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China Implements New Laws in Foreign-Related Products Liability Cases

In 2010, the People's Republic of China ("PRC") enacted two laws that together will substantially affect all civil litigation in China – and, in particular, product liability litigation regarding foreign entities. The Law of the Application of Law for Foreign-Related Civil Relations of the PRC ("the Choice of Law Statute") covers almost all aspects of the application of law in foreign-related civil cases. The Tort Law of the PRC ("the Tort Law") comprehensively governs tort liabilities. This article will focus on the provisions of these laws relevant to product liability disputes, particularly as they affect foreign entities.

The new laws will likely lead to increased litigation and compensation awarded to plaintiffs. Under the Choice of Law Statute, foreign law will be applied more widely, which could frequently be more favorable to plaintiffs. Under the new Tort Law, manufacturers and sellers now have substantive obligations to recall, implement remedial measures, and warn of potentially defective products. Punitive damages may now also be awarded for all kinds of product defects. Because the laws are so new, it is still unclear how Chinese courts will resolve legal issues arising from application of foreign law in actual cases.

New Choice of Law Rules in Foreign-Related Product Liability Cases

In China, product liability constitutes a distinct kind of tort liability. Previously, there was no special provision in Chinese law governing the choice of law in foreign-related product liability cases. The choice of law rules were the same as in ordinary tort liability cases, *lex loci delictus*, requiring the application of the law of the place in which the tort occurred. If damage occurred in China in a foreign-related product liability case, Chinese law generally governed.

The Choice of Law Statute now requires the application of the rule of *lex loci domicilii* in foreign-related product liability cases, thus making defendants subject to the law of their place of habitual residence. Although the law of the habitual residence of the plaintiff (foreign or Chinese) will ordinarily apply, the plaintiff

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Quinn Emanuel Launches Moscow Office

The firm has announced it is opening an office in Moscow later this year. This will be the firm's third European office, following London and Mannheim. Ivan Marisin and Vasily Kuznetsov, both litigators from the Moscow office of Dechert, will join the firm as partners. Marisin will serve as Managing Partner of the new Moscow office.

Marisin, head of the dispute resolution practice at Dechert for the past two years, was previously a partner at Clifford Chance for fourteen years where he served as both Senior and Managing Partner. Both Marisin and Koznetsov are highly ranked by *Chambers Global.* They have represented both Russian and international clients in more than one hundred major litigations and international arbitrations worldwide. Their recent matters include representing Bank of New York Mellon in a $22.5 billion claim brought by the Federal Customs Service of the Russian Federation in the largest case ever heard by a Russian state court, and obtaining an arbitration award for Russian uranium seller Tenex in a U.S. $1 billion international arbitration in Stockholm.

The Moscow office will follow the same litigation-only model the firm has in the U.S., UK and Germany serving clients in both domestic Russian and international litigations, particularly arbitrations and litigations involving Russian companies and Russian citizens in the U.S. and London. The Moscow partners will work closely with the firm's London office, whose partners are already deeply involved in cases that emerge from this region. Q

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may instead choose to apply the laws of the defendant's main business place (*i.e.*, the law of the manufacturer's home country) or the laws of the location where the damage occurred (*i.e.*, China) – unless the defendant has no relevant business operations at the habitual residence of the plaintiff, in which case only the latter two choices are available.

As a result of this reform, successful plaintiffs may now be awarded the same compensation as they would under the law of their state of habitual residence. That will likely be more than Chinese substantive law would permit. The damages awarded by Chinese courts are assessed conservatively to reflect necessary costs within China, which may well be less than the costs that injured parties would incur in their home states.

For example, if a Beijing hospital purchased defective medical equipment from a U.S. manufacturer, resulting in harm to patients from China, the U.S., Germany, and Cuba, the following outcomes could arise in suits against the manufacturer. The plaintiffs could choose to apply U.S. law (*i.e.*, the tortfeasor's principal place of business) or Chinese law (*i.e.*, the law of the place where the injuries occurred). Alternatively, the plaintiffs could choose to allow *lex loci domicilli* to apply by default, in which case the laws of China, the U.S., Germany and Cuba would apply depending on each plaintiff's nationality. That would, however, prejudice the plaintiffs domiciled in Cuba because U.S. companies have no relevant operations there. Thus, the Cuban plaintiffs would want to elect U.S. or Chinese law.

What will the consequences of the new choice of law rules be for multinational companies? Here, we discuss only a few briefly. But, in general there will be a lot of uncertainty as courts work through how to implement the new regime.

First, the choice of law may determine the elements of product liability and burden of proof issues – as to both the allocation of burdens and the required evidentiary showing – and might therefore be outcome determinative. Consider the potential difference in outcome if the plaintiff or the defendant bears the burden of proof for a required element, or if rules governing joint-and-several liability vary. Chinese law could be more favorable than foreign law. The provisions of the new Tort Law of the PRC shift the burden on many elements to the defendants, through the introduction of proactive duties. Yet, at the same time, foreign law on damages may be much more favorable. So, new flexibility in choice of law rules means increased strategic complexity.

Second, if the availability of foreign law proves attractive to plaintiffs, then foreign manufacturers will likely face more direct proceedings. The Tort Law maintains provisions of the former Product Quality Law of the PRC regarding liability for product liability claims, thus allowing plaintiffs to sue both manufacturers and sellers. Previously, for the sake of procedural convenience, Chinese plaintiffs preferred to sue local distributors or domestic manufacturers of foreign-trademarked goods. But targeting foreign manufacturers will likely become more attractive now, if doing so results in more generous damage awards. Pursuant to an interpretation of the Supreme People's Court of 2002, any entity that allows a product to be labeled with its name, trademark, or distinguishable sign qualifies as a manufacturer in the context of product liability. While this "quasi-manufacturer" principle was developed under the previous Product Quality Law, it likely also applies to the new legal regime established by the Choice of Law Statute and Tort Law. Consequently, foreign manufacturers will likely face more direct product liability claims in China, and will be unable to confine litigation risk to their Chinese distributors and manufacturers.

