# TRENDS. YOUR BUSINESS AND THE LAW

JANUARY 2007

RISK MANAGEMENT Taming the Data Dragon: Protecting Your Company from Liability Due to Data Security Breaches Page 1

> REGULATORY COMPLIANCE FDA Under Fire: Summaries of the Recent Criticisms Page 4

FRANCHISE But It Doesn't Walk or Talk Like a Duck: The Perils of the Hidden Franchise Page 8

> FIRM NEWS Page 12

INTELLECTUAL PROPERTY When "Obvious" is Not Obvious: The Supreme Court Reviews a Key Legal Test for Patentabililty Page 17

> LABOR AND EMPLOYMENT Global Employment Law Update Page 20



WWW.FAEGRE.COM

MINNESOTA | COLORADO | IOWA | ENGLAND | GERMANY | CHINA

Whatever your business, we have a practice that knows it. And the numbers to support it.



# focus your business

\*According to the 2007 edition of Best Lawyers in America, published by Woodward White, Inc.



attorneys worldwide

WWW.FAEGRE.COM

UNITED STATES | ENGLAND | GERMANY | CHINA

TRENDS® is published bi-monthly by the law firm of Faegre & Benson LLP. Further details are necessary for a complete understanding of the subjects covered by this newsletter. For this reason, the specific advice of legal counsel is recommended before acting on any matter discussed within.

For the latest legal news, or copies of any article in this newsletter, visit Faegre & Benson online at www.faegre.com. For address and other changes, contact info@faegre.com.

© 2007 Faegre & Benson LLP. All rights reserved.

more than

# Taming the Data Dragon: Protecting Your Company from Liability Due to Data Security Breaches

#### By Michael M. Krauss and Charles F. Webber





Michael Krauss (mkrauss@faegre.com) is a senior associate and Chuck Webber (cwebber@faegre.com) is a partner in the firm's business litigation practice in Minneapolis. They are also members of the firm's financial services litigation team.

Identity theft is rampant-or so it would seem from the headlines these days. The Web site of one consumer-advocacy group declares that data-security breaches over the last two years subjected the personal information of more than 97 million people (nearly half of all adult Americans) to an increased risk of identity theft. People can debate whether the epidemic of identity theft is real or so much media-fed hysteria. But perception is often reality, and there is no doubt that recent security breaches-including the inadvertent display of customers' personal information on corporate Web sites, the loss or theft of company laptops containing personal data, and the disappearance en route to storage of computer back-up tapes with personal information-have been very much in the public eye. Moreover, courts, state legislatures, federal regulators, and Congress have reacted to the rash of recent high-profile incidents in distinct ways. Your company should take each into account when establishing its own data-security policy to guard against any breach of security, and when responding to any data breach that does occur.

#### Putative Class Action Litigation

Fortunately, data breach has not yet led to high-cost damage awards in court. Despite

the volume of personal data involved, the plaintiff bar has been unable to maintain class actions on behalf of customers whose personal information—such as Social Security, bank account, or credit-card numbers—was potentially exposed to would-be identity thieves. The key word is potentially. In the last year, at least seven federal courts dismissed tort actions seeking damages on the theory that a data breach placed customers at an increased risk of identity theft. Although the customers sought to show damages in the form of time and money spent monitoring their credit, the courts held that the claimed injuries flowed from the perceived, speculative risk of future harm-and so were not compensable. As one court explained: "[The plaintiffs] overlook the fact that their expenditure of time and money was not the result of any present injury, but rather the anticipation of future injury that has not materialized."

Instead, damages are available only where a customer can prove that she suffered identity theft or some other concrete harm as a result of the data breach. This can be difficult. There often is no indication that lost personal information—such as that contained on a misplaced laptop or wayward back-up tape—has been accessed by anyone, much less would-be fraudsters. And criminals in possession of stolen computers often are interested

TRENDS® January 2007

only in the hardware itself, and don't even know that they possess sensitive customer information before they erase the hard drive. Even in instances of true identity theft, the customer must establish the causal link between the data breach and the subsequent fraud, and that is no easy link to prove.

Although the courts generally have not held companies accountable for data breaches

in the absence of proven consumer harm, the same is not true of state legislatures, federal agencies, and Congress.

