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FTC v. Actavis: The Future of Pharmaceutical Patent Settlements After the Court's Adoption of a "Rule of Reason" Framework

The recent Supreme Court decision in *Federal Trade Commission v. Actavis* was closely watched and anticipated because of the importance of patent litigation in the legal/regulatory scheme codified in the Hatch-Waxman amendments to the Federal Food Drug and Cosmetic Act. *FTC v. Actavis*, 133 S. Ct. 2223 (2013). On June 17, 2013 the United States Supreme Court reinstated the Federal Trade Commission's complaint against pharmaceutical manufacturers which had entered into "reverse payment" settlements of patent infringement litigation where the brand name drug manufacturer had provided the potential generic competitors with economic benefits in return for the generic applicants' agreement to hold their competitive products off the market for some time period prior to expiration of the patent. Due to provisions of the Hatch-Waxman amendments, which allow a generic drug manufacturer to challenge the validity of the patent to an already approved brand name drug, this type of settlement benefits both the brand name drug manufacturer and the generic manufacturer. The brand name drug manufacturer can continue to market and sell the drug without generic competition or fear of its patents being invalidated, while the generic manufacturer receives monetary compensation and an agreement as to the date on which it can enter the market prior to expiration of the patent. By reversing the lower court's decision dismissing the FTC's complaint, the Court rejected the position adopted by the Eleventh, Second, and Federal Circuits that economic arrangements between parties settling pharmaceutical patent litigation are generally not subject to antitrust scrutiny, even if they have anticompetitive effects, so long as the terms of the settlements stay within the "scope of the patent." The Court, however, also declined to adopt the FTC's

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Quinn Emanuel's London Office Continues Expansion with Addition of Leading Litigator Ted Greeno

The firm is pleased to announce that Ted Greeno has joined the London office as a partner. Greeno joins the firm from Herbert Smith Freehills, where he was a partner in the dispute resolution group. A well-known and highly-respected commercial litigator, Greeno has litigated a wide range of matters involving antitrust, tax, product liability, defense contracts, intellectual property, and public law. A significant amount of his work is devoted to the energy sector and many of his clients include top gas, oil, and power companies. Some of his more notable achievements include acting as counsel to BSkyB in its recovery of £320 million damages and costs from Electronic Data Systems, and acting as counsel to Chevron in its successful defense of a claim by Total for around £500 million arising from an oil depot explosion. Greeno has substantial experience in international arbitrations involving oil, gas, and minerals disputes in Africa, Asia, the Middle East, and South America. As *Chambers UK 2012* describes him, Greeno is at the "top of the league." Q

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longstanding position, adopted by the Third Circuit, that reverse payment settlements are presumptively unlawful. Instead, the Court instructed the lower courts to apply antitrust law's longstanding "rule of reason" analysis to cases alleging violation of antitrust laws in instances of reverse payment settlements. Notably, and of significant concern to the industry and their legal teams, the Court left the details of how to apply the rule of reason to the nation's trial and intermediate appellate courts to define.

Background

Solvay Pharmaceuticals is the owner of the regulatory approvals and patents covering the branded drug AndroGel®, a gel used in testosterone replacement therapy. Subsequently, Actavis, Inc. (then known as Watson Pharmaceuticals) and Paddock Laboratories separately filed abbreviated new drug applications ("ANDAs") seeking FDA approval to market generic equivalents of AndroGel®. The Hatch-Waxman Act requires the generic manufacturers to assure that the generic will not infringe the branded drug patents. Both generic manufacturers certified under Paragraph IV of the Hatch-Waxman Act that Solvay's patent "is invalid or will not be infringed" by the manufacture, use, or sale of their proposed generic alternatives. 21 U.S.C. § 355(j). By invoking Paragraph IV, the generic manufacturers essentially conceded patent infringement. Such a concession frequently results in litigation, as occurred here where Solvay then sued Actavis and Paddock for patent infringement. 35 U.S.C. § 271(e)(2)(A); *FTC v. Actavis*, 133 S. Ct. at 2228. Although the FDA subsequently cleared the Actavis product for marketing, Actavis did not launch its product into commerce. Instead, pursuant to the terms of a settlement reached in the patent litigations, Actavis, Paddock, and another competing drug manufacturer agreed not to bring their generic drugs onto the market until 65 months prior to expiration of the patent (unless someone else marketed a generic drug sooner) in return for Solvay agreeing, among other things, to provide the settling generic applicants with cash payments and a license to market and promote branded AndroGel® to doctors while they were bound not to launch their generic equivalents. *Id.* at 2229.

The Federal Trade Commission ("FTC") filed suit against all parties to the settlement claiming a violation of Section 5 of the Federal Trade Commission Act based on an alleged unlawful agreement to abandon patent challenges, refrain from bringing the low-cost generic drugs to market, and share in Solvay's monopoly profits. The District Court dismissed the complaint, finding that it did not set forth an antitrust violation. *In re Androgel Antitrust Litigation (No. II)*, 687 F. Supp. 2d 1371, 1379 (N.D. Ga. 2010). The Eleventh Circuit affirmed that decision, noting that "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298, 1312 (2012). The Supreme Court granted the FTC's petition for *certiorari* because of the split of authority between the Second, Eleventh, and Federal Circuits on the one hand which find these settlements generally permissible, and the Third Circuit which found such settlements to be generally impermissible. *Compare In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (settlements generally immune from antitrust attack); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006) (similar); *with In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214-218 (3d Cir. 2012) (settlements presumptively unlawful).