Third, an important uncertainty concerns what legal issues will be subject to the plaintiff's choice of law. Generally, courts apply *lex fora* ("law of the forum") principles for procedural rules, which would require their application of Chinese rules. However, it is not always clear whether a particular rule is procedural or substantive. In the United States, for example, courts have sometimes interpreted the burden of proof requirements on elements as "procedural" rather than "substantive."

Another open question concerns the application of discovery rules. China has no equivalent to U.S.-style discovery. Similarly, Chinese procedural rules also affect litigation timelines. The application of such procedural rules can have significant substantive consequences, potentially diminishing the extent to which the ability to apply foreign law will change Chinese product liability suits. The situation will remain uncertain and possibly vary from court to court until either the Supreme People's Court or the legislators provide guidance on the extent to which *lex fora* should be applied to Chinese procedural law.

On the whole, the new choice of law regime will likely increase the cost and duration of the proceedings. As outlined here, courts will face complex new technical questions, as will multinational companies defending product liability suits. If foreign legal and scientific experts are used, additional costs for translation and travel will be incurred. Most of all, the application of foreign law will pose a significant challenge to Chinese lawyers, who typically lack education and expertise in foreign legal regimes.

Product Liability Under the New Tort Law

Once a court holds that Chinese law applies to a product liability case pursuant to the Choice of Law Statute, it will apply the new Tort Law. Most provisions regarding product liability in the Tort Law are derived from and remain consistent with the Product Quality Law promulgated in 1993 and revised in 2000. There are, however, four significant differences that apply to product liability suits.

First, the scope of liability includes the defective products themselves, which was not the case under the now-obsolete Product Quality Law. This eliminates the last vestiges of the civil law privity-of-contract principle, in which a party to a contract who suffered damage could recover only from the other party to the contract and not another party. The reform is intended to reduce the litigation burden on victims, who may now seek compensation for product losses in the same action as for other harms caused by the product defect.

However, this change raises new questions. For instance, if an injured party sues the manufacturer to recover compensation, should the manufacturer compensate the plaintiff at its direct wholesale price or at the ultimate retail price paid by the plaintiff? If the latter, could the manufacturer indemnify itself by suing the distributor? If there are multiple levels of distributors, against which should the manufacture pursue an action for indemnification? Multinational corporations facing these kinds of issues should closely monitor the attitudes expressed by jurists and legislators as actions are brought under the new Tort Law regime.

Second, the Tort Law extends the duty of manufacturers and sellers to recall all defective products. Previous regulations applied to limited classes of products, such as automobiles, foods, medicines, and toys. The failure to recall products will result in tort liability if the defect causes harm. This change makes multinational manufactures responsible for tracking potential defects. Doing so will require new infrastructure and management practices, including additional oversight of distribution networks.

Third, the new Tort Law also imposes a duty to warn "after the product is put in circulation." By contrast, under Article 41 of the Product Quality Law, producers were not held responsible if they could prove that the defect could not be found at the time of circulation due to scientific or technological reasons. This means that after first sale, even if there are technical obstacles that might prevent warning or recall of a defective product, the manufacturer or seller will nonetheless face tort liability for any harm that occurs. This removes a broad exception that manufacturers and sellers formerly used to avoid strict liability for product defects.

Fourth, and perhaps most controversially, the Tort Law allows for the award of punitive damages in product liability cases. Traditionally, Chinese courts have applied equitable principles in civil cases, making the recoverable compensation equal to the victim's harm as measured by medical costs and lost income, for example, the award of punitive damages emerged in consumer fraud laws. Regulations imposing punitive damages have also been adopted for abuses in the sale of residential housing and food.

The Tort Law now extends the availability of punitive damages to all products, but important limitations remain. Article 47 requires that the manufacturer or seller know of the defect while continuing to manufacture or sell the product, and that the defect cause death or serious bodily harm. Even with these limitations, manufacturers and sellers will face more complaints seeking punitive compensation. They will have to take this into account in planning their public relations response to product liability lawsuits.

Conclusions and Next Steps

The new product liability provisions of the Conflict of Law Statute and Tort Law are part of an effort by Chinese authorities to stem the growing problem posed by large-scale and individual product defect-related incidents. These reforms represent an important legal component of China's economic transformation. But, the adoption of novel principles, such as the choice of foreign law provisions, the expansion of duties imposed on manufacturers, and Western-style punitive awards, will inject new questions into the Chinese legal landscape.

Starting now, multinational companies should carefully monitor manufacturing and distribution systems to meet the duties of recall, warning and remedial measures. Companies will have to implement institutional procedures before any problems engender litigation, not only to avoid the consequences of litigation, but to comply with the Tort Law. Further, companies should determine in advance whether their Chinese counsel have the capability to address suits brought under foreign law, including the ability to understand differences between the foreign tort law and Chinese law, and perform tasks that may be new for them, such as selecting and training expert witnesses from abroad, conducting extensive legal translation work, and the like.

Finally, companies should encourage the counsel who represent them to engage in mock trials and other exercises to understand how the new laws may affect product liability claims and maintain close communications with legislators, jurists, and

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Inducement of Patent Infringement: The Supreme Court Sets a New Standard for Proving Intent

The Supreme Court's recent decision in *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011) establishes a new standard for proving intent to induce patent infringement. 35 U.S.C. § 271(b) provides that a defendant may be liable for "indirect infringement" if it actively induces another to infringe. Unlike direct infringement, which is a strict liability offense, indirect infringement requires a showing of intent.

