any user involvement altogether, such as the device's perception of user's attention state. Despite the fairly technical inquiry into the intrinsic history of the patent, the court found that no construction was needed and proceeded to assign the plain and ordinary meaning to all twelve terms at issue in the claim construction.

Recently, the District of New Jersey grappled with the scope of a "plain" meaning construction that plaintiff proposed in *Sucampo, AG v. Dr. Reddy's Laboratories, Inc.* There, the court took the novel approach of requiring the plaintiff to say whether defendants' proposed construction fell within the plain meaning of the term.

FINAL THOUGHTS

In view of the recent cases on "plain and ordinary" meaning, plaintiffs and defendants would be well advised to consider their proposed constructions in the context of the venue in which they are likely to be heard. Plaintiffs are often tempted to seek a plain and ordinary meaning construction in the hopes that it will cover a wide array of accused products, and there can be real benefits to pursuing this strategy. But the strategy can backfire. The *Patent Case Management Judicial Guide* advises:

> The more that outstanding claim construction issues are deferred until the late phases of litigation or are not resolved until trial, the greater the likelihood of legal error and surprises at trial. Resolving the material claim construction disputes well in advance of trial will prevent procedural aberrations from distracting from or distorting the merits of a case and minimize the risk of reversal and the need for retrial.[11]

O2 Micro creates real issues for case management but can provide the support a defendant needs to build a case

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that real claim construction of even commonly understood terms is required. Venue can have an outsize effect on the success of this argument at the trial court level. Defendants planning long term, however, realize that, barring settlement, the ultimate audience for any claim construction disputes will be the Federal Circuit.

1 *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008).
2 *Id.* at 1362 n.3 (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-89 (1996) (explaining why judges "are the better suited to find the acquired meaning of patent terms").
3 *Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1207 (Fed. Cir. 2010).
4 *Kaneka Corp. v. Xiamen Kingdomway Grp. Co.*, 790 F.3d 1298, 1304 (Fed. Cir. 2015).
5 *Id.* at 1302-4 (adopting the construction used by the International Trade Commission in a parallel proceeding, based on the definition from *Merriam–Webster's Collegiate Dictionary*).
6 *Eon Corp. IP Holdings v. Silver Spring Networks, Inc.*, 815 F.3d 1314 (Fed. Cir. 2016).
7 *TVIIM, LLC v. McAfee, Inc.*, No. 13-CV-04545-HSG, 2015 WL 3956313, at *1 (N.D. Cal. June 28, 2015).
8 *NobelBiz, Inc. v. LiveVox, Inc.*, No. 13-CV-1773-YGR, 2015 WL 225223, at *11 (N.D. Cal. Jan. 16, 2015).
9 *Queen's Univ. at Kingston v. Samsung Elecs. Co.*, No. 2:14-CV-53-JRG-RSP, 2015 WL 2250384, at *10 (E.D. Tex. May 13, 2015).
10 *Sucampo AG et al. v. Dr. Reddy's Labs., Inc. et al.*, No. 3-14-cv-07114 (D.N.J. Mar. 4, 2016) (Letter Order) (Arpert, M.J.).
11 Menell, Peter S. et al., *Patent Case Management Judicial Guide*, Third Edition (July 29, 2015) at 5-12. UC Berkeley Public Law Research Paper No. 2637605.

BREXIT: THE UK CLARIFIES ITS POSITION ON INTELLECTUAL PROPERTY

By Alistair Maughan, Sue McLean and Rakesh Grubb-Sharma*


The process of Brexit will take time, and the implications for our clients' businesses will unfold over time. Our MoFo Brexit Task Force is coordinating across all our offices and working with clients on your key concerns and issues, now and in the coming weeks and months. We will also be providing MoFo Brexit Briefings on a range of key issues. We are here to support you in any and every way that we can.