Majority Decision

In a 5-3 decision, (Justice Alito did not take part in consideration or decision of the case) the Court held that the Eleventh Circuit erred in dismissing the complaint, finding that although the anticompetitive effects of the reverse payment settlement may fall within the scope of Solvay's patent, that fact does not immunize the agreement from antitrust liability. The Court noted that reverse payment settlements are unusual, because the plaintiff has paid the defendants millions of dollars even though they had no monetary claim against the plaintiff, and noted its concern that these forms of settlements may have an adverse effect on competition. *FTC v. Actavis*, 133 S. Ct. at 2231. Accordingly, the Court found that "it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against precompetitive antitrust policies as well." *Id.* The Court also declined to adopt the FTC's position that reverse payment settlements are presumptively unlawful under a "quick look" approach. Instead, the Court indicated that a "rule of reason" approach should be applied to determine the legality of a reverse payment settlement. The Court did not elaborate on how this rule of reason should be applied to these types of antitrust lawsuits, instead leaving the structuring of rule of reason antitrust lawsuits to the lower courts. *Id.* at 2237.

The main concerns addressed by the majority

opinion were the general legal policy favoring settlement of disputes and the related concern that antitrust scrutiny of reverse payment settlements would require time-consuming and costly litigation regarding the underlying validity of the patent. The Court laid out five sets of considerations leading to its decision that the FTC should be entitled to prove its antitrust claim. *First*, the specific restraint at issue has the "potential for genuine adverse effects on competition." *Id.* at 2234-35. The Court reasoned that payments to keep a competitor out of the market allow the patentee to set market prices and divide the profits between the patentee and the challenger rather than allowing the consumer to benefit from lower prices. "*Second*, these anticompetitive consequences will at least sometimes prove unjustified;" therefore, the mere possibility that a settlement did not have anticompetitive effects does not justify outright dismissal of the lawsuit. *Id.* at 2235-36. "*Third*, where a reverse payment settlement threatens to work unjustified anticompetitive harm, the patentee likely has the power to bring about that harm in practice." Specifically, the Court noted that the "size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power." *Id.* at 2236. "*Fourth*, an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed." The Court opined that on most occasions the lower courts would not have to consider whether the patent was valid because "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." *Id.* at 2236-37. "*Fifth*, the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuits" because the parties may settle in other ways, including by allowing the generic manufacturer to enter the patentee's market before the patent expires without paying the challenger to stay out prior to that point. *Id.* at 2237. The Court concluded that the five considerations taken as a whole outweighed the interest in promoting settlements.

Dissent

Chief Justice Roberts dissented from the majority opinion, joined by Justices Scalia and Thomas. The dissenting justices would have adopted the "scope of the patent" test, which would not subject a settlement to antitrust scrutiny if it was within the scope of the patent (in other words, would not extend the life of the patent in time or extend its scope to cover non-infringing variants) unless: (1) there was sham litigation; or (2) the patent was obtained through fraud on the Patent and Trademark Office. *FTC v. Actavis*, 133 S. Ct. 2223 (2013) (Roberts, C.J., dissenting). The dissent argued that applying the "amorphous" rule of reason to anticompetitive effects was without statutory support and would discourage settlement of patent litigation, which the dissent notes is particularly complex and costly. *Id.* at 2238, 2243-44. The dissent viewed the majority's conclusion that parties will still be able to settle because they can negotiate for earlier entry into the market as unsupported and unconvincing, claiming that "parties are more likely to settle when they have a broader set of valuable things to trade." *Id.* at 2247.

The dissent also took issue with the majority assumption that courts will not be required to undertake a detailed analysis of the validity of the patent because large payments generally indicate a patent owner's doubt about the validity. The dissent noted that a party that is 95% sure that its patent is valid might pay a large sum of money to settle a lawsuit if the party is particularly risk averse. *Id.* at 2244-45.

***Structuring Settlements Between Brand and Generic Drug Manufacturers After* FTC v. Actavis**

Although the Court largely defers to the lower courts in the application of the rule of reason to any alleged anticompetitive effects of a settlement, it does provide some guidance regarding which types of settlements are likely to be upheld. For example, in addressing concerns that the failure to adopt the scope of the patent rule will prevent parties from settling their lawsuits, the Court states that parties can "as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *FTC v. Actavis*, 133 S. Ct. at 2237.

The Court seems particularly wary of large payments from a branded drug manufacturer to settle a lawsuit, indicating that Courts will be more suspicious on balance of larger settlements. For example, the Court states: "[a]t least, the 'size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power'—namely, the power to charge prices higher than the competitive level." *Id.* at 2236. Moreover, "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." *Id.* This same sentiment is expressed throughout the decision: "[i]n a word, the size of the unexplained reverse payment can provide a

workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." *Id.* at 2236-37.

Notably the Court does not describe what constitutes a "large" payment. However, the Court did express skepticism over the size of the payments in the *Actavis* case—$12 million to Paddock, $60 million to Par, and an estimated $19-$30 million annually to Actavis for nine years. The Court states that "[t]he rationale behind a payment of this size cannot in every case be supported by traditional settlement considerations. The payment may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market." *Id.* at 2235.

The Court does acknowledge that there are legitimate reasons why companies may prefer to structure a reverse payment settlement. However, it notes that "if the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement." *Id.* at 2237. Therefore, while the Court does not provide significant guidance about how to structure a settlement that is likely to withstand a lawsuit, reverse payment settlements for large sums of money without significant and documented mitigating circumstances will more likely face greater scrutiny.

Victory for Whom?