For decades, the Federal Circuit was split over whether inducement merely requires that the defendant intend that a third-party perform the infringing acts, or whether the defendant must also intend that the induced acts infringe the asserted patent. *Compare Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990), *with Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990). In *DSU Med. Corp. v. JSM Co., Ltd.*, 471 F.3d 1293 (Fed. Cir. 2006) (en banc), the Federal Circuit resolved the split, holding that intent to induce requires that the defendant "knew or should have known that [its] actions would induce actual infringements." In doing so, that "[t]he requirement that the alleged infringer knew or should have known his actions would induce actual infringement necessarily includes the requirement that he or she knew of the patent." In *DSU*, the defendant had actual knowledge of the patent, so that element was plainly satisfied.

In *SEB*, the Federal Circuit squarely addressed the required standard for knowledge of the asserted patent. *SEB S.A. v. Montgomery Ward & Co., Inc.*, 594 F.3d 1360 (Fed. Cir. 2010), *aff'd on other grounds sub nom. Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011). It held that the knowledge of the patent requirement is satisfied if the defendant acted with a "deliberate indifference to a known risk" that the asserted patent existed. It explained that "the standard of deliberate indifference of a known risk is not different from actual knowledge, but is a form of actual knowledge."

In *Global-Tech,* the Supreme Court overturned the "deliberate indifference" standard, instead, holding that the required intent for inducement is actual knowledge or "willful blindness." Significantly, the Supreme Court also considered more generally the intent standard for inducement. It remains to be seen how the new standard for intent will affect inducement claims given the unusual facts in *Global-Tech*.

Facts of the Case

SEB, a French manufacturer of consumer appliances, developed a popular T-Fal deep fryer. This fryer incorporated an innovative design that allowed the outer surface to remain cool while the fryer was in use. The design used inexpensive plastic to form the outer shell coupled with an air gap separating a heated cooking pan from the outer shell to insulate the shell from the pan. The novel design avoided the use of special, high-temperature plastics.

Global-Tech's subsidiary Pentalpha, a Hong Kong-based manufacturer of consumer household goods, set out to commercialize a competing fryer. Pentalpha purchased a T-Fal fryer in Hong Kong that did not bear any U.S. patent markings, as it was not intended for the U.S. market. After copying everything but the cosmetic features of SEB's T-Fal fryer, Pentalpha sought an opinion of counsel regarding freedom to operate, but did not inform its patent attorney that its fryer *was nearly an exact copy of SEB's T-Fal product*. Pentalpha's attorney did not locate any patent that appeared to be infringed by the product – not even SEB's patent covering the T-Fal fryer design – and provided a right-to-use opinion to that effect.

Proceedings in the District Court

SEB subsequently sued Pentalpha for patent infringement, asserting two theories of liability: First, SEB claimed that Pentalpha had directly infringed SEB's patent in violation of 35 U.S.C. § 271(a) by selling or offering to sell its deep fryers. Second, SEB claimed that Pentalpha had violated § 271(b) by actively inducing third parties to sell or to offer to sell Pentalpha's deep fryers in the U.S. At trial, the jury found for SEB on both claims. The district court subsequently denied Pentalpha's motion for JMOL, holding that there was sufficient evidence to find inducement even though Pentalpha did not actually know of SEB's patent until it received notice of the lawsuit.

Federal Circuit Appeal

On appeal, Pentalpha argued that the jury's verdict was not supported by the evidence because it did not know that SEB's T-Fal fryer was patented or that there was a risk that such a patent existed. The Federal Circuit disagreed. Although it acknowledged the lack of direct evidence that Pentalpha was aware of SEB's patent, Pentalpha's pattern of behavior suggested that it had purposefully remained ignorant of the existence SEB's patent. Pentalpha had chosen to reverse engineer a product purchased outside the U.S. that would not be marked with any U.S. patents and did not inform its attorney that it had copied SEB's fryer. These facts, according to the Federal Circuit, demonstrated

Pentalpha's deliberate indifference to the risk that a patent covering the T-Fal product existed.

The Supreme Court granted certiorari to review: "Whether the legal standard for the state of mind element of a claim for actively inducing infringement under 35 U.S.C. § 271(b) is 'deliberate indifference' to a known risk that an infringement may occur, as the Court of Appeals for the Federal Circuit held, or 'purposeful, culpable expression and conduct' to encourage an infringement, as this Court taught in *MGM Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 937 (2005)." Notably, the question under review was broadly directed to intent to induce, even though the appeal to the Federal Circuit had focused on Pentalpha's knowledge of the asserted patent and did not explicitly address intent with respect to the inducement of infringing acts performed by a third-party.

The Supreme Court's Decision

In an 8-1 decision on May 31, 2011, the Supreme Court affirmed the result below, but rejected the Federal Circuit's "deliberate indifference" standard. Instead, the Supreme Court held that inducement of infringement requires actual knowledge or "willful blindness" that the induced conduct itself infringes.

The Court noted the common origin of both inducement and of contributory infringement, concluding that the same actual knowledge requirement applies to both. It further refined the actual knowledge requirement by analogy to criminal law, where courts have held that statutes requiring proof that a defendant acted willfully or knowingly may be satisfied – even though the defendant lacked actual knowledge – if the defendant "deliberately shield[ed] [himself] from clear evidence of critical facts that [were] strongly suggested by the circumstances." By analogy, the Court explained that the actual knowledge of infringement requirement to prove inducement may be shown by "willful blindness," which involves a two-part test: First, the defendant must subjectively believe that there is a high probability that a fact exists; second, the defendant must take deliberate actions to avoid learning of that fact. According to the Court, these requirements give willful blindness an "appropriately limited scope that surpasses recklessness and negligence."