INTRODUCTION

In the wake of the UK's decision to leave the European Union in June 2016 (followed by the announcement by UK Prime Minister Theresa May that the Article 50 mechanism would be triggered by the end of March 2017), there has been speculation about the possibility and need for changes to the UK's intellectual property regime post-Brexit. Although the UK government intends to introduce a "Great Repeal Act," which (despite its name) will incorporate existing EU legislation into national law to avoid a legislative gap post-Brexit, there is still uncertainty over what will happen to intellectual property rights when the UK formally leaves the EU.

But what we do have is an initial view from the UK Intellectual Property Office (IPO), one of the first UK government bodies to issue an official statement following the Brexit referendum. The statement sets out the IPO's thoughts on the implications that Brexit will have on the future of intellectual property rights in the UK.

In this Brexit Briefing, we examine the views contained in the IPO's statement to see what, if anything, it tells us that we didn't already know.

PATENTS

As pointed out in our previous Brexit Briefing *European Patent Applications, Unitary Patents and the Unified Patent Court System*, the IPO agrees that Brexit will have little or no impact on the UK's participation in the existing European patent system. The European Patent Office (EPO) was created to examine and grant patents under the European Patent Convention (EPC). Upon grant, one can validate an EPO patent in one or more of the 38 contracting countries under the EPC. This system will not be affected by the UK's eventual exit from the EU because the EPC was not established through EU legislation. The UK will remain a contracting member under the EPC post-Brexit.

By contrast, it is expected that the Brexit decision will have an effect on the UK's participation in the EU's planned Unitary Patent System (UPS) and the forthcoming Unified Patent Court (UPC) system. The IPO's statement recognises that the relationship between the UK and the European UPS has been thrown into doubt following the referendum but reiterates that, in the interim, the UK remains a contracting Member State and, for the moment at least, will continue to participate in meetings in line with the position of the UPC Preparatory Committee.

"There will be no immediate changes" is the IPO's official line – although it would have been nice to have had an idea of the timescale within which to expect some decisions, or at least consultation, about the changes that might be expected. One possibility could be that the UK and EU agree that the UK will make an early ratification of the UPC Agreement (which is one of the prerequisites to the UPC system coming into effect) with negotiation on the UK's future role to follow – but the IPO has not been drawn into that debate.

For patentees and stakeholders, uncertainty as to whether the UK will participate in the UPC and UPS raises serious concerns about the viability and financial logic of a unified system that may go forward without a critical member.

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TRADE MARKS

The European Union Trade Mark (the "EUTM") is a popular and versatile vehicle used to protect trade mark rights across the 28 Member States of the EU. The EUTM system is explored in more detail in our previous *Brexit Briefing, Brexit and Your European Trademarks*.

Brexit could result in the UK no longer being part of the EUTM regime because the EUTM Regulation would no longer be directly applicable in the UK. At worst, in the absence of transitional legislation, existing EUTMs would no longer extend to the UK, and applicants would have to register a separate national trade mark to cover the UK.

The IPO is keen to ease any fears of UK trade mark owners – although its statement avoided any mention of the one main approach that could have allayed such fears, *i.e.*, transitional legislation to ensure the future recognition of EUTMs in the UK. It emphasises in its statement that the UK government is exploring "various options" to ensure the long-term coverage of EUTMs, but fails to elaborate on exactly what these options may be. The IPO also hints at a future consultation to gauge the popularity of likely options among users of the trade mark system, so we can expect further detail on the government's plans in due course (although, again, the IPO makes no comment on timings).

The IPO does clarify that, even after the UK leaves the EU, UK businesses will still be able to register an EUTM which will cover all remaining EU Member States – but anything other than that position would have been particularly surprising.

More tellingly, the IPO points to the fact that the UK is also a member of the Madrid system for the international registration of marks (the "Madrid System"), which could possibly signal a greater role for this international regime in the future of UK trade mark protection. The Madrid System is an international trade mark system, which allows users to file one application in one language and pay one set of fees to protect trade marks in up to 113 territories, including the EU.

