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Supreme Court Business Briefing

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SUPREME COURT BUSINESS BRIEFING

The Supreme Court's 2011 Term once again produced a number of decisions of critical importance to the business community.

One highlight, of course, was the landmark decision upholding the "individual mandate" of the Patient Protection and Affordable Care Act—a decision that has not only profound and immediate consequences for the healthcare industry, but also broader implications for federal authority to use the Tax Code to affect individual conduct as part of a regulatory scheme. It would be a mistake, however, to let that case overshadow the many other cases from this Term with important implications for business.

The Court issued several important intellectual property decisions, upholding Congress's authority to remove creative works from the public domain and clarifying important points of substance and procedure under the patent laws. The Court also rejected corporate liability for human rights abuses abroad under one federal statute and set the stage for a potentially more significant decision under a related statute next Term. Finally, the Court continued its recent trends of enforcing arbitration provisions in consumer contracts and broadly construing preemption clauses in federal statutes.

With those and other leading decisions in mind, we are pleased to present the second annual MoloLamken Supreme Court Business Briefing. In preparing this document, we have identified cases with the greatest potential impact on a wide range of businesses. For each case, we have distilled the facts and holdings down to a concise summary and highlighted why the decision matters to business. Our aim is to allow busy corporate counsel and executives to stay current on the Supreme Court's docket and understand the potential impact of its decisions with a minimum of time and effort.

Of course, if your company is involved in or considering litigation, our experienced professionals would be more than pleased to discuss any of the issues raised by these cases in more detail.

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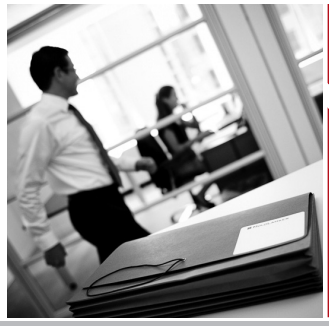

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National Federation of Independent Business v. Sebelius, No. 11-393 (June 28, 2012)

constitutionality of the Patient Protection and Affordable Care Act

The Supreme Court's landmark case this Term concerned the constitutionality of the Patient Protection and Affordable Care Act, a law designed to increase the number of individuals with health insurance and decrease overall healthcare costs.

Two provisions of the Act were at issue: the individual mandate, which requires most individuals to obtain health insurance coverage or potentially pay a penalty as part of their income taxes; and an expansion of Medicaid granting funds to States if they offer certain minimum levels of healthcare coverage. The case before the Supreme Court (one of many similar suits) arose out of the U.S. Court of Appeals for the Eleventh Circuit. The Eleventh Circuit had struck down the individual mandate but held the Medicaid expansion constitutional.

The Supreme Court upheld the individual mandate. Chief Justice Roberts, joined by Justices Ginsburg, Breyer, Sotomayor, and Kagan, held that Congress could enact the mandate as an exercise of its power to impose taxes. The mandate, the Chief Justice explained, has several features of a tax: It requires an individual who does not obtain insurance to pay additional money to the Internal Revenue Service; that money is paid when the individual files his tax return; and the payment requirement does not apply at all to individuals who pay no federal income tax. Although Congress labeled the payment a "penalty" rather than a "tax," Chief Justice Roberts concluded that the label did not change the result. He instead adopted a functional approach that looked at what the mandate did, not what Congress said it was doing.

In a separate portion of his opinion joined by no other Justice, Chief Justice Roberts concluded that the individual mandate could *not* be justified under the Commerce Clause. Although the Commerce Clause grants Congress broad power to "regulate Commerce . . . among the several States," the Chief Justice concluded that this authority did not include the power to compel individuals to engage in commercial activity they otherwise might not. Even though the failure of many individuals to obtain health insurance may have a substantial and pernicious effect on interstate commerce, the Chief Justice stated that Congress could not regulate the *inactivity* of refusing to purchase insurance.

Chief Justice Roberts also stated that the individual mandate could not be justified under the Necessary and Proper Clause, which allows Congress to "make all Laws which shall be necessary and proper for carrying into Execution" its other enumerated powers. The Act's proponents had argued that the individual mandate was "necessary and proper" because other provisions of the statute—such as those requiring insurers to offer coverage without regard to preexisting conditions—would not function properly if individuals could simply wait until they became sick to obtain coverage. The Chief Justice stated that the individual mandate was not sufficiently incidental to the Act's other provisions to qualify under the Necessary and Proper Clause.

Justices Scalia, Kennedy, Thomas, and Alito dissented. They agreed that neither the Commerce Clause nor the Necessary and Proper Clause could justify the individual mandate. But they contended that it could not be sustained as a tax either. Because a majority rejected that latter claim, however, the individual mandate was upheld.