Although the Supreme Court rejected the Federal Circuit's "deliberate indifference" standard, it nevertheless affirmed the judgment because the evidence was "plainly sufficient to support a finding of Pentalpha's knowledge under the doctrine of willful blindness." Q

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government agencies to help guide their implementation and refinement of those laws. Q

This article was authored by Liu Hong Huan, Liu Chi and Zhou Xi, attorneys from Jun He Law offices, and was published in original format in Asian Counsel Magazine, *Vol. 8, Issue 10. Jun He is widely recognized as a leading full-service law firm in China, positioned to provide superior legal services in commercial transactions and disputes. For more information on the firm, please visit www.junhe.com.*

High-Profile Litigator Andrew Schapiro Joins Quinn Emanuel

The firm recently announced that trial lawyer Andrew Schapiro has joined the firm as a partner. Schapiro will divide his time between the firm's New York and Chicago offices. Schapiro has eighteen years of trial and appellate experience representing major corporations and individuals in sensitive, high-profile, and high-stakes matters. He works primarily in the areas of intellectual property, white-collar and securities litigation, and complex commercial litigation. He has first-chaired fourteen federal jury trials, managed large litigation teams, and argued and won high-profile appeals in state and federal courts. He recently won summary judgment for YouTube and its parent, Google, in the billion-dollar copyright infringement suit brought by Viacom in federal court in New York and garnered wide attention for his acquittal on all counts for an N.Y.S.E. specialist broker accused of securities fraud in a contentious jury trial in the Southern District of New York.

Schapiro is a *magna cum laude* graduate of Harvard Law School, where he was an editor of *Harvard Law Review* and winner of the Sears Prize. He clerked for Judge Richard A. Posner on the Seventh Circuit Court of Appeals and for Justice Harry Blackmun on the United States Supreme Court. Q

Appellate Litigation Update:

Overview of Intellectual Property Cases Before the Supreme Court in the October 2011 Term: In keeping with its recent trend, the Supreme Court has so far agreed to hear one copyright and several patent cases during the October 2011 Term.

Golan v. Holder, No. 10-545, was argued October 5, 2011, and addressed a copyright law issue. It concerns the constitutionality of Section 514 of the Uruguay Round Agreements Act ("URAA"). Congress enacted the URAA in 2004 to implement Article 18 of the Berne Convention for the Protection of Literary and Artistic Works, which requires that member countries afford the same copyright protection to foreign authors as they provide to their own authors. Because certain works by foreign authors had already entered the public domain in the United States by virtue of failures to comply with prior U.S. copyright formalities, lack of subject matter protection, or lack of national eligibility, Section 514 of the URAA restored the authors' copyrights in those foreign works (with certain time-limited protections afforded to persons, called "reliance parties," who were exploiting the foreign works in the United States). In other words, works that were in the public domain would now become subject to U.S. copyright protection.

A group of persons who have relied on public domain works for their livelihoods (including orchestra conductors, educators, performers, publishers, film archivists, and motion picture distributors) brought suit in the U.S. District Court for the District of Colorado, challenging Section 514 of the URAA as unconstitutional under the Copyright Clause of the U.S. Constitution, *see* U.S. Const., art. I, § 8, cl. 8 (granting Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"), and the First Amendment. The district court ruled in favor of the government, and the Tenth Circuit affirmed in a 2007 decision as to the Copyright Clause and a 2010 decision as to the First Amendment. Among the governmental interests cited by the Tenth Circuit in rejecting the First Amendment challenge was that U.S. protection of foreign works is necessary to ensure that other countries extend the protection of their copyright laws to U.S. works.

The Supreme Court granted certiorari on both the Copyright Clause issue and the First Amendment issue. The case has attracted the attention of numerous *amici curiae* on both sides. A decision is expected by June 2012.

Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, No. 10-844, scheduled for oral argument on December 5, 2011, involves the interpretation of the counterclaim provision of the Hatch-Waxman Act. The Hatch-Waxman Act, as described by the Federal Circuit, seeks to balance the goal of encouraging the development of new drugs and methods with the potentially conflicting goal of facilitating introduction of low-cost generic copies of those drugs and methods. The Act provides a streamlined approval process, known as an abbreviated new drug application ("ANDA") for generic manufacturers, which allows the generic manufacturer to rely on the safety and efficacy studies of an already-approved drug upon a showing of bioequivalence between the approved drug and generic drugs. The ANDA process includes a certification by the generic manufacturer that the approved drug is not covered by a patent, the approved drug is covered by a patent that has expired or will expire, or, as relevant here, the patent is invalid or will not be infringed by the proposed generic drug. The last option, if invoked by the generic manufacturer, is deemed an act of patent infringement and allows the patent owner to file suit, and in turn allows the generic manufacturer to file a counterclaim challenging the accuracy of the "patent information" submitted to the FDA.