Both sides praised the majority opinion as a victory for American consumers. FTC Chairwoman Edith Ramirez issued a press release lauding the decision as having "made it clear that pay-for-delay agreements between brand and generic drug companies are subject to antitrust scrutiny, and it has rejected the attempt by branded and generic companies to effectively immunize these agreements from the antitrust laws." "Statement of FTC Chairwoman Edith Ramirez on the U.S. Supreme Court's Decision in *FTC v. Actavis, Inc.*," June 17, 2013, at *http://www.ftc.gov/opa/2013/06/actavis.shtm*. Actavis President and CEO Paul Bisaro stated: "We are pleased that the Court rejected the FTC's proposed 'quick look' test, and did not rule that settlement agreements are presumptively unlawful. Rather, the Court has established that the 'rule of reason' be applied, and left it to the lower courts to determine if the benefits of the settlement outweigh harm to consumers." "U.S. Supreme Court Reverses U.S. Court of Appeals Decision in *FTC v. Actavis*" June 17, 2013, at *http://ir.actavis.com/phoenix.zhtml?c=65778&p=irol-newsArticle&ID=1830404*.

These statements illustrate that both sides benefitted in some respect from the decision, though the exact bounds of the decision will remain unclear until these cases are litigated in the lower courts. In the interim, one thing is certain—by declining to adopt either side's "bright line" test, the Supreme Court has guaranteed that branded companies who have invested hundreds of millions of dollars to develop their key franchises, and generic applicants seeking to gain early entry to those markets, will lack clear guidance on the proper paths to the settlement of patent disputes.

Jennifer Kash and Diane Doolittle Named Top Women Leaders in Technology Law by The Recorder

San Francisco co-managing partner Jennifer Kash and Silicon Valley partner Diane Doolittle have been named to *The Recorder*'s 2013 list of the 50 Women Leaders in Technology Law. Kash and Doolittle were recognized for "demonstrat[ing] leadership and expertise in solving the most pressing legal concerns tech companies can face" and for "handling game-changing, law-shaping, market-moving work in and around the technology sector." In selecting Kash for this award, *The Recorder* referenced her work for clients like Symantec, Yahoo!, and Qualcomm in "big-ticket" patent litigation, including defeating a $1 billion infringement claim against Symantec in a Delaware jury trial. Doolittle, a former prosecutor and Co-Chair of Quinn Emanuel's National Trial Practice, was recognized for her 67 trial wins ranging from intellectual property and complex commercial litigation to white collar crime and wrongful death. Doolittle's representative clients include the founders of Marvell, the co-founder of Broadcom, and Google. Recently, she successfully defended Russian Internet giant Yandex against allegations of massive copyright infringement, making new law defining the territorial reach of the U.S. Copyright Act.

Sargon Enterprises, Inc. v. University of Southern California: A New "Gatekeeper" Role for the Admission of Expert Testimony in California State Court

What is the likely effect of the California Supreme Court's decision in *Sargon Enterprises, Inc. v. University of Southern California ("USC")*, 55 Cal. 4th 747 (2012), on the admissibility of expert testimony in California? This major decision, in which Quinn Emanuel won a 7-0 victory for USC, upheld a trial court's exclusion of expert lost profits testimony as unduly speculative and unreliable. Sargon, a small dental implant company, claimed that had USC completed a clinical study of the efficacy of a dental implant device, Sargon would have rocketed from a tiny market share to a market share as high as any of the six leading dental implant device makers in the world, earning profits from $220 million to as high as $1.2 billion, depending on how "innovative" the jury determined the plaintiff's device to be. After lengthy pretrial evidentiary hearings, the trial court agreed with Quinn Emanuel that the expert testimony should be excluded as speculative and unable to assist the jury in determining damages. (*Id.* at 765.)

While the Court of Appeal reversed the trial court in a 2-1 decision, holding that the jury was entitled to hear the excluded testimony and that the trial court's ruling would be "tantamount to a flat prohibition on lost profits in any case involving a revolutionary breakthrough in an industry," a unanimous California Supreme Court reversed and reinstated the trial court's decision to exclude. It cited California's Evidence Code §§ 801(b) and 802 to conclude that "the trial court acts as a gatekeeper to exclude expert opinion testimony that is (1) based on a matter of a type on which an expert may not reasonably rely, (2) based on reasons unsupported by the material on which the expert relies, or (3) speculative." (*Id.* at 771-772.)

To understand the likely effect of *Sargon v. USC* in California state court, it is useful to recall how *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), fundamentally changed the process for determining the admissibility of expert testimony in federal court. In *Daubert*, the Supreme Court ruled that the Federal Rules of Evidence, not the "*Frye*" test (based on *Frye v. United States*, 54 App. D.C. 46 (1923)), governed the admissibility of expert testimony. The *Frye* test required that the techniques used by the expert, and the data to which those techniques were applied, be "generally accepted" as reliable by experts in the field. Justice Blackmun wrote for the Court that the *Frye* test did not survive the 1975 adoption of the Federal Rules of Evidence, observing that "a rigid 'general acceptance' requirement would be at odds with the 'liberal thrust' of the Federal Rules and their general approach of relaxing the traditional barriers to 'opinion testimony.'" (509 U.S. at 588.) The Court held instead that *Frye*'s "austere standard, absent from and incompatible with, the Federal Rules of Evidence, should not be applied in federal trials." (*Id.* at 589.) Six years later, *Kumho Tire* made express what was implicit in *Daubert* —the *Daubert* test applied to *all* expert testimony, not simply "scientific" expert testimony.