#### State Data Breach Notification Laws: The Importance of Encryption

Nearly 35 states—13 in 2006 alone—have passed laws requiring companies to notify customers about data breaches involving personal information. Importantly, though, disclosure is generally not required if the compromised data is encrypted. Some states

require notification whenever the security of unencrypted personal data has been compromised, regardless of the likelihood that the information would actually be misused. Others do not require notification if the company concludes after investigation that there is no reasonable possibility of misuse. Required notification procedures can also vary from state to state. Although most statutes vest exclusive enforcement responsibility with the state's attorney general, some allow customers to sue for actual damages flowing from any failure to timely disclose a data breach. Finally, many notification statutes are part of a legislative scheme that also requires companies to reasonably secure personal data in their possession.

Your company should be familiar with the data-breach-notification statute in each

state where it does business. As a practical matter, companies with customers in more than one state generally comply with the most stringent notification rules applicable in responding to a data breach. California's Security Breach Notification Act was the first of its kind and remains among the most rigorous. The Minnesota statute, which took effect in January 2006, tracks California's in many respects, but does not apply to financial institutions. The Colorado statute,

which took effect last September, also tracks California's in key ways, but notification is not required if the company determines that misuse of the compromised data is unlikely. Iowa currently has no databreach-notification statute.

#### Federal Regulatory Enforcement

Your company should also be familiar with any applicable federal regulatory data-security requirements and the risk of administrative action following a data

breach. Financial institutions overseen by the Federal Reserve Board, FDIC, OCC, or OTS must comply with informationsecurity guidelines issued in 2005. The guidelines direct financial institutions to develop a program that reasonably secures customers' personal information in light of assessed risk. When a financial institution learns of unauthorized access to personal information, it should promptly investigate to determine whether the data likely has been or will be misused. If so, the institution should notify the affected customers as soon as possible. But the institution's primary regulator should be notified of any breach implicating sensitive customer information. These guidelines supplement the Safeguards Rule issued by the Federal Trade Commission (FTC) in 2002, which requires financial institutions to maintain

an information-security plan that protects the confidentiality of personal customer information. All of these regulations have been issued under the Gramm-Leach-Bliley Act of 1999, which also requires financial institutions to notify customers of their privacy policies and to allow customers to limit the institution's ability to share personal information with third parties.

Additionally, the FTC recently created a **Division of Privacy and Identity Protection** within its Bureau of Consumer Protection. According to the FTC, failing to reasonably secure personal information in a company's possession constitutes an unfair practice in violation of federal law. Examples include lack of encryption and storing personal information longer than necessary on more computers than necessary. After data broker ChoicePoint unwittingly disclosed the personal information of 163,000 people to would-be identity thieves, the FTC imposed a civil fine of \$10 million (not including customer redress of \$5 million), and required ChoicePoint to implement a comprehensive information-security program, to ensure that information is disclosed only to legitimate business, and to submit to third-party audits for twenty vears. Misuse of lost data or actual harm to consumers is not required for the FTC to act. Although DSW Inc. avoided tort liability following a data breach that did not result in fraud or identity theft, it remained subject to an FTC consent order requiring it to implement a comprehensive information security program and to undergo regular third-party audits for twenty years.

#### **Congressional Action**

Meanwhile, Congress is considering several competing data-privacy and breachnotification bills. The goal is to replace the current patchwork of state laws with a uniform, nationwide scheme. Each proposal requires businesses to reasonably protect customers' personal information and to investigate promptly any data breach in order to determine the likelihood of harm to customers. But one bill pending in the House would require companies to disclose breaches unless they can affirmatively show that there is no reasonable risk of harm, while another vests companies with more discretion in deciding whether notification is required. Other key differences include the degree to which the bills would take the place of current state data-security laws and the form of notice required (with one bill requiring businesses to inform affected customers that identity theft is "reasonably likely"). Multiple bills are also winding their way through the Senate. No bill is scheduled for a floor vote in either chamber, and there is no timetable for the legislation.

#### What Your Company Should Do

Most important, ensure that your company is familiar with all applicable state laws, federal regulatory requirements, and federal statutes governing data security and notification of security breaches. While the specifics can vary, your company should implement a data-security policy that reasonably protects personal customer information in its possession. You should also consider whether (and to what degree) this involves encrypting sensitive personal data. Although no state statute expressly requires encryption, state laws generally provide that a breach involving encrypted data need not be disclosed to customers. And the FTC has cited the lack of encryption as one factor in charging companies with unfair practices involving the protection of consumers' personal information. But encryption is easier said than done. The process of encrypting data is timely and costly, and can unduly burden data access by authorized company personnel. Regardless of whether your company chooses encryption, all employees should be trained on the data-security policy. and ideally, should confirm in writing that they understand the policy and will abide by it.