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In its landmark decision this Term, the Supreme Court largely upheld key provisions of the Patient Protection and Affordable Care Act. But aspects of the Court's ruling call into question Congress's authority to regulate inactivity under the Commerce Clause or to attach new conditions to existing federal funding arrangements.

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constitutionality of the Patient Protection and Affordable Care Act

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The Supreme Court also largely upheld the expansion of Medicaid. Congress has broad authority under the Spending Clause to provide federal funding to States for their programs and to condition those funds on state compliance with specified conditions. In this case, the Act's expansion of Medicaid offered States additional federal funding if they expanded healthcare coverage. If a State refused to agree to those new conditions, however, the Act authorized federal regulators to prohibit the State from receiving any federal Medicaid funding—not just the additional funds offered under new provisions of the Act.

The Court concluded that, although the Act's expansion of Medicaid funding and accompanying conditions on that *new* funding were constitutional, the threat to revoke *existing* funds went too far. A majority of Justices concluded that that condition was impermissibly coercive: Congress could not withdraw existing Medicaid funds merely because a State chose to reject new funds with new strings attached. There was no single majority opinion reaching both of those results, however. Chief Justice Roberts and Justices Breyer and Kagan agreed with both aspects of the analysis. Justices Ginsburg and Sotomayor would have upheld the funding scheme in its entirety (providing a total of five votes to uphold the authority to withdraw new funds for non-compliance). And the four dissenting Justices would have found the entire Act invalid (providing a total of seven votes for striking down the government's authority to withdraw existing funds for non-compliance with new requirements).

The Court's decision is important to businesses across the Nation. The decision has a profound impact on all participants in the healthcare industry: Both the ruling upholding the individual mandate and the ruling largely upholding the expansion of Medicaid funding mean a substantial increase in the number of individual consumers of healthcare services. The share price of many for-profit healthcare providers, like hospitals, for example, rose immediately after the decision. Stock prices in other sectors—such as health insurers and medical devices—fell sharply. The long term effects of the decision on health insurance, healthcare markets, and employers providing insurance remain uncertain.

The Court's decision may have even broader ramifications. The ruling that Congress may not use its Commerce Clause powers to regulate inactivity may have implications for Congress's ability to use compulsory mandates as part of larger regulatory schemes. Because laws targeting pure inaction are relatively rare, however, those effects may be limited. The more far-reaching aspect of the Court's decision may be the ruling on the Medicaid expansion. Federal funding programs are ubiquitous, and States may now challenge amendments to those programs on the ground that they attach additional strings to existing funds that make the programs unconstitutionally coercive. The Court drew no precise lines as to when funding conditions become impermissibly coercive, so the full effect of the decision may not be clear for years.

Mayo Collaborative Services v. Prometheus Laboratories, Inc., No. 10-1150 (March 20, 2012)

patents — standards for patentability
(Disclaimer: MoloLamken LLP represented an amicus curiae *in this case)*

Mayo addressed the dividing line between an unpatentable law of nature and a patentable invention that applies a law of nature.

Section 101 of the Patent Act defines patentable subject matter to include "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." It has long been settled, however, that laws of nature, natural phenomena, and abstract ideas are not patentable.

Prometheus develops and markets medical diagnostic tests. Prometheus was the exclusive licensee of patents covering certain processes for determining whether a doctor had administered the correct dosage of thiopurine, a class of drugs used to treat autoimmune diseases. The Prometheus test measured levels of thiopurine metabolites that appear in a patient's blood as a result of the drug's administration, comparing those against specified, threshold levels that correspond with ineffective or harmful dosages of the drug. The Mayo Clinic had purchased and used the Prometheus test, but eventually began using its own test that relied on new, supposedly refined metabolite-level thresholds.

Prometheus sued Mayo for patent infringement, and the district court sided with Mayo on patentability. It reasoned that the key feature of the Prometheus patent, correlations between the thiopurine metabolite levels in the patient's blood and the effectiveness or toxicity of the thiopurine dosages being administered, was a law of nature or natural phenomenon that cannot be patented. The U.S. Court of Appeals for the Federal Circuit reversed, reasoning that the patents added sufficient steps in addition to those correlations—namely administering a drug to a patient and determining the resulting metabolite levels—to render Prometheus's claims patentable.