Daubert replaced the *Frye* "general acceptance" test with the now familiar "relevant" and "reliable" test—if the district court determines that the proffered expert testimony is both relevant to the questions the fact-finder would answer and reliable, then it should be admitted, whether or not it had been "generally accepted" by the relevant expert community. "The inquiry envisioned by [Federal] Rule [of Evidence] 702 is, we emphasize, a flexible one. Its overarching subject is the scientific validity—and thus the evidentiary relevance and reliability—of the principles that underlie the proposed submission." (509 U.S. at 594-595.) In short, in *Daubert* and *Kumho Tire*, the Court replaced the "austere" *Frye* test with a more "flexible," more "liberal," Rule 702 "relevant" and "reliable" test.

There is a good deal of irony in that. The actual impact of *Daubert* and *Kumho Tire* has been to make possible the exclusion of expert testimony from leading experts in economics and other disciplines, an outcome virtually unthinkable under *Frye*. The reason for this is that the *Daubert* test gave the trial court an important role—that of "gatekeeper." Under *Frye*, qualifying an expert's testimony was rote: the examiner would elicit from the expert the techniques he had used and the data to which he had applied them, then elicit that those techniques and data were "generally accepted" as reliable by experts in the field. The court had little to do but nod. *Daubert* and *Kumho Tire* changed that: "under the Rules [of Evidence] the trial judge *must ensure* that any and all scientific testimony or evidence admitted is not only relevant, but reliable"—or what the Court characterized as "a gatekeeping role for the judge." (*Id.* at 589 & 597; emphasis added.)

This background provides a suggestive context to predict the likely effect of *Sargon v. USC.* While the California Supreme Court did not alter California's adoption of the *Frye* test (called *Kelly-Frye* in California, after the California case which adopted the *Frye* test), *Sargon* contains two rulings that will likely prove important to practitioners in California state court. One is its ruling that excluded lost profits testimony was "speculative" because the plaintiff was an "unestablished" company and the expert had based the future profitability of the plaintiff not on its *own* (limited) financial performance, but on the performance of much larger "established" companies that were not "substantially similar" as to any objective business metric. The opinion could make it difficult in the future for a newly-established business to claim lost profits entirely out-of-line with its more limited, start-up earnings; as the Court observed, the "trial court's ruling merely meant that Sargon could not obtain a massive verdict based on speculative projections of future spectacular success." (*Id.* at 781.)

A second holding—*Sargon*'s articulation, based on the California Evidence Code, of a "gatekeeper" role for California's trial courts—will likely have a broader impact, just as *Daubert*'s articulation, based on the Federal Rules of Evidence, of a gatekeeper role for federal trial courts has had on federal practice. *Sargon* tells California trial courts that they have an affirmative duty at the gate to ensure the jury does not hear expert testimony based on unreasonable comparisons, or not supported by the materials on which the expert purports to rely, or otherwise speculative. California trial courts have always had the duty to exclude such testimony, but in practice some trial courts have been reluctant to exclude expert testimony, reasoning that the many alleged errors or faulty assumptions in the expert's reasoning identified by the adverse party should make excellent fodder for cross-examination, but affect only the weight to give to the evidence, not its admissibility. *Sargon*'s express identification of a "gatekeeper" role may change that. As was the case in federal court with the application of the *Daubert* gatekeeper role, *Sargon* is likely to raise the hurdle of the admissibility of expert testimony as a practical matter, which could prove to be case dispositive where the plaintiff badly overreaches in its damages case.

Quinn Emanuel Wins ILASA's Gold Award for "Best USA Law Firm: Growth Strategy"

The firm has received the Gold Award for "Best USA Law Firm: Growth Strategy" at the 7th Annual International Legal Alliance Summit & Awards in New York. The selection process was overseen by more than 100 General Counsels of Fortune 500 companies, including Nestle, L'Oreal, Bayer Healthcare, Mitsubishi, and Barclays. Nomination in this category was based upon excellent results, development strategy and management organization, level of achievement in the national market, and lasting performance in management and leadership. Quinn Emanuel was recognized for its rapid international expansion, and its growing products liability and antitrust practices.

Susheel Kirpalani Receives SABANY's 2013 Litigation Achievement Award

The South Asian Bar Association of New York ("SABANY") has awarded Quinn Emanuel partner Susheel Kirpalani its 2013 Litigation Achievement Award. SABANY's decision was based on Susheel's professional achievements, contributions to the legal field, and dedication to the South Asian community. As Chair of Quinn Emanuel's Bankruptcy and Restructuring Group, Susheel is known for his wealth of experience in bankruptcy litigation and out-of-court restructurings. With a record that includes serving as the court appointed examiner in *Dynegy*, as well as leading roles in *Lehman Brothers, Washington Mutual*, *LyondellBasell*, and *SemGroup*, Susheel has provided legal and strategic advice from Dubai, UAE to Jefferson County, Alabama. Susheel is internationally recognized for his advocacy and creativity in the area of creditors' rights. His efforts in the bankruptcy arena and overall leadership qualities have promoted the professional development of the South Asian legal community.

Sports Litigation Update

Athletes Prevail in Right of Publicity Suits Against Video Game Designer. Two federal appellate courts held this summer that the First Amendment does not insulate video game maker Electronic Arts ("EA") from right of publicity suits brought by football players whose likenesses it used as part of the video game *NCAA Football*. In *Hart v. Electronic Arts* and *Keller v. Electronic Arts,* the Third and Ninth Circuit Courts of Appeals each held that, to successfully invoke a First Amendment defense to a right of publicity claim, the use of a player's identity must be sufficiently transformative, *i.e.*, the depiction of a celebrity must be "something more than a 'merely trivial' variation" of the celebrity's likeness. *Hart v. Electronic Arts*, 717 F.3d 141, 153, 160 (3d Cir. 2013); *Keller v. Electronic Arts*, No. 10-15387, 2013 WL 3928293, *5 (9th Cir. July 31, 2013). EA plans to appeal both cases to the U.S. Supreme Court, and a decision there could pose considerable challenges for video game designers to sufficiently recast avatars of football players without sacrificing the realism sought after by sports fans.