We continue to believe that, because of the current uncertainties and in order to minimize any risks associated with the Brexit change-over, anyone who owns EUTMs and views the United Kingdom as an important market may want to consider filing for United Kingdom trade mark registrations now, rather than waiting to see what happens when the United Kingdom formally exits the EU. And for new trade marks, we recommend filing in both the EU and the United Kingdom if the United Kingdom will be an important market for you. This increases costs only slightly and clearly secures a priority date for the United Kingdom.

DESIGNS

When talking about the implications of Brexit, there are many parallels to be drawn between trade marks and design rights in the UK. Registered community designs (RCDs) are similar to EUTMs in that they are registered on a European level and backed by EU legislation. Following Brexit, new and existing RCDs would no longer cover the UK, and a supplementary application for UK registered design protection would be required.

Interestingly, the IPO confirms the UK government's intention to ratify the Hague System for the International Registration of Industrial Designs ("Hague Agreement") in a national capacity. The Hague Agreement provides a practical solution for registering up to 100 designs in over 65 territories through filing one single international application.

So, just as with trade marks and the Madrid System, we may see a shift towards reliance on an international regime to fill the legislative void left in the wake of the UK's withdrawal from the EU.

COPYRIGHT

Copyright law is a largely national regime – albeit one harmonised in some respects by EU law such as the EU Copyright Directive (2001/29/EC), which has been implemented in the UK through the amended Copyright, Designs and Patents Act 1988 (CDPA). National UK legislation (such as the CDPA) that transposes EU directives into UK law will remain applicable post-Brexit unless explicitly repealed.

Another of the EU's main contributions to the protection of copyright in the UK comes in the form of the Directive on the enforcement of intellectual property rights (2004/48/EC) (the "Enforcement Directive"), which harmonises civil remedies for breaches of copyright. The EU has also introduced protections from claims of secondary infringement for online intermediaries, including hosts, caches and conduits.

Ultimately, the IPO gave away very little in its commentary on the impact of Brexit on the UK copyright regime. One thing that's already clear is that the European Commission has made no secret of its desire to substantively reform and harmonise copyright law across the EU under its *Digital Single Market strategy*. The UK's departure from the EU will mean that, depending on the exit scenario chosen, it could be left behind as the remaining Member States implement a modernised set of copyright law reforms – and the UK would need to decide whether to follow suit.

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ENFORCEMENT

Other than emphasising the UK's on-going participation in international organisations such as the EUIPO Observatory and Europol, and its continued involvement in the on-going review of the Enforcement Directive, the IPO has said very little about how enforcement of UK intellectual property rights might be affected by Brexit.

Brexit will at the very least have some impact on the way that intellectual property judgements are recognised and enforced in the remaining Member States. For example, the UK would no longer have access to the EUTM courts, so the English courts would no longer be available as a venue for resolving EUTM disputes or obtaining pan-European injunctions. Without the re-cast *Brussels Regulation* (EU 1215/2012), there would also be no automatic recognition or enforcement of judgment in the courts of other Member States.

Please do not hesitate to contact us with any question or concern you have. We're here to help.

* Co-author Rakesh Grubb-Sharma is a Trainee Solicitor in our London office..

DON'T TRIFLE WITH COPYRIGHTS (DECODING THE *DE MINIMIS* TEST)

By Paul Goldstein and Joyce Liou

The essence of the *de minimis* doctrine is that "the law does not concern itself with trifles." A judge neatly summarized the doctrine's operation in copyright law over a century ago: "Some copying is permitted. In addition to copying, it must be shown that this has been done to an unfair extent." *W. Publ'g Co. v. Edward Thompson Co.*, 169 F. 833, 861 (E.D.N.Y. 1909). Only when the unauthorized copying rises above *de minimis* do courts then determine whether the copying is actionable or whether fair use or some other defense to infringement applies.