The Supreme Court reversed. After reaffirming the longstanding principle that a law of nature is not patentable, the Court held that the additional steps described in the patent claims were insufficient to turn the natural phenomenon at issue—the correlation between metabolite levels and thiopurine efficacy and toxicity—into processes that qualify as patent-eligible *applications* of a law of nature. According to the Court, the step of administering the drug merely identified the preexisting practice of doctors treating patients with thiopurine drugs. Likewise, the claims' broad description of steps for determining the resulting metabolite levels added nothing new to previously well-known methods for metabolite testing. The Court indicated that an inventor must add more to a natural phenomenon than broad descriptions of conventional steps in order to produce a patentable invention; to allow otherwise would impede technological progress and grant patentees monopoly power over laws of nature or natural phenomena.

Mayo may have important implications for inventors and companies working in the biotechnology and pharmaceutical fields. Because the Court's precedents treat mathematical algorithms as unpatentable laws of nature, *Mayo*'s influence may extend to the software industry and other industries as well. *Mayo* could be cited by alleged patent infringers in attempts to invalidate existing patents, since many patents necessarily rely on laws of nature (physics, chemistry, etc.) for their operation. Inventors and companies should also be mindful that *Mayo* has specifically cautioned that this threshold cannot be met solely through clever drafting of claims language.

***Mayo** holds that an inventor must add more to a natural phenomenon than broad descriptions of conventional steps in order to produce a patentable invention, and warns that the threshold cannot be met merely through clever drafting of claims language.*

CompuCredit Corp. v. Greenwood, No. 10-948 (January 10, 2012)

arbitration — credit repair organizations

CompuCredit addressed whether the Credit Repair Organizations Act ("CROA")—a federal statute that regulates businesses purporting to improve consumer credit ratings—precludes enforcement of arbitration agreements in suits alleging violations of the statute.

The plaintiffs filed a federal class-action complaint against a credit card marketing company. They alleged that the company misleadingly stated that using its credit card could rebuild poor credit and assessed exorbitant fees when accounts were opened. Defendants moved to compel arbitration, citing a mandatory arbitration provision in the credit card application agreement. The district court denied the motion, holding that the CROA prevented enforcement of the arbitration provision. The U.S. Court of Appeals for the Ninth Circuit affirmed.

The Supreme Court reversed. The Court explained that the Federal Arbitration Act establishes a broad policy favoring enforcement of arbitration agreements. Plaintiffs had claimed that the CROA carved out an exception from that policy, pointing to several provisions that, in their view, evinced Congress's intent to guarantee access to the courts. For example, the CROA contains a disclosure provision informing customers that they have a "right to sue" credit repair organizations for violations. The CROA includes a civil-liability provision that uses terms like "action," "class action," and "court." And the CROA contains a provision preventing courts from enforcing any waiver of the consumer rights it grants. The Court, however, found those features of the Act insufficient to overcome the presumption in favor of enforcing arbitration agreements. In the Court's view, if Congress had intended to depart from that presumption, it would have been more explicit.

Justice Sotomayor, joined by Justice Kagan, concurred in the judgment. Justice Sotomayor stated that the CROA could plausibly be read to grant plaintiffs a nonwaivable right to sue in court. But she found the majority's contrary construction equally plausible. Because those competing interpretations were in "equipoise," she concluded that plaintiffs could not overcome the strong federal policy of enforcing arbitration agreements. Justice Ginsburg dissented, urging that Congress intended to preclude enforcement of arbitration provisions under the CROA.

CompuCredit is an important decision for any company that uses arbitration clauses in consumer contracts. Many businesses consider arbitration preferable to litigation because arbitration typically lacks features such as extensive discovery, jury trial, and class actions, which increase costs and uncertainty. The Court's decision makes it more likely that clauses mandating arbitration will be enforced.

Because the Court's decision turned on the particular language of the CROA, it is most relevant to companies in the credit repair industry. But the decision continues the Court's trend—highlighted by last Term's decision in *AT&T Mobility LLC v. Concepcion*—of enforcing arbitration clauses. The Court did not state how clearly Congress must speak to create an exception to the federal policy of enforcing such clauses. But the examples the Court cited included statutes where Congress had expressly prohibited arbitration. Unless a particular statute makes clear that a plaintiff has a nonwaivable right to sue in court, a company will normally be on solid ground when seeking to enforce an arbitration clause.

***CompuCredit** holds that arbitration clauses in consumer contracts are enforceable in suits under the Credit Repair Organizations Act, continuing a trend of enforcing such clauses in a variety of contexts.*

Mohamad v. Palestinian Authority, No. 11-88 (April 18, 2012)

Torture Victim Protection Act — organizational liability
(Disclaimer: MoloLamken LLP represented respondents in this case)

The Torture Victim Protection Act of 1991 ("TVPA") establishes a cause of action against any "individual" who commits an act of torture or extrajudicial killing under color of foreign law. *Mohamad* addressed whether that provision authorizes suits against organizational defendants that are not natural persons.