The right of publicity protects against the unauthorized appropriation of a person's name or likeness for the benefit of another, and thus affords a sort of property interest in one's persona. At issue in both cases was the extent to which the First Amendment protects artistic expressions that nonetheless violate the right of publicity—and, more specifically, which legal test is appropriate for evaluating that tension. In both cases, EA argued for the test used by the Second Circuit in *Rogers v. Grimaldi*, 875 F.2d 994 (2d Cir. 1989), which seeks to balance Lanham Act trademark claims with First Amendment defenses. Under *Rogers*, a defendant's use of a plaintiff's likeness is protected if the likeness is relevant to the expressive work in issue and does not explicitly mislead consumers. The appellate courts in *Hart* and *Keller*, however, rejected the *Rogers* test and instead adopted a version of the "transformative use" test, a component of copyright law's fair-use analysis. Transformative use focuses on whether the work "adds significant creative elements so as to be transformed into something more than a mere celebrity likeness or imitation." *Keller*, 2013 WL 3928293, *3. The courts reasoned that the *Rogers* test was inappropriate for evaluating right of publicity claims because it was "designed to protect consumers from the risk of consumer confusion," whereas the right of publicity "'protects a form of intellectual property [in one's person].'" *Id.* at *8; *Hart*, 717 F.3d at 158.

Both courts found that *NCAA Football* did not sufficiently transform the players' identities. Even though the game does not identify the players by name, the courts both found that the game's use of the players' vital and game statistics, physical characteristics, jersey numbers, and biographical information was a sufficient depiction of the players' likenesses so as to run afoul of their publicity rights. The courts characterized the games as depicting the players in the very settings in which they had achieved renown—college football games—and thus as literally recreating, rather than creatively transforming, their identities. That the game allowed users to modify physical aspects of the athletes counted "for little where the appeal of the game lies in users' ability to play as" their preferred football players. *Hart*, 717 F.3d at 168. Each court pointed to the example of *Kirby v. Sega of America, Inc.*, 144 Cal.App.4th 47 (2006), where a video game depicting singer Kierin Kirby as a futuristic reporter from outer space named Ulala was a sufficiently transformative use of the singer's likeness.

Judge Thomas, who dissented in *Keller*, opined that the majority misapplied the transformative use test by focusing on "how a single athlete's likeness is represented in the video game, rather than examining the transformative and creative elements in the video game as a whole." *Keller*, 2013 WL 3928293, *13. He argued that *NCAA Football* is "a work of interactive historical fiction," the creative and transformative elements of which, as a whole, predominate over the commercial use of the players' likenesses. *Id.* Similarly, Judge Ambro, who dissented in *Hart*, argued that the majority limited the "transformative inquiry to Hart's identity alone, disregarding other features of the work" that signified "sufficient expressive transformation" so as to "merit First Amendment protection." 717 F.3d at 171, 174-75.

Given what little law exists on this issue and the disagreement over whether it is the game as a whole or the individual athlete's avatar that must be transformative, and the degree of alteration that is required to be transformative, video game designers may have to wait for additional clarity from the Supreme Court as to how game designs can appease both the law and the fans.

Insurance Litigation Update

Deductibles Need Not Be Made Whole. On July 30, 2013, the Connecticut Supreme Court released its opinion in *Fireman's Fund Insurance Company v. TD Banknorth Insurance Agency, Inc.*, SC 18796 (Conn. 2013), answering a certified question from the Second Circuit on the "make whole" doctrine. The make whole doctrine is an equitable insurance law principle, which holds that in the absence of a valid

contractual obligation to the contrary an insurer will not receive any of the proceeds from the settlement of a claim, except to the extent that the settlement funds exceed the amount necessary to fully compensate the insured for the loss suffered. Insurers who settle claims on behalf of their insureds typically have rights of subrogation, allowing them to pursue claims to recoup the amount paid in settlement. In *Fireman's Fund*, the court was asked how subrogation recoveries would be applied where the insured had a large deductible and claimed that any recoveries should be paid to it, rather than the insurer. The Second Circuit certified the following question to the Connecticut Supreme Court: "Are insurance policy deductibles subject to Connecticut's make whole doctrine?" *Fireman's Fund Insurance Company v. TD Banknorth Insurance Agency*, 644 F.3d 166, 172-73 (2d Cir. 2011).

The Connecticut Supreme Court held that the "make whole" doctrine does not require an insurer to forgo subrogation recoveries when an insured has not recovered its deductible. The decision makes clear that insureds that purchase policies with high deductibles will be held to the bargain they struck with their insurer.

The case arose when Haynes Construction Company sued TD Banknorth for negligence. Fireman's Fund was TD Banknorth's errors and omissions carrier. Jointly, Fireman's Fund and TD Banknorth settled with Haynes for $354,000—$150,000 from TD Banknorth (its deductible), and the remainder from Fireman's Fund. As part of the settlement, Haynes assigned any right of recovery against others to Fireman's Fund and TD Banknorth. Ultimately, there were subrogation recoveries of $208,000. TD Banknorth claimed it was entitled to recover its deductible under the "make whole" doctrine, and Fireman's Fund filed suit in the District of Connecticut for a declaratory judgment that TD Banknorth was entitled to nothing, because Fireman's Fund's payments for defense and indemnity exceeded the $208,000 recovered.