If a data breach occurs, promptly investigate the breach in an effort to determine whether it is reasonably possible that compromised personal information actually may be misused. Regardless of whether notification to customers is legally required, this early assessment will help inform your strategy in the event of litigation. In communicating about the data breach, employees should keep in mind that a lawsuit or government inquiry may follow. Consider establishing a clearinghouse for all communications and documents generated in responding to the breach. Be prepared to investigate reports by customers of actual instances of identity theft or other concrete harm. Of course, counsel should participate in the process from the outset, in order to ensure that the company meets its obligations under the law.

Doing business today typically entails dealing with personal information about your customers. And no precaution can completely eliminate the risk that sensitive data may become compromised. But your company can minimize the impact of a data breach and ensure compliance with all legal requirements.

# FDA Under Fire: Summaries of the Recent Criticisms

#### By James A. O'Neal and Davina S. Carson



Jim O'Neal (joneal@faegre.com) is a partner and Davina Carson (dcarson@faegre.com) is an associate in the firm's Minneapolis office. Both practice in the area of general litigation.

The U.S. Food & Drug Administration (FDA) has come under significant attack in recent months from a wide variety of sources. Several factors—a quick succession of prominent medical device recalls; adverse safety findings with respect to several pharmaceuticals, most notably Vioxx; and political imbroglios at the agency—have contributed to a growing level of skepticism as to whether the FDA is effectively accomplishing its mission of regulating the safety and efficacy of drugs and medical devices marketed in the U.S.

In the midst of this storm, the agency published a new set of "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products." The new requirements include a preamble which enunciates the agency's position with respect to the preemptive effects of its labeling regulations on potential tort liabilities for manufacturers, 71 Fed. Reg. 3922-39976 (January 24, 2006). On the one hand, the positions expressed in the preamble and in certain amicus briefs filed by the FDA in tort cases are generally felt to be friendly to industry interests. On the other hand, anecdotal reports from industry suggest that the new drug application process has slowed and become more difficult in recent months, purportedly as the FDA's response to ongoing criticism. (See, e.g., "New Sense of Caution at FDA" by Andrew Pollock, *New York Times*, September 29, 2006.)

Manufacturers who have suffered under the rigors of FDA scrutiny may be tempted to take satisfaction in the public derision directed at the agency. They shouldn't. To function effectively, the system requires the respect of the general public as well as a healthy level of mutual respect between the regulator and industry. If the current environment does not improve, industry can expect significant adverse effects: a lessening of the agency's willingness to advocate the preamble's preemption positions as well as increasing delays in the handling of applications for approval of new drugs and medical devices.

Two major reports in 2006 advanced particularly pointed criticisms of the FDA: a report from the U.S. Government Accountability Office (GAO) and a report from the Institute of Medicine (IOM). The GAO Report focuses principally on a structural analysis of the FDA's operations, while the IOM Report examines the agency's relationships with the industries it regulates, and the scope and implementation of its regulatory authority.

#### **The GAO Report**

In its recent report to Congress, the GAO focused on the FDA's ability to monitor postmarket drug safety issues. The GAO Report provides an outline of relevant FDA organizational structures and offices and those offices' procedures for postmarket drug safety decision making. The report discusses why the GAO deems the FDA's present organizational structure and procedures to be ineffective in handling postmarket drug safety issues, and it analyzes recent measures taken by the FDA in an attempt to approve its methods for postmarket decision making and implementation. Finally, the GAO Report makes recommendations that it believes will improve the FDA's ability to make and enforce postmarket drug safety decisions.

The GAO Report discusses the roles of two distinct FDA offices actively engaged in postmarket drug safety monitoring activities. The first is the Office of New Drugs (OND). The second is the Office of Drug Safety (ODS). After the Prescription Drug User Fee Act of 1992 (PDUFA) was passed, pharmaceutical manufacturers —referred to as "sponsors" in the report —began to pay fees to the FDA. These fees were used to hire additional drug application reviewers and implement other changes that resulted in a more expeditious drug application review process. In view of this more efficient process made possible by PDUFA, Congress reauthorized the Act in 2002 and incorporated as a new goal that the FDA monitor postmarket drug safety in an effort to protect the public from unforeseen adverse effects. OND and ODS, which are part of the FDA's Center for Drug Evaluation and Research (CDER), have been jointly responsible and actively engaged in carrying out the FDA's postmarket monitoring responsibilities.