The scope of the counterclaim provision is at issue. Novo owns a patent that claims one of the three methods for using repaglinide to treat type 2 diabetes. Caraco, the generic manufacturer, submitted an ANDA asserting that Caraco was not seeking approval for the method claimed by Novo's patent, and the FDA indicated that it would approve Caraco's proposed drug label carving out the Novo method. Novo then asked the FDA to broaden Novo's use code narrative for its patent so that it would no longer be specific to the one method claimed by Novo; that in turn led the FDA to change its initial position and reject Caraco's carve-out label. Without the carve out, Caraco's product would infringe Novo's patent. Caraco counterclaimed, alleging that the new use code narrative was overbroad because it improperly suggested that Novo's patent covered all three approved methods of using repaglinide to treat type 2 diabetes. The district court granted summary judgment in favor of Caraco on its counterclaim. A panel of the Federal Circuit reversed, over the dissent of Judge Dyk. The majority reasoned that the statute limits counterclaims to those alleging that the "patent does not claim … an approved method of using the drug." The majority held that Novo's method was "an approved method" and that the alleged overbreadth of the use code narrative was irrelevant. Judge Dyk argued that the majority's approach left the generic manufacturer without a remedy and was contrary Congress' purpose in ending the law.

Several *amici curiae* have filed briefs in support of Caraco, including the United States, Representative Henry Waxman, and the Generic Pharmaceutical Association.

Mayo Collaborative Servs. v. Prometheus Labs., Inc., No. 10-1150, scheduled for argument on December 7, 2011, was initially decided by the Federal Circuit in 2009. The Supreme Court then vacated that decision and remanded it to the Federal Circuit for further consideration in light of *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). In *Bilski*, the Court held that the "machine-or-transformation" test is not the sole, definitive test for determining the patentability of a process under 35 U.S.C. § 101. (The machine-or-transformation test deems a process eligible for patent protection if it (1) is tied to a particular machine or apparatus; or (2) transforms a particular article into a different state or thing.) Instead, the Court resolved *Bilski* by resorting to the principle, established by its earlier decisions, that abstract ideas are not patentable. *Mayo* was re-decided by the Federal Circuit following the remand and is now back before the high court.

Prometheus is the exclusive licensee of patents that claim methods for determining the optimal dosage of thiopurine drugs used to treat autoimmune diseases. The claimed methods involve administering a drug to a patient and then determining the levels of the drug's metabolites in the subject. The measured metabolite levels are then compared to pre-determined metabolite levels, allowing the level of drug to be corrected to minimize toxicity and maximize treatment efficiency in the particular patient. The patents were not directed to the drugs, or to any novel diagnostic test kit. Instead, Prometheus marketed a test that relied upon the levels of drug metabolites found in the human body. Mayo purchased that test for a time, but then announced that it would use its own test, which measured the same metabolites but looked to different benchmark levels to determine toxicity. Prometheus sued Mayo for patent infringement, and Mayo responded by arguing that the technology was not patentable under § 101 because the patents claimed natural phenomena involving the correlation between drug metabolite levels, on the one hand, and efficacy and toxicity, on the other.

The district court accepted Mayo's argument and granted summary judgment that the patents were invalid. The Federal Circuit initially reversed, applying the machine-or-transformation test and finding that the administering-of-the-drug and determining-of-metabolite-levels steps were transformative and not merely data-gathering steps, and holding the claims did not wholly preempt the use of the recited correlations between metabolite levels and drug efficacy or toxicity. On remand after *Bilski*, the Federal Circuit adhered to its pre-*Bilski* decision, explaining this time that it would not rely solely on the machine-or-transformation test, but additionally on the fact that the claims at issue did not preempt every use of the natural correlations between drug metabolites and efficacy/toxicity, but rather utilize them in a series of specific steps that involve particular methods of treatment. The Federal Circuit also found transformation in that the administered drug is transformed by the human body into its metabolites; even though this is a natural phenomenon, it is preceded by the administration of a drug, which is not a natural phenomenon.

The United States has filed an *amicus* brief arguing that the Federal Circuit correctly held that the subject matter is patentable, but that the patents are likely invalid because they fail the novelty and nonobviousness requirements of 35 U.S.C. §§ 102 and 103. Quinn Emanuel has filed an *amicus* brief on behalf of two leading blood testing laboratories, ARUP and LabCorp, arguing that the subject matter is not patentable; specifically, Quinn Emanuel's brief argues that the patents cross the line in patenting natural phenomena by asserting exclusive rights over the process of providing a medicine and observing the results – a biochemical reaction that occurs in the human body.

Kappos v. Hyatt, No. 10-1219, presents the questions (1) whether a plaintiff who files a civil action in federal district court against the Director of the United States Patent and Trademark Office ("PTO") pursuant to 35 U.S.C. § 145 may introduce new evidence that could have been presented to the PTO; and (2) whether, if the plaintiff is allowed to introduce new evidence under Section 145, the district court may decide *de novo* the factual questions to which the evidence pertains, without giving deference to the PTO's decision.

A patent applicant who is dissatisfied with a PTO decision may appeal the decision to the Federal Circuit or file an action in federal district court to determine whether the applicant "is entitled to receive a patent for his invention … as the facts in the case may appear." 35 U.S.C. § 145. An *en banc* Federal Circuit majority concluded that there is no limitation on an applicant's right to introduce new evidence in district court (apart from the evidentiary limitations applicable in all civil actions). The majority further held that the district court may consider whether the new evidence is inconsistent with any evidence or proceedings before the PTO in determining what weight to give it. The

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majority additionally held that if the applicant does not introduce new evidence that was not before the PTO, the district court should apply the Administrative Procedure Act's deferential "substantial evidence" standard.

Judge Newman concurred as to the holding that an applicant may introduce new evidence in the district court, but dissented from the holding that if an applicant does not introduce new evidence, the "substantial evidence" standard of review applies. Instead, Judge Newman argued that the district court should decide the case *de novo*.

Judges Dyk and Gajarsa dissented, arguing that a Section 145 proceeding allows only for introduction of live testimony that was presented in written form in the PTO, not to any other introduction of new evidence. Further, the dissenters argued that the deferential "substantial evidence" standard applies in all Section 145 cases.