On summary judgment, the District Court (Droney, J) ruled for Fireman's Fund, concluding that the subrogation clause in Fireman's Fund's policy was sufficient to overcome Connecticut's "make whole" doctrine. On appeal, the Second Circuit disagreed that the language in the policy was sufficient to abrogate the doctrine, but certified the issue of whether the doctrine even applied in the first instance to the Connecticut Supreme Court.

In answering the question, the Connecticut Supreme Court first concluded that the "make whole" doctrine applies in Connecticut, but that it does not allow the insured to recoup its deductible. (Slip. Op. at 4). The Court noted that "[a] deductible represents the level of risk the insured has agreed to assume" and the Court was "not of the opinion that equity dictates a departure from the terms of the insurance contract into which the parties voluntarily entered." On that basis, the Court reasoned that applying the equitable considerations of the make whole doctrine to deductibles would "effectively disturb the contractual agreement into which [the insured] and [the insurer] entered, thereby creating a windfall for [the insured] for a loss that it did not see fit to insure against in the first instance when it contracted for lower premium payments in exchange for a deductible." (Slip. Op. at 14).

EU Litigation Update

Update (Europe): Unitary Patent and Unified Patent Court. Back in December 2012, the European Union (EU) adopted two Regulations regarding so-called European patents with unitary effect (Unitary Patent) and respective translation requirements (Regulation (EU) No. 1257/2012 and Council Regulation (EU) No. 1260/2012). The Unitary Patent is a European patent, granted by the European Patent Office (EPO) under the rules and procedures of the European Patent Convention, to which unitary effect is given for the territory of the 25 Member States participating in the Unitary Patent scheme. The Unitary Patent will co-exist with national patents and with classical European patents.

In February 2013, the 25 Member States that opted for enhanced cooperation in the EU completed the legal framework by signing the Agreement on a Unified Patent Court (UPC). This agreement creates a specialized patent court with exclusive jurisdiction for litigation relating to European patents and Unitary Patents. The UPC will comprise a Court of First Instance, a Court of Appeal and a Registry. The Court of First Instance will be composed of a central division (with seat in Paris and two sections in London and Munich) and by several local and regional divisions in the Contracting Member States to the Agreement. The Court of Appeal will be located in Luxembourg.

Different from the current system in Europe with decision on infringement and validity only having national effect, the decisions of the UPC will generally have effect in all participating Member States. This has huge implications for potential Plaintiffs and Defendants: On the one hand, one lawsuit will be enough to obtain injunctive relief in the most relevant European markets. On the other, one lawsuit also suffices to invalidate a Unitary Patent per se. The consequences of the adoption of the UPC are even

more drastic if one takes into account that this new European court will also be competent to hear cases on "regular" European patents.

It cannot be stressed often enough: The European patent litigation landscape will soon change significantly!

When Will the Unitary Patent Scheme and the UPC Be Available? In theory, the so-called EU Patent Package could be applicable starting on January 1, 2014. But before this happens, several hurdles must be cleared that make a starting date before 2015 rather unlikely.

The two Regulations creating the Unitary Patent became effective on January 20, 2013. However, these Regulations will only be applicable together with the Agreement on the UPC entering into force as well. Generally speaking, being a contract between sovereign states, the Agreement will have to be ratified by the legislators of the contracting states. Specifically, the Agreement requires ratification of at least 13 Members States, including Germany, France, and the United Kingdom. As of August 2013, none of the Member States had ratified the Agreement. The United Kingdom has already made some of the necessary arrangements to ratify the Agreement by announcing the Intellectual Property Bill, which will enable the implementation of the Agreement. In Germany, the ratification process should commence after the General Election in October 2013.

In addition, the Court of Justice of the European Union (CJEU) will once more have to decide on the admissibility of the European Patent Package. In 2011, Spain and Italy brought a complaint against the EU for the so-called enhanced cooperation of the Member States, which is the legal basis of the two Regulations that form the foundation of the Unitary Patent. Right after the CJEU dismissed the action in early 2013, Spain filed another complaint, this time against one of the Regulations itself. Spain alleges language discrimination since only the official languages of the European Patent Convention—English, German and French—will be official languages in the new European patent litigation framework. At the moment it is not clear when the CJEU will render its decision.

Finally, getting the Unitary Patent and the UPC started will require a huge effort both by the EPO and the Member States. Committees have already started to work on the details of the system. But it will take a tremendous amount of effort to find facilities, staff and—last but not least—experienced judges who will make the new system work.

International Trade Commission Update

ITC Unveils New Pilot Program Aimed at Early Resolution of 337 Investigations. The United States International Trade Commission recently unveiled a new pilot program aimed at faster, less expensive resolution of 337 investigations. As part of the pilot program, the Commission "will identify, at institution, investigations that are likely to present a potentially dispositive issue, such as the existence of a domestic industry, importation, or standing." *Id.* For those investigations, the Commission will direct the Administrative Law Judge (ALJ) to expedite discovery and fact-finding, hold an evidentiary hearing, and issue an initial determination (ID) on the potentially dispositive issue(s) within 100 days of institution. The Commission will then determine whether to review the ID within 30 days. The Commission believes that this procedure will reduce costs and limit unnecessary litigation. (Additional information on the pilot program may be found on the ITC website. *See Pilot Program Will Test Early Disposition of Certain Section 337 Investigations*, USITC, http://www.usitc.gov/press_room/documents/featured_news/337pilot_article.htm).