The Ninth Circuit recently addressed the application of the *de minimis* doctrine to sound recordings in *VMG Salsoul, LLC v. Ciccone*. In determining whether a 0.23-second horn sampling of plaintiff's composition and sound recording by Madonna's "Vogue" was below the *de minimis* bar, the Ninth Circuit framed the question as whether "a reasonable juror could conclude that the average audience would recognize the appropriation." 824 F.3d 871, 878 (9th Cir. 2016). After comparing plaintiff's and defendants' sound recordings, the Ninth Circuit found that an audience would not: "Even if one grants the dubious proposition that a listener recognized some similarities between the horn hits in the two songs, it is hard to imagine that he or she would conclude that sampling had occurred." *Id.* at 880. In the court's view, there is no infringement in the absence of public recognition of the appropriation because the copier does not benefit from the copyright owner's expression, and the rule should be no different for sound recordings than for the underlying musical work. *Id.* at 881.

Salsoul marked a sharp split from the Sixth Circuit, which, in *Bridgeport Music, Inc. v. Dimension Films*, snubbed the *de minimis* test and established an absolute rule for infringement of sound recordings. 410 F.3d 792, 797-98 (6th Cir. 2005). Reversing the district court's grant of summary judgment to the defendant on the ground that the sampling of a guitar chord in plaintiff's recording was *de minimis* use, the Sixth Circuit construed 17 U.S.C. § 114(b)'s prescription of a unique reproduction right for sound recordings – the right only to "recapture the actual sounds fixed in the recording" – as conferring on the copyright owner an exclusive right to sample his or her own recording, and concluded that "even when a small part of a sound recording is sampled, the part taken is something of value." *Id.* at 801-02. In *Salsoul*, the Ninth Circuit carefully considered the Sixth Circuit's reasoning in Bridgeport but concluded that Congress did not intend to create a special rule for sound recordings, and the *de minimis* doctrine applied to *all* copyrighted works. *Salsoul*, 824 F.3d at 882, 884.

Even without parsing the statutory distinction between rights in sound recordings and in all other forms of copyrighted works, determination of the *de minimis* threshold is a complex task. Courts analyzing for de minimis use have typically considered a wide range of factors, from the length of use in the defendant's work to the prominence of the work copied. For instance, in the case of pictorial and visual works displayed in televised broadcasts, the Sixth Circuit found that particular illustrations appearing for at least seven seconds in a commercial constituted de minimis use, while the Second Circuit found that a poster appearing for sixteen seconds in a TV episode did not. *See Gordon v. Nextel Commc'ns*, 345 F.3d 922 (6th Cir. 2003); *Ringgold v. Black Entm't Television, Inc.*, 126 F.3d 70 (2d Cir. 1997). Ultimately, however, the length of use was not the only factor: the Sixth Circuit in *Gordon* determined that a seven-second display was *de minimis* because the illustrations appeared "fleetingly" and were "primarily out of focus," 345 F.3d at 925, and the Second Circuit in *Rinngold* noted that the poster was displayed with "sufficient observable detail" such that the "average lay observer" could discern the artist's colorful style, 126 F.3d at 77.

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The question of whether the average reasonable person would be able to identify an appropriation has come up repeatedly, regardless of the medium of copying. *See, e.g.*, *Sandoval v. New Line Cinema Corp.*, 147 F.3d 215, 218 (2d Cir. 1998) (plaintiff's photographs as used in a movie were not sufficiently observable to the average observer as they were "obscured" and "virtually unidentifiable"); *Newton v. Diamond*, 388 F.3d 1189, 1196 (9th Cir. 2004) (an average audience would not discern the plaintiff's hand as a composer from defendants' sampling in a music recording). Against this backdrop, the Sixth Circuit's *Bridgeport* decision left in its wake great uncertainty about the status of the *de minimis* doctrine for sound recordings, with many district courts not bound by *Bridgeport* choosing to continue to apply a *de minimis* analysis.

In establishing a circuit split, the Ninth Circuit's ruling in *Sasoul* now increases the present uncertainty about the availability of the *de minimis* doctrine for sound recordings. But it also reaffirms a judicial theme prior to *Bridgeport* that *de minimis* use is judged by the observability of the appropriation. Copyright owners and accused infringers alike should recognize that the threshold inquiry of de minimis use is intensely factual, not simply measured by the extent or duration of the use, but also by the degree to which the copying is identifiable to an average observer.

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