Intel Corp. and Verizon Communications Inc. have filed *amicus* briefs in support of petitioner, the Director of the PTO (who is represented by the Solicitor General's Office); several *amicus* briefs in support of neither party, including one by the Intellectual Property Owners Association, have also been filed. The respondent's brief is due October 31st with the amicus briefs supporting the respondent to follow shortly thereafter.

Trial Update:

***Five-Minute Limitation on Voir Dire Warrants Reversal in Criminal Case*:** The New York Court of Appeals overturned the conviction of a criminal defendant on the ground that the trial court improperly limited defense counsel to five minutes of questioning for each round of voir dire. Although the governing criminal procedure statute grants New York trial courts broad discretion to limit the scope of voir dire, the Court held that the courts' discretion is not unlimited and that fixed time constraints on voir dire can in certain circumstances constitute reversible error.

The Court of Appeals did not establish any baseline requirement for the length of voir dire, reasoning that the appropriate allotment will vary with the circumstances. Acknowledging that New York appellate courts had previously upheld time limits of ten and fifteen minutes, the Court ruled that five minutes was unreasonable in light of the facts and complexity of the case. In this regard, the Court emphasized that the defendant had been charged with four serious violent felonies and that the limited questioning revealed several areas of potential bias that defense counsel was unable to effectively probe. In particular, the victim was a popular DJ in the New York area and several potential jurors were aware of his celebrity. In addition, a number of potential jurors were themselves crime victims and the case involved sensitive issues of self-help, as the victim had pursued and constrained the defendant with considerable force prior to his apprehension by police. The Court ruled that the five-minute limitation on voir dire resulted in prejudice because it appeared, based on the uncontroverted contention of defense counsel, that a number of problematic jurors ultimately sat on the jury.

Two dissenting judges concluded that the defendant had not preserved a challenge to the voir dire time limit because counsel lodged only a generic objection in the trial court and failed to articulate why additional time was needed. The case is *People v. Steward*, 950 N.E.2d 480 (N.Y. 2011).

Non-Resident Cannot Be Compelled to Travel to California for Deposition: A California Court of Appeal ruled that non-residents cannot be ordered to appear in California for deposition. The court's holding extends both to residents of other nations and to residents of states other than California.

The plaintiffs, who were injured in an Idaho car accident, noticed the depositions of five Toyota employees who lived in Japan. After the trial court ordered the production of the Japanese witnesses, Toyota obtained a writ of mandate from the appellate court vacating the order. The Court of Appeal relied on the *California Code of Civil Procedure* § 1989, which provides that a witness cannot be obligated "to attend as a witness before any court, judge, justice or any other officer, unless the witness is a resident within the state at the time of service." Drawing on the legislative history and text of the provision, the court concluded that § 1989 covers not only trial witnesses, but also witnesses testifying at deposition. In so holding, the court rejected the reasoning of *Glass v. Superior Court*, 204 Cal. App. 3d 1048 (1988), which had reached the opposite conclusion. This split among the California appellate courts may well prompt the California Supreme Court to take the case on review.

Concurring Justice Klein invited the legislature to act. Agreeing that the statutory scheme precluded trial courts from ordering non-residents to appear for deposition in the state, Justice Klein reasoned that such a prohibition makes little sense in a global economy and grants non-resident corporations an unfair advantage over California corporations by shielding their personnel from extensive discovery. Justice Klein implored the legislature to revisit § 1989 "at the earliest opportunity."

In a subsequent order modifying its opinion, the Court of Appeals clarified that its analysis was limited to depositions of natural persons and that it had expressed no view as to whether trial courts can compel the deposition of an individual testifying on behalf of a non-resident corporation. *See Toyota Motor Corp. v. Super. Court*, 197 Cal. App. 4th 1107 __ Cal. Rptr. 3d __, (2011).

Internet Litigation Update:

Cloud-Based Music Storage Services Win DMCA Protection: On August 22, 2011, Judge William H. Pauley III of the Southern District of New York ruled that cloud-based music storage services are entitled to substantial protection under the Digital Millennium Copyright Act ("DMCA"). (Cloud computing offers computation, storage and other services that do not require end-user knowledge of how the system works, much like the use of electricity in one's home does not require that a homeowner understand the electrical grid that supplies the electricity.)

Defendant MP3tunes created a system that allowed its users to search and download free MP3s from third-party sites. Its service allowed users to store downloaded music in private accounts and stream it on any device. At the same time, MP3tunes.com enforced policies prohibiting the use of its services by persons who had repeatedly downloaded music unlawfully and uploaded it to their accounts.

Notwithstanding that policy, the EMI Group brought suit because users of MP3tunes.com's services were, predictably, downloading its music, which was not being offered for free. EMI sent "takedown notices" to MP3tunes.com under OCILLA (the "Online Copyright Infringement Liability Limitation Act") and alleged that MP3tunes.com was liable for infringing the 472 songs that it failed to remove after receiving the notices. Under OCILLA, that was a given. Notably, though, EMI also sought to impose liability based on the unlawful downloading of files as to which it had never sent takedown notices. EMI alleged that 3,189 sound recordings, 562 musical compositions, and 328 images of album cover art had been infringed and that MP3tunes.com was liable because it was well aware that its services were being used for unlawful purposes.