The formal unveiling of this pilot program comes on the heels of the Commission's successful use of similar procedures in *Certain Products Having Laminated Packaging, Laminated Packaging, and Components Thereof*, Inv. No. 337-TA-874 ("*Laminated Packaging*"). There, the Commission directed the ALJ to hold an evidentiary hearing, find facts, and issue an early ID on whether the complainant satisfied the economic prong of the domestic industry requirement. The complainant objected to the Commission's order and the ALJ's accelerated procedural schedule as violating its rights under the Administrative Procedures Act (APA). The ALJ overruled complainant's objection and permitted discovery and the evidentiary hearing to proceed.

In his ID, the ALJ revisited the complainant's objection and agreed that the Commission's order violated the APA. In particular, the ALJ found that the Commission's order deviated from long-established Commission rules and that the changes were made without justification or adherence to APA procedure. Notwithstanding his views that the accelerated proceeding on the economic prong was procedurally improper, the ALJ found that the complainant failed to satisfy the economic prong of the domestic industry requirement.

On the merits, the ALJ determined that the "article protected by the patents" is "limited to the packaging

(continued on page 11)

VICTORIES

Regulatory Victory for Entergy

In a vitally important ruling for Entergy Corporation and for the safety of the citizens of Vermont, Quinn Emanuel recently obtained a favorable ruling from the Vermont Public Service Board, the state regulatory agency responsible for overseeing Entergy's Vermont Yankee Nuclear Power Station.

Under a regulation of the federal Nuclear Regulatory Commission, a nuclear facility like Vermont Yankee is required to maintain an alternate source of backup power in the event that the general electric grid suffers an outage (say, due to a storm) and the plant's primary backup generators are unavailable. Such a source of power is needed to run safety systems at the plant, including cooling of the fuel in the reactor core. For several years, Vermont Yankee relied on a nearby hydroelectric dam as its backup power source. However, Entergy learned in 2012 that the dam would soon no longer qualify under the federal regulation. Entergy researched various replacement options, and determined that the only feasible option was installation of a diesel generator at the plant site. Although Entergy thus determined that the generator is required by federal law, Vermont law purports to require a separate state approval for new construction by a facility that generates electrical power. Accordingly, Entergy set out to obtain that approval. Given the *de minimis* nature of the generator in the context of the broader plant, Entergy pursued a fast-track approval from the Vermont Public Service Board.

The Board delayed for several months taking any action on Entergy's application, apparently because the Board had earlier deemed Entergy to be operating the plant in violation of Vermont law since March 21, 2012, the expiration date of Entergy's existing state license to operate the plant. (Entergy, by contrast, has maintained that the operations license is extended by operation of Vermont's timely-renewal statute because Entergy timely filed its petition for a new operations license, but the Board failed to decide that petition before the March 21, 2012 expiration date of Entergy's existing operations license. That issue is currently pending before the Vermont Supreme Court.) Entergy persisted in its effort to obtain the state license to construct the backup generator, explaining that the dam would be unavailable as of September 1, 2013, and therefore that Entergy needed to begin construction by June 11, 2013 in order to have the new backup generator in place by September 1. Entergy further explained that, while it did not wish to pursue litigation of this matter, it would be compelled to do so absent any assurance from the Board that the license would be granted.

Having received no such assurance, Entergy filed a federal lawsuit in late April 2013, arguing that Vermont's state license requirement, as applied here, is preempted by federal law. Entergy soon thereafter moved for a preliminary injunction barring the Board or other state officials from enforcing the requirement to block construction of the generator or to punish Entergy for commencing construction. The Vermont Attorney General opposed the motion, primarily arguing that Entergy's construction schedule was longer than necessary. Expedited discovery ensued, and a hearing was held in the federal district court in Burlington, Vermont, on June 4, 2013, just days before Entergy's deadline to begin construction. At the end of the hearing, the court signaled that it was ready to act on the injunction if necessary, and on the morning of June 6 it asked Entergy to submit a proposed order granting the injunction. The Board, aware of these developments, granted the state license that very afternoon. Having finally received the license, Entergy was able to withdraw its federal lawsuit. Entergy then commenced construction on schedule, and is on track to complete the project in time to assure compliance with the federal regulation.

An "Artful" Victory

Quinn Emanuel recently secured a victory for one of its hedge fund clients, helping the client recover a substantial portion of a $100 million loss it suffered at the hands of convicted fraudster, Marc Dreier. From 2004 through 2008, Dreier, while heading a prominent New York law firm, perpetrated a Ponzi scheme and bilked investors out of hundreds of millions of dollars. Using forged signatures, imposters, and bogus legal opinions, Dreier convinced numerous prominent hedge funds and other investors to purchase notes that he claimed had been issued by a well known New York realty concern. The notes, however, were literally not worth the paper they were printed on, as they were entirely fake. When the fraud came to light, Dreier quickly pled guilty and was sent off to jail, where he is now serving 20 years.

The firm's client was the last of Dreier's victims and lost almost $100 million. Unlike the rest of the hedge funds Dreier defrauded, however, the firm's client had the good sense to obtain a security agreement from Dreier, in which he pledged his valuable art collection—which includes works by Lichtenstein, Warhol, Rothko and others—as security for payment of the notes. After Dreier was convicted, however, the Government forfeited all of his assets, including his art, leaving

the client's ability to recover on its security interest in jeopardy.