OND is responsible for approving drugs and monitoring safety issues throughout the lifecycle of approved drug products. It has the authority to address postmarket drug safety issues when they arise and to impose policies and procedures to mitigate safety concerns. OND staff is made up of physicians, pharmacologists, toxicologists, and microbiologists whose focus is to provide physicians and patients with the drugs needed to treat a variety of diseases and conditions. OND devotes approximately 50% of its time to drug safety issues. In contrast, ODS's sole focus is on postmarket drug safety. Its staff consists of pharmacists and epidemiologists who are responsible for reviewing and analyzing adverse event reports. The ODS works closely with the OND, yet has no authority of its own.

The GAO Report faults the FDA's lack of unambiguous critical standards and the agency's poor internal communications for the difficulties which OND and ODS have had in determining when postmarket drug concerns require FDA intervention and what methods of intervention should be employed. Additionally, the GAO Report cites problems that it believes are the result of the FDA's lack of authority and inability to require drug sponsors to monitor and report postmarket adverse events. This lack of authority, coupled with an ineffective means of data collection. only further acts to increase response delays resulting from communication difficulties that exist between OND and ODS. As a result, the FDA's reliance on drug sponsors to conduct studies voluntarily and to provide the agency with data and trial results creates difficulties in the FDA's tracking and monitoring of drug safety issues, which forces it to rely upon incomplete or untimely information or results in its own risk-benefit analyses of postmarket products. Moreover, although ODS and its staff are primarily epidemiologists focused on postmarket drug safety issues and how drugs are actually being used in the general population, the GAO Report implies that ODS's lack of specific goals and independent authority result in additional delays in the FDA's handling of drug safety issues and concerns.

Furthermore, although the FDA has recently created the Drug Safety Oversight Board (DSB) and implemented new policies and process teams to improve how the agency responds to postmarket drug safety issues, the GAO Report strongly suggests that the FDA's newest measures are simply not enough. The report recommends that the FDA, through the DSB, create a clear and unambiguous dispute resolution process to facilitate decision-making and future communications between OND and ODS. Additionally, the GAO maintains that increased funding is necessary to allow the FDA to expand its capabilities to monitor and develop sources for collection of postmarket drug safety data. According to the report, although the FDA has begun to work with the Centers for Medicare and Medicaid Services in an effort to obtain additional drug data, this method could prove to be risky and unreliable for the FDA, when compared to its having the ability to conduct active surveillance and independent clinical research to ensure that postmarket drugs are safe.

The report concludes that the Commissioner of the FDA should take the following four actions:

- establish a mechanism for systematically tracking ODS recommendations and subsequent safety actions;
- with input from the DSB and the Process Improvement Teams, revise and implement the draft policy on major postmarket drug safety decisions;

- improve CDER's dispute resolution process by revising the pilot program to increase its independence; and
- clarify ODS's role on FDA's scientific advisory committee meetings involving postmarket drug safety issues.

#### **The IOM Report**

Another recent report published by the IOM, discusses the present role of the FDA in ensuring drug safety and suggests how the FDA could increase its capabilities. The report presents five recommendations that the IOM believes would greatly improve the efficacy of the FDA and its abilities to monitor and ensure drug safety.

#### **Organizational Culture**

First, the report discusses the "organizational culture" of the CDER. According to the IOM, the instabilities and high turnover rates render the agency incapable of operating efficiently and implementing clear, consistent policies and procedures. The agency's leadership is described as being polarized and politicized, which reduces its efficiency and ability to coordinate its efforts. Additionally, the IOM alleges that the high turnover rate is indicative of low morale, which results not only from office politics and the agency's polarization, but also from poor organization and handling of scientific disagreements and differences of opinion.

The IOM Report recommends the creation of an external Management Advisory Board comprised of individuals experienced in changing and leading large-complex organizations. It further suggests clear and unambiguous assignments of goals and roles for ODS and for the Office of Surveillance and Epidemiology (OSE). Additionally, to treat the imbalance of authority that exists between the OND and OSE, the IOM Report recommends changes that would result in the OND and OSE having joint authority in postmarket regulatory actions.