Rejecting that argument, the court held that MP3tunes.com had no duty to search for instances of copyright infringement: "While a reasonable person might conclude after some investigation that the websites used by MP3tunes executives were not authorized to distribute EMI's copyrighted works, the DMCA does not place the burden of investigation on the internet service provider." The court further observed that "[i]f enabling a party to download infringing material was sufficient to create liability, then even search engines like Google or Yahoo! would be without DMCA protection." Accordingly, MP3tunes.com was liable only for the pirated works it failed to remove after receiving takedown letters. *See Capitol Records, Inc. v. MP3tunes, LLC*, No. 07 Civ. 9931 (WHP), 2011 WL 366735, 2011 LEXIS 93351 (S.D.N.Y. Aug. 22, 2011).

Your Company's Name (Not) Here?: When the Internet Corporation for Assigned Names and Numbers ("ICANN") announced on June 19 that it would allow virtually any word or name to be registered as a top-level domain ("TLD"), many pundits predicted a digital gold rush. After all, why would a business want a www.ourproduct@xyzcorp.com Web site when it could instead have www.ourproducts.xyz? Moreover, wouldn't it want to register ".xyz" as a TLD to prevent competitors or cyber squatters from doing so?

Many business are increasingly answering "no" to the above questions. Each applicant for a generic TLD must submit an application likely to take several hundred hours to complete, must pay a $185,000 evaluation fee, and can be required to pay a Registry Services Review Fee anticipated to cost an additional $50,000. If there are other applicants for the same or a substantially similar domain name, an applicant could become entangled in an expensive dispute resolution proceeding that could cost it both the TLD and most or all of the fees paid to ICANN. Moreover, winning the right to a new TLD has its own cost: successful applicants for the new TLDs will incur a minimum $25,000 annual fee to "operate" a registry for their TLDs, even if they do not use them. As a consequence, many well-known companies, including PepsiCo, Ikea, Wells Fargo, and Morgan Stanley, have chosen not to apply to register their names as TLDs.

Class Action Update:

Class-Less Actions: Depending on which side of the class action divide you are on, 2011 has been either a very good year or a disaster. In April, and again in June, the United States Supreme Court issued decidedly pro-business decisions, cutting back on the availability of class actions to address large-scale consumer and employment practices.

In the first of the decisions, *AT&T Mobility, LLC v. Concepcion*, 131 S. Ct. 1740 (2011), a 5-4 Court decided that contracts of adhesion with arbitration clauses containing class action waivers are enforceable. Prior to *Concepcion,* trial courts frequently struck

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Complete Victory on Appeal for Faulty Insurance Claim

Following four years of litigation, the California Court of Appeal granted complete dismissal of a faulty claim brought by spinach packager Fresh Express against firm clients QBE Insurance Ltd. and Beazley Syndicate 2623/623 at Lloyd's. Fresh Express filed suit after being denied coverage for the E. Coli spinach outbreak in 2007. Notwithstanding that its insurance policy was limited to self-initiated recalls arising from errors it caused, Fresh Express sought coverage for all losses associated with the market event of the E. Coli crisis. The trial court interpreted the policy favorably for Fresh Express, as covering any accidental contamination caused by any source so long as Fresh Express could point to an error that it made, regardless of its connection to the outbreak. However, following briefing and oral argument, the Court of Appeal reversed the trial court, remanded the case for full dismissal, and awarded appellate costs. It held that "[t]he trial court's finding that the 'Insured Event' was 'the E. coli outbreak' is entirely inconsistent with the plain language of the policy." This was a major victory for insurance carriers, who have well-founded concerns that coverage could be extended to market events that can affect an entire industry at once.

Class Action Victory for Major Printer Manufacturer

The firm recently obtained a significant victory for its client, a major printer manufacturer, in a consumer class action lawsuit. Although the class representatives initially alleged a wide variety of purportedly unfair consumer practices under California's Unfair Competition Law and Consumer Legal Remedies Act, Quinn Emanuel whittled plaintiffs' case down to claims based on only two theories. First, plaintiffs claimed that the printer manufacturer was liable based on an omission theory for failing to inform consumers that its products were somehow "less efficient" than other manufacturers' printers. Quinn Emanuel successfully obtained a summary judgment ruling rejecting this novel theory. A subclass of plaintiffs alleged a second theory, based on a purportedly misleading description of a product feature. Shortly after obtaining summary judgment of the class claims, Quinn Emanuel defeated certification of the subclass.

Securities Class Action Victory for Charles Schwab

The firm recently obtained dismissals of two securities class actions against, Charles Schwab. The plaintiffs in both cases were investors in a mutual fund called the Schwab Total Bond Fund. They filed suit in the Northern District of California, alleging that Schwab invested too heavily in certain mortgage-backed securities (MBS). The percentage of the Fund's investments in MBS peaked in 2008, just as the market for those securities started tanking. Plaintiffs' firms swarmed in, and several lawsuits against Schwab mutual funds, including these two, soon followed.

In one case, the plaintiff made only a single claim under California's Unfair Competition Law ("UCL"). After two rounds of briefing, Judge Koh dismissed the plaintiff's prayer for relief, holding that because the plaintiff's lost share value was not in Schwab's possession, the plaintiff could not get UCL restitution. The plaintiff then gave up and dismissed her claim. In the other case, the plaintiff asserted a broad range of state-law claims, but following successive motions, Judge Koh dismissed each claim with prejudice.

Patent Victory for Major LED Manufacturer

The firm recently won summary judgment in the Eastern District of Virginia for Cree, Inc., a leading U.S. manufacturer of LEDs. The plaintiff, a failed semi-conductor technology company, sued Cree for infringement of two patents pertaining to high quality silicon carbide, a material often used in the manufacture of LEDs.

The Court's "rocket docket" required the submission of summary judgment motions before a claim construction ruling issued and before the vast bulk of discovery was completed. Quinn Emanuel took advantage of the fast-paced schedule to conduct targeted discovery, and tailored its summary judgment motions to account for various potential claim constructions.