According to the complaint in *Mohamad*, Palestinian Authority intelligence officers abducted, tortured, and killed a U.S. citizen during his visit to the West Bank. His relatives brought a TVPA action against the Palestinian Authority and the Palestine Liberation Organization. The defendants moved to dismiss, arguing that they could not be liable under the TVPA because the term "individual" includes only natural persons, not organizations. The district court agreed and granted the motion, and the U.S. Court of Appeals for the D.C. Circuit affirmed.

The Supreme Court likewise affirmed. The Court began by noting that the word "individual" in everyday parlance means natural persons, not organizations. It also cited federal statutes that distinguish between an individual and an organization. Although the Court recognized that it is possible for "individual" to mean something other than "natural person," it found nothing in the text, structure, or legislative history of the TVPA to suggest that unnatural usage. Finally, the Court rejected the plaintiffs' policy argument that the TVPA would be rendered toothless if it applied only to human beings. The Court concluded that Congress purposely intended to create a limited cause of action, and that it was not the place of the federal judiciary to rewrite the statute.

Mohamad clarifies that organizations cannot be held liable under the TVPA. Although the defendants in *Mohamad* were political organizations, the Court's reasoning clearly also extends to corporations and other business entities. That holding is important because plaintiffs have often invoked the TVPA to sue multinational corporations doing business in countries with checkered human rights records—suits that can be expensive to defend and can cause significant reputational damage regardless of their merits. Although most courts had rejected such claims under the TVPA even before the Supreme Court's decision, *Mohamad* provides a definitive answer.

Nevertheless, the question of corporate liability under a closely related statute, the Alien Tort Statute, remains unresolved. As with the TVPA, plaintiffs often invoke the Alien Tort Statute to sue multinational companies doing business abroad. Unlike the TVPA, however, the Alien Tort Statute does not use the word "individual"—the key term in the Supreme Court's analysis in *Mohamad*. The Supreme Court granted review to address corporate liability under the Alien Tort Statute in *Kiobel v. Royal Dutch Petroleum* (No. 10-1491), a case argued the same day as *Mohamad*. In an unusual development, however, the Court ordered re-briefing and re-argument in *Kiobel* to address a different question—whether the Alien Tort Statute applies to events outside the United States at all. That case will be re-argued next Term. A decision upholding corporate liability for acts abroad under the Alien Tort Statute may mean that corporations will derive little comfort from the Court's ruling in *Mohamad*. Conversely, a ruling narrowing the scope of the Alien Tort Statute—on whatever ground—could eliminate a significant source of litigation expense and reputational risk for multinational corporations.

***Mohamad** holds that organizations—whether political groups or multinational corporations—cannot be sued for human rights abuses under the Torture Victim Protection Act of 1991. But the Court left for next Term whether such entities may be sued under the Alien Tort Statute instead.*

Golan v. Holder, No. 10-545 (January 18, 2012)

intellectual property — protection for works in the public domain

Golan addressed whether the Constitution's Copyright Clause or the First Amendment prevents Congress from granting copyright protection to works that were previously in the public domain.

To fulfill the United States' obligations under the Berne Convention—the chief international copyright agreement—Congress enacted the Uruguay Round Agreements Act in 1994. Section 514 of that Act granted U.S. copyright protection to existing foreign works that were protected in their countries of origin but, for various reasons, not protected in the United States. Section 514 thus granted protection to many foreign works that previously were in the public domain. A group of musicians, publishers, and others challenged §514, alleging that it violated the Copyright Clause and the First Amendment because it restricted the previously unfettered right to use works in the public domain. The U.S. Court of Appeals for the Tenth Circuit rejected both challenges.

The Supreme Court affirmed. The Court relied heavily on its 2003 decision in *Eldred v. Ashcroft*, which had upheld a statute extending copyright terms of existing works. Like the statute in *Eldred*, the Court explained, §514 did not violate the Copyright Clause's requirement that copyrights last only for "limited Times." It merely gave foreign authors the same limited copyright term as U.S. authors. Section 514 was also consistent with the Copyright Clause's purpose of "promot[ing] the Progress of Science and Useful Arts." Although giving protection to existing works may not directly spur the creation of new works, it does provide financial incentives for the dissemination of knowledge and learning. Congress, moreover, has a long history of restoring copyright and patent protection to works or inventions that had lost protection.