Quinn Emanuel responded to the forfeiture by petitioning the Court to have the forfeiture of the art vacated to give effect to the client's security interest. The firm then persuaded the government that, in the interests of justice, it should not oppose the petition. A group of Dreier's other hedge fund victims, however, did oppose the petition, arguing that the security interest should be voided and the art returned to the government and liquidated for the benefit of all of Dreier's victims. The so-called "Victim's Group" argued that various circumstances—not least of which was Dreier's unusual willingness to pledge his personal art to guarantee a purported client's debt—should have put the client on notice that something was amiss, such that it could not claim to have taken its security interest as an innocent purchaser for value.

The Court, upon reading the Victim's Group objection, decided that it could not be decided on the papers and held a full-day hearing in which Quinn Emanuel had to put its client's business people on the stand to explain how and why they obtained the security interest and why that did not reflect a suspicion on their part of possible fraud. With the firm's guidance, the witnesses detailed the entire process that led them to make the investment with Dreier and persuasively explained the business-related concerns that led them to seek the security interest in Dreier's art. Among other things, they reminded the Court that their transaction with Dreier occurred at the height of the financial crisis, when credit markets were frozen and parties had to resort to unusual and even unprecedented means to make transactions work.

In a written decision, the Court completely accepted the testimony of Quinn Emanuel's witnesses and all of the firm's legal arguments in finding that the client acted reasonably and without reason to suspect that Dreier was engaged in fraud. The client recovered possession of the art and expects to recover a significant portion of the loss it suffered when the art is auctioned.

(Practice Area Notes from page 9)

only and does not include the products contained within those packages." *Id.* at 31. The ALJ based this decision on his finding that the laminated packaging used by the complainant's licensees is not integral to the products, so the product and packaging should not be considered as a whole. The ALJ then found that the complainant's licensees failed to satisfy the economic prong under § 1337(a)(3)(A)-(C), based largely on the complainants failure to put forth evidence for expenses related to just the packaging and expenses that were incurred near or after the time the license agreements were executed.

The ALJ also rejected the complainant's alternative basis for proving the economic prong—that its investments in licensing activities related to the asserted patents were substantial. While the ALJ found that the complainant had shown a sufficient nexus between its activities and the patents-in-suit, he found that the investments were not sufficiently linked to licensing activities. The ALJ further found that the complainant's purported investments were not "substantial" within the meaning of the statute because the complainant failed to set forth any evidence establishing their quantitative or qualitative importance within the industry.

Finally, the ALJ rejected the complainant's argument that it should be permitted to offer evidence that its domestic industry is "in the process of being established" at some later point in the investigation. Specifically, the ALJ found that because the Commission ordered that the issue as to whether the economic prong of the domestic industry has been satisfied was to be definitively answered within 100 days, the complainant was required to put on all evidence supporting its position during the two-day evidentiary hearing.

On review, the Commission determined that the ALJ correctly found that the complainant had failed to satisfy the economic prong of the domestic industry requirement, but rejected the ALJ's finding that the accelerated procedures violated the APA. The Commission held that its order requiring an ID on the economic prong within 100 days was merely a procedural requirement that is exempt from notice-and-comment rulemaking pursuant to section 4 of the APA. Moreover, the Commission determined that the complainant was not prejudiced by the accelerated schedule because the complainant had ample opportunity to develop evidence of a domestic industry in advance of filing its complaint.

To date, the Commission has not ordered similar expedited schedules in any investigation following *Laminated Packages*. Whether the Commission's pilot program ultimately will prove to be successful in reducing litigation costs will depend, in large part, on the frequency of its use and respondents' success. Nevertheless, the program is an important first step in minimizing the number of complaints with questionable merit that are filed at the ITC.

quinn emanuel
865 South Figueroa Street, 10th Floor, Los Angeles, California 90017

business litigation report

quinn emanuel urquhart & sullivan, llp

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LOS ANGELES
865 S. Figueroa St., 10th Floor
Los Angeles, CA 90017
213-443-3000

NEW YORK
51 Madison Ave., 22nd Floor
New York, NY 10010
212-849-7000

SAN FRANCISCO
50 California St., 22nd Floor
San Francisco, CA 94111
415-875-6600

SILICON VALLEY
555 Twin Dolphin Dr., 5th Floor
Redwood Shores, CA 94065
650-801-5000

CHICAGO
500 West Madison St., Suite 2450
Chicago, IL 60661
312-705-7400

WASHINGTON, D.C.
1299 Pennsylvania Ave. NW, Suite 825
Washington, DC 20004
202-538-8000

TOKYO
NBF Hibiya Bldg., 25F
1-1-7, Uchisaiwai-cho, Chiyoda-ku
Tokyo 100-0011
Japan
+81 3 5510 1711

LONDON
One Fleet Place
London EC4M 7RA
United Kingdom
+44 (0) 20 7653 2000

MANNHEIM
Mollstraße 42
68165 Mannheim
Germany
+49 (0) 621 43298 6000

HAMBURG
An der Alster 3
20099 Hamburg
Germany
+49 (0) 40 89728 7000

MUNICH
Oberanger 28,
80331 Munich, Germany
+49 (0) 89 20608 3000

PARIS
25 rue Balzac
75008 Paris
France
+33 (0)1 53 53 68 97

MOSCOW
Paveletskaya Plaza
Paveletskaya Square, 2/3
115054 Moscow
Russia
+7 499 277 1000

HONG KONG
1307-1308 Two Exchange Square
8 Connaught Place
Central Hong Kong
+852 3464 5600

SYDNEY
Level 25, RBS Tower
88 Phillip Street
Sydney NSW 2000, Australia
+61 2 8211 0690