Quinn Emanuel argued that one patent would not be infringed, regardless of whether a broad or narrow construction was ordered. The plaintiff was unable to respond to the motion, merely arguing that it required more discovery. When the claim construction ruling was ordered, the plaintiff was forced to concede that Cree did not infringe, and the Court entered summary judgment of non-infringement.

The firm sought summary judgment as to the second patent under a narrow claim construction, arguing that Cree did not infringe. In the alternative, the firm argued that, under a broad claim construction, the patent was invalid over Cree's own prior art, specifically "breakthrough" work performed by Cree's engineers. Ultimately, the Court found that the patent was invalid in light of Cree's prior art and entered summary judgment of invalidity as well. Q

(Class Action Update continued from page 9)

down such clauses as unconscionable, recognizing that class actions are necessary to remedy wide-spread consumer frauds or unfair business practices, because individual claims are almost always too small to motivate or justify individual action. California, for example, followed the *Discover Bank* rule, which held that class action waivers were not enforceable if they served as exculpatory clauses, letting companies off the hook for large schemes to defraud. *Discover Bank v. Super. Court*, 36 Cal. 4th 148 (2005). In *Concepcion* the Court held that *Discover Bank* was preempted by the Federal Arbitration Act.

Although upholding the arbitration clause at issue, *Concepcion*, did not close the door entirely to challenges to arbitration provisions based on unconscionability or other contract-formation defenses, such as fraud and duress. And some courts continue to find arbitration clauses unconscionable. *See, e.g., Kanbar v. O'Melveny & Myers*, 2011 U.S. Dist. LEXIS 79447 (N.D. Cal. July 21, 2011)(finding a law firm's arbitration provision for employment disputes unconscionable because it was a one-sided, take-it-or-leave-it condition of employment, among other infirmities).

On the whole, lower courts are giving *Concepcion* an expansive reading, accepting the proposition that the threshold for unconscionability has been raised. *See, e.g.*, *Bellows v. Midland Credit Mgmt., Inc.*, 2011 U.S. Dist. LEXIS 48237 (S.D. Cal. May 4, 2011); *Bernal v. Burnett*, 2011 U.S. Dist. LEXIS 59829 (D. Colo. June 6, 2011); *Day v. Persels & Assocs.,* 2011 U.S. Dist. LEXIS 49231 (M.D. Fla. May 8, 2011). And, even where an arbitration agreement contains unconscionable terms, some courts find that the objectionable provisions can be severed "blue pencilled," allowing the arbitration to proceed. *See, e.g.,* the unpublished opinion from California's Fourth District Court of Appeal (Div. 3) in *Mission Viejo Emergency Med. Assocs. v. Beta Healthcare Grp.*, (June 29, 2011).

Notwithstanding the broad reading of *Concepcion*, companies that wish to benefit from it need to give careful consideration to the arbitration clauses in their adhesion contracts. The AT&T clause approved by the Court was unusually consumer-friendly. Among other things, AT&T agreed to pay all arbitration costs for non-frivolous claims, conduct the arbitration in the consumer's county of residence, and guarantee recovery of $7500 plus double attorneys' fees if the consumer obtained more in the arbitration than AT&T had offered beforehand. How consumer friendly an arbitration clause needs to be under *Concepcion* awaits further development.

Within days of the decision, Senator Al Franken and two colleagues announced their intention to circumvent *Concepcion* through legislation known as the Arbitration Fairness Act. The bill, first introduced in 2009, was re-introduced within weeks following the decision in *Concepcion*, but is unlikely to advance this term.

The Court's second class action blockbuster was *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 795 (2011), which decertified the largest employment discrimination class in history. The decision effectively closed the door to nationwide disparate-impact class actions and may have made it more difficult to certify other types of large class actions.

The plaintiffs' theory was that the nation's largest retailer had a strong corporate culture that permeated individual hiring and promotion decisions, thereby subjecting every female employee to a common discriminatory practice. The plaintiffs introduced statistical evidence of pay and promotion disparities and anecdotal evidence from 120 class members. An expert sociologist also opined that the corporate culture made it vulnerable to gender discrimination. The class was certified under Rule 23(b)(2), on the theory that the plaintiffs primarily sought injunctive relief and that their request for back pay awards was merely incidental.

A unanimous Court found that a (b)(2) class was not warranted because the individual back pay awards were not incidental relief and that it was not appropriate to try a random sample of cases, devise a formula, and extrapolate to the entire class. Instead, the case should have been brought as a (b)(3) class action, an approach plaintiffs clearly had avoided because of the more stringent requirements for predominance and superiority that such a large class likely could not meet.

In a second aspect of the decision, the Court, held 5-4 that the class did not meet the basic Rule 23(a) requirements for class certification because there was inadequate proof of commonality, which the Court defined not as the ability to raise myriad common *questions,* but as the ability to generate common *answers*. The majority were unable to discern a glue binding the challenged employment decisions together, such as a single discriminatory practice. The majority's holding noted that the plaintiffs' expert could not say what percent of employment decisions were affected by the strong corporate culture. The Court also concluded that anecdotes from the 120 class members did not represent a large enough percentage of the class to support commonality.

Because commonality was previously viewed as a relatively easy bar for plaintiffs to surmount, the Court's discussion of commonality surely will change

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the way class certification motions are opposed and decided.

As the U.S. appears to be restricting the use of class actions, other nations continue to adopt them. Most recently, Mexico passed legislation permitting class actions in consumer, environmental, and antitrust actions. The legislation provides a very speedy procedure – five days to submit arguments against class treatment after the case is filed, and two weeks thereafter for the court to decide the issue. Q

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