The Supreme Court also rejected the plaintiffs' First Amendment challenge. Section 514 did not impermissibly restrict free expression, the Court held, because it left in place the traditional limits on copyright, namely the fair-use defense and the rule that only the form of expression, not ideas themselves, can be copyrighted. Particularly in light of Congress's goal to comply with international copyright law, the Court found no First Amendment problem with affording foreign authors the same protection enjoyed by their American counterparts.

Golan reinforces the Supreme Court's deference to congressional judgments about the appropriate scope of intellectual property protection. The Court confirmed that Congress has wide latitude not only to extend existing copyright protection but also to grant new protection to works previously in the public domain. The decision is thus important to publishers or other companies that own copyrights. Moreover, because the Court's analysis relied on both copyright and patent precedents, it is a fair inference that the Court's holding applies to patents as well. For that reason, the decision is significant to a variety of companies that own intellectual property.

After *Golan*, authors and inventors may seek greater intellectual property protections from Congress with assurance that the Supreme Court will afford substantial deference to reasonable legislative judgments in this area—particularly if those laws implement an international agreement. Conversely, *Golan* suggests that arguments for restricting the scope of intellectual property protections are best made to Congress, not the courts. So long as Congress does not grant a truly perpetual copyright or patent, the Supreme Court seems unlikely to second-guess its decisions.

***Golan** upholds Congress's authority to grant copyright protection to works that had already entered the public domain, confirming that the Court will afford substantial deference to reasonable legislative judgments in this area.*

Christopher v. SmithKline Beecham Corp. d/b/a GlaxoSmithKline, No. 11-204 (June 18, 2012)

Fair Labor Standards Act — "outside salesman" exemption

Christopher addressed whether pharmaceutical sales representatives qualify as "outside salesm[e]n," a class of employees that are not entitled to overtime wages under the Fair Labor Standards Act ("FLSA").

The plaintiffs in this case were two pharmaceutical sales representatives—called "detailers"—who sued their employer, GlaxoSmithKline ("GSK"), for overtime pay under the FLSA. The FLSA requires employers to pay certain employees at a rate of 1½ times their regular wages for all hours worked in excess of 40 per week. That requirement, however, does not apply to "outside salesm[e]n." The district court granted GSK summary judgment, finding that detailers fell within the "outside salesman" exemption. The U.S. Court of Appeals for the Ninth Circuit affirmed, creating a split with the Second Circuit.

The Supreme Court affirmed in a 5-4 decision. Congress did not define "outside salesman" in the FLSA, leaving the Department of Labor to do so through regulations. Before the Court, the Department of Labor argued that pharmaceutical detailers were not "salesmen" under its regulations because a "sale" requires the transfer of title of property. Detailers, it urged, do not complete sales of pharmaceuticals; at most, they can obtain nonbinding commitments from doctors to prescribe a certain drug. The Court, however, held that the agency's interpretation was not entitled to deference. The agency's "transfer of title" theory was a recent change from its prior rationales, the Court found, and did not reflect considered judgment. The Court also found that the agency had not given the industry reasonable notice of its interpretation, having never initiated enforcement actions against pharmaceutical companies despite their long practice of not paying detailers overtime.

The relevant regulations, moreover, refer to anyone "employed … *in the capacity of* [an] outside salesman." The Court read that language as favoring a functional approach that looks to the employee's responsibilities in the context of the relevant industry. The Court noted that pharmaceutical detailers look much like salesmen: They are hired for their sales experience, they work outside the office with minimal supervision, and they receive incentive compensation. The regulations also incorporate the FLSA's general definition of "sale," which includes not just transfer of title but also "other dispositions." The Court held that while pharmaceutical detailers do not "sell" a product in the traditional sense, they seek to obtain a non-binding commitment from a physician to prescribe one of the company's products which, given the regulatory environment in which pharmaceutical companies operate, is an "other disposition" tantamount to a sale. The Court thus held that pharmaceutical detailers are "outside salesm[e]n" who are not entitled to overtime wages under the FLSA.

Christopher is a victory for pharmaceutical manufacturers, who would have faced significant liability had the Court required them to pay overtime to pharmaceutical detailers. The decision is also significant for any company that employs people to sell even though the employee might not actually consummate the sale. The decision, however, may be most significant for its refusal to defer to the Department of Labor's construction of its own regulation. The full impact of the Court's ruling concerning deference remains to be seen.

***Christopher** holds that pharmaceutical detailers are "outside salesmen" who are exempt from the Fair Labor Standards Act's overtime requirement. It also raises substantial questions concerning judicial deference to an administrative agency's interpretation of its own regulations.*

Kappos v. Hyatt, No. 10-1219 (April 18, 2012)

intellectual property — district court review of decisions denying patent applications

Hyatt addressed the evidentiary standards and standard of review applicable in district-court review of decisions of the United States Patent and Trademark Office ("USPTO") denying patent applications.