# regulatory compliance

#### Science & Expertise

Second, the IOM Report points to the FDA's Adverse Event Reporting System (AERS) as "outdated and inefficient," although there are adequate technologies available that would increase the FDA's capability to monitor and track adverse events when they occur. Similarly, the report criticizes the FDA's abilities to test drug safety hypotheses and make continuing riskbenefit assessments throughout the lifecycle of a drug. The IOM suggests that the FDA revamp its technology and its methods for assessing both drug safety and drug efficacy, so as to improve its risk-benefits analysis. Additionally, the IOM suggests the implementation of Risk Minimization Action Plans, to ensure that drug safety continues beyond the approval of a product. Moreover, the IOM Report suggests that the FDA restructure its organization by creating additional leadership positions for experts and scientists. Similarly, the report recommends that by increasing the number of epidemiologists and other such experts it employs, the FDA would increase its credibility and be better prepared to monitor complex-scientific drug safety issues.

#### **Regulatory Authorities**

Third, the report concludes that the FDA is lacking in regulatory authority. The IOM views the FDA's role as too much of an advisory or collaborative role. It strongly recommends that Congress require postmarket trials and monitoring programs. It also suggests restricted distribution of drugs to facilities, pharmacists, or physicians with special training and expertise. Additionally, the IOM Report recommends that the FDA's authority be increased to allow the FDA to enforce harsh penalties and sanctions against drug sponsors that fail to comply with drug safety monitoring standards. Finally, the report recommends that drug sponsors be required to accumulate and submit data relating to their products and label new products or new combinations of drugs with a special symbol, such as the black triangle used in the United Kingdom.

#### Communication

Fourth, the IOM Report finds that the public would benefit from having more information as to how drugs are studied. It states that patients would be better prepared to make health care decisions if they were more aware of how the FDA functions. Additionally, the IOM concludes in its report that sources of information presently employed by the public result in consumers receiving incomplete or inaccurate pictures of the risks or benefits of drugs. It recommends that the FDA increase its monitoring and establish stricter controls governing advertising directed at the public and prescribing physicians.

#### **Financial Resources**

Finally, the IOM Report points to ending the FDA's reliance upon sponsor paid fees mandated under PDUFA as a crucial step necessary to assure the agency's ability to implement needed systemic and technological changes. The report implores Congress to approve increased funding and resources for the agency, so that it can conduct independent research and hire more effective leadership and expert personnel.

#### Conclusion

The findings and recommendations of the GAO Report and the IOM Report are the subject of much debate. The broader debate over the appropriate relationship between a government agency and the industries it regulates will likely always be with us, especially with industries that are as important to the health and welfare of the country as the pharmaceutical and medical device industries.

It is important for representatives of those industries to understand the criticisms of the FDA that have been advanced, so they can serve as effective partners to the regulators in making the system work. Anticipating the pressures faced by the regulators in the current environment, industry should be more careful than ever to relate well and appropriately to FDA personnel and to provide the necessary scientific information to support their applications.

## But It Doesn't Walk or Talk Like a Duck: The Perils of the Hidden Franchise

#### By William L. Killion and Sarah J. Yatchak





Bill Killion (wkillion@faegre.com) is a partner in the firm's Minneapolis office and practices in the area of business litigation and franchise law. Sarah Yatchak (syatchak@faegre.com) is an associate in Minneapolis and practices franchise law.

Mitsubishi did not think its business was a franchise. Trial and appeals courts thought otherwise. The cost of this legal lesson: a \$1.525 million jury verdict in favor of Mitsubishi's alleged franchisee.

In refusing to second-guess a judge's summary judgment ruling that a forklift distributor was a franchisee, the Seventh Circuit Court of Appeals observed in *To-Am* Equip. Co., Inc. v. Mitsubishi Caterpillar Forklift America, Inc., 152 F.3d 658, 660-61 (7th Cir. 1998) that

legal terms often have specialized meanings that can surprise even a sophisticated party. The term "franchise" or its derivative "franchisee" is one of those words.

The court concluded that

while we understand [Mitsubishi's] . . . concern that dealerships in Illinois are too easily categorized as statutory franchisees, that is a concern appropriately raised to either the Illinois legislature or Illinois Attorney General, not to this court.

Id. at F.3d at 666.

#### **Of Ducks and Franchises**

A wide variety of business arrangements that do not look, walk or talk like a franchise have been labeled just that by the courts. Typically referred to as "hidden" or "inadvertent" franchises, they include everything from sales representatives and appliance parts distributors to cafeterias in office buildings.

The line between a pure distributorship and a license arrangement is often thin, but—as Mitsubishi learned the hard way —the consequence of crossing it can be costly indeed. This article will examine the uncertainty surrounding these legal definitions of business arrangements and offer guidance for avoiding the perils of the hidden franchise.

# Sailors, Widows and Franchisees

Franchising as we know it today was unheard of until