Under 35 U.S.C. §145, an individual whose patent application has been denied by the USPTO and the Board of Patent Appeals and Interferences ("BPAI") can challenge the decision by filing a civil action against the Director of the USPTO in federal district court. In the alternative, the individual can seek review under 35 U.S.C. §141 in the U.S. Court of Appeals for the Federal Circuit in the first instance.

The plaintiff in this case submitted a patent application to the USPTO. The Examiner denied all claims on the ground that the claimed invention was insufficiently supported by the patent specification. The BPAI affirmed in part. The applicant challenged the decision under §145, bringing suit against the Director in federal district court. In that court, the plaintiff submitted a declaration, which had not been submitted to the USPTO, identifying the portions of the patent specification supporting the rejected claims. The district court disregarded the declaration, stating that it could not consider new evidence absent a compelling reason why it had not been provided to the USPTO. The district court then reviewed the USPTO's findings under a deferential "substantial evidence" standard and granted summary judgment to the Director.

Sitting *en banc,* the U.S. Court of Appeals for the Federal Circuit reversed. The court held that a party is free to introduce new evidence in §145 proceedings subject only to the ordinary Federal Rules of Civil Procedure and Rules of Evidence. The court also ruled that, when new evidence is introduced, the district court must make its own findings and need not defer to the USPTO.

The Supreme Court affirmed. The Court found that neither the text of §145 nor general principles of administrative law limit the admissibility of new evidence in district court or require the district court to apply a deferential standard of review to the USPTO's decision. The Court agreed with the Federal Circuit that a party may introduce new evidence in §145 proceedings subject only to the Federal Rules of Evidence and Rules of Civil Procedure. It also held that a *de novo* standard of review was appropriate because, while the USPTO has expertise in evaluating patent applications, the district court cannot meaningfully defer to the USPTO's decision when the USPTO was not presented with all of the same facts.

Hyatt has tremendous significance for patent applicants who suffer a denial before the USPTO. An applicant who chooses to seek district court review under §145 (rather than immediately seeking review in the court of appeals) can now present new evidence in support of its application without justifying its failure to present that evidence to the USPTO. And if the applicant does present new evidence, the district court offers a blank slate on which to argue the merits of the claim—the prior denial by the Examiner, even if affirmed by the BPAI, now carries no more weight than the district court chooses to give it.

***Hyatt** gives a person whose patent application was denied by the USPTO incentives to challenge that denial in district court rather than appealing directly to the Federal Circuit.*

Credit Suisse Securities (USA) LLC v. Simmonds, No. 10-1261 (March 26, 2012)

insider trading — statute of limitations

Credit Suisse addressed when the two-year limitations period for recovering a corporate insider's profits from "short-swing" transactions under the Securities Exchange Act of 1934 begins to run.

Section 16(a) of the Exchange Act requires corporate insiders to publicly disclose changes to their ownership interests in the corporation's stock. Section 16(b) permits a security holder to bring suit against any insider subject to §16(a) who realizes profits from the purchase and sale (or sale and purchase) of the securities within any six-month period. The statute requires insiders to disgorge such short-swing profits even if they did not trade on inside information. Section 16(b) provides that a suit by a security holder must be brought within "two years after the date such profit was realized."

Most §16(b) suits are brought against the officers and directors of the corporation. The plaintiff in this case, however, sued underwriters of initial public offerings under a novel theory of liability. The plaintiff, who owned stocks underwritten by Credit Suisse and other investment banks, alleged that the underwriters had employed mechanisms to inflate the aftermarket price of the stock to a level above the IPO price, allowing them to profit from the aftermarket sale. The plaintiff's complaints, however, were filed more than two years after the alleged profits were realized. She nonetheless argued that §16(b)'s two-year period never began to run because the underwriters never filed §16(a) disclosure statements. The underwriters maintained that they were exempt from §16(a)'s disclosure requirements and, in any event, that §16(b) is a statute of repose that is not subject to tolling. The district court rejected the plaintiff's argument and dismissed her suits. The U.S. Court of Appeals for the Ninth Circuit reversed, holding that §16(b)'s limitations period is tolled until the short-swing transactions are disclosed in a §16(a) filing.

The Supreme Court reversed in part. The Court observed that, under the plain language of the statute, the limitations period starts on "the date such profit was realized," not the date a §16(a) disclosure statement is filed. The Court also found that the Ninth Circuit's ruling, which would allow tolling beyond when a plaintiff is or should have been aware of the facts underlying a §16(b) claim, was inconsistent with established principles of equitable tolling. With Chief Justice Roberts not participating, however, the Court was divided 4-4 on Credit Suisse's argument that §16(b) establishes a period of repose that is not subject to tolling of any sort. The Court thus affirmed, without precedential effect, the Ninth Circuit's rejection of that argument and remanded for consideration of how traditional equitable tolling principles would apply to the facts in the case.

The Supreme Court's ruling is an important decision for both investors and corporations. It eliminates the Ninth Circuit's extremely plaintiff-friendly rule and, although it leaves existing circuit law on the availability of equitable tolling undisturbed, holds open the possibility of a later Supreme Court ruling that equitable tolling is not permitted under §16(b) at all.

Credit Suisse *eliminates one plaintiff-friendly rule for tolling the statute of limitations in suits to recover short-swing profits by corporate insiders, and holds open the possibility that tolling is not permitted at all.*

Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S, No. 10-844 (April 17, 2012)

pharmaceuticals — challenges to brand drug use codes

Caraco addressed the right of generic drug manufacturers to challenge, by means of a counterclaim in a patent infringement suit, the accuracy of a pharmaceutical use code submitted to the Food and Drug Administration ("FDA") by the brand-name manufacturer.

When the FDA assesses a pharmaceutical company's application to market a generic drug, it begins by considering whether the generic would infringe any patents held by the drug's brand manufacturer. The FDA makes that determination based on "use codes" that brand manufacturers must submit to the FDA. Those codes describe the scope of the manufacturer's patents, and the FDA accepts the codes without independently evaluating their accuracy. Under 21 U.S.C. §355, however, a generic manufacturer sued for patent infringement may assert a counterclaim seeking to require that the brand manufacturer correct the patent information it submitted on the ground that the patent does not claim an FDA-approved method of using the drug.

In this case, plaintiff Caraco sought to market a generic version of Prandin, the brand name of repaglinide, a drug manufactured by defendant Novo Nordisk. The FDA has approved three uses of Prandin to treat diabetes. Novo currently holds patents covering only one of those three FDA-approved uses. Yet when Caraco filed its application with the FDA, Novo sued Caraco for patent infringement and expanded its FDA use code to indicate that its patents covered all three of Prandin's FDA-approved uses. That use-code change effectively blocked Caraco's application to introduce a repaglinide generic. Caraco filed a counterclaim under §355 seeking to require Novo Nordisk to correct its use code. The district court granted Caraco's motion for summary judgment on its counterclaim. The U.S. Court of Appeals for the Federal Circuit reversed, holding that Caraco's counterclaim lacked a statutory basis. In its view, §355 allowed a claim only where the listed patent does not cover *any* of the drug's FDA-approved uses; Novo's patent by its terms did cover *one* of the three approved uses. The Federal Circuit also held that §355's allowance of a counterclaim to correct erroneous "patent information" did not extend to use codes.

The Supreme Court reversed. The Court conceded that the text of §355 could support different interpretations. Looking to the overall statutory scheme established under the Hatch-Waxman Amendments, the Court observed that one of the legislation's central purposes was to speed the availability of generic drugs by allowing the FDA to approve their marketing for unpatented uses more quickly. The Court held that, in that context, §355 must be construed to provide the manufacturer of a generic drug with a counterclaim when the brand manufacturer has submitted information to the FDA incorrectly stating that a *particular* FDA-approved use is patented, regardless of whether other FDA-approved uses are patented. The court also ruled that use codes are "patent information" that may be the subject of a §355 counterclaim.

Caraco will be seen by generic manufacturers as putting an end to certain efforts to keep generics off the market. But brand manufacturers will view the case as addressing only a very narrow set of facts, and as unlikely to dramatically alter the battleground between generics and brands.

***Caraco** expands the circumstances under which generic drug manufacturers sued for patent infringement can bring a counterclaim under 21 U.S.C. §355.*

Hosanna-Tabor Evangelical Lutheran Church v. EEOC, No. 10-553 (January 11, 2012)

employment — discrimination and religious freedom

Hosanna-Tabor addressed whether and to what extent the First Amendment prohibits religious organizations from being sued for employment discrimination.

Federal statutes such as Title VII of the Civil Rights Act of 1964 largely forbid organizations from discriminating in employment on a variety of grounds. Lower courts, however, have long recognized a "ministerial exception" forbidding suits that would require courts to pass judgment on a religious group's employment decisions about its own clergy. Courts had reached different results on who qualifies as a "minister" for purposes of that exception.

In this case, the U.S. Court of Appeals for the Sixth Circuit allowed a teacher in a Lutheran school to sue under the Americans with Disabilities Act, alleging that she had been fired on account of her narcolepsy. Even though the teacher was ordained as a minister and taught religious subjects, the court held that the ministerial exception did not apply because her duties were largely identical to those of lay teachers.

The Supreme Court unanimously reversed. The Court recounted a long tradition—dating back to the Revolution—of supporting the right of churches and religious groups to choose their ministry free from government interference. While the Court declined to create a specific formula to identify "ministers," it cited several facts to conclude that the teacher here qualified. The Lutheran Church held her out to the public as an ordained minister, a title she had earned through extensive training and through ceremony. And her job duties included clearly religious activities, such as leading students in prayer, accompanying them to chapel, and occasionally leading or arranging religious services. The Court rejected the Sixth Circuit's argument that the teacher could not be a minister because she devoted only a relatively small portion of her time to that religious work.

Hosanna-Tabor is an important decision for all hospitals, schools, or other businesses affiliated with religious organizations. The Court's ruling—that an employee may be a "minister" exempt from federal discrimination laws, whether or not her duties are primarily religious—means that the ministerial exception now applies to a wider range of employees. The Court's reasoning appears to foreclose discrimination claims by such individuals even where the rationale for the employment decision is alleged to be pretextual. While the full scope of the decision remains unclear, *Hosanna-Tabor* appears to protect religious employers from almost any discrimination claim related to their hiring, firing, or other job decisions involving ministerial employees.

The Court recognized a broad "ministerial" exemption from federal discrimination laws, applicable whether or not an employee's duties are primarily religious.

National Meat Association v. Harris, No. 10-224 (January 23, 2012)

federal preemption — Federal Meat Inspection Act

National Meat Association addressed whether a California law regulating the treatment of nonambulatory animals (i.e., animals that can no longer walk) at federally inspected slaughterhouses was preempted by the Federal Meat Inspection Act ("FMIA").

Originally enacted in 1908, the FMIA sets forth a comprehensive regime governing slaughterhouse operations, including the inspection and treatment of animals. The Department of Agriculture's Food Safety and Inspection Service has also issued detailed regulations. Those federal standards mandate inspection of each animal brought to a slaughterhouse. If an animal is classified as "suspect," it must be isolated and monitored to determine whether it may be processed into food. The Act contains an express preemption provision barring States from imposing any "[r]equirements within the scope of this [Act] with respect to premises, facilities and operations ... which are in addition to, or different than those made under this [Act]."

Prompted by a video showing mistreatment of animals at a California slaughterhouse, the California legislature passed a law that barred slaughterhouses from processing nonambulatory animals for human consumption and instead required them to euthanize the animals. A trade association of meatpackers and processers sued to enjoin those requirements. The district court granted an injunction, but the U.S. Court of Appeals for the Ninth Circuit vacated it.

The Supreme Court unanimously reversed, holding that the California statute was preempted. The California law, the Court explained, imposed numerous requirements that the federal statute does not. Among other things, the state law mandated that a slaughterhouse immediately euthanize nonambulatory animals, while the FMIA permits such animals to be held for further monitoring to determine whether they may be processed. The Court also rejected the argument that the California law fell outside the scope of the FMIA because it merely excluded certain animals from the slaughtering process. That argument, the Court reasoned, established only that the California law differed from the FMIA, not that it fell outside the Act's scope.

The Court's decision has significant implications for food processing companies. As the Court noted, two other Circuits had previously upheld other state laws that prohibited the slaughter of certain types of animals entirely. While not directly addressing those statutes, the Court's decision arguably casts doubt on their validity. The Court made clear that the operations of federally inspected slaughterhouses are generally not subject to additional state regulation.

More broadly, *National Meat Association* is one of several recent decisions in which the Court has interpreted statutory preemption provisions broadly to preclude additional state regulation. That trend is significant to the business community, and companies will undoubtedly rely on this latest decision to urge broad interpretations of other preemption provisions. That said, the case should not be overread. The FMIA's preemption clause is unusually broad, barring not only "different" state requirements, but also any requirements "in addition to" the FMIA's mandates. That sweeping language made *National Meat Association* a relatively easy case, and the Court's reasoning may not directly apply to statutes with more narrowly drawn text.

National Meat Association *invalidates a California statute regulating the treatment of nonambulatory animals at federally inspected slaughterhouses, confirming the Court's willingness to interpret statutory preemption provisions broadly to preclude additional state regulation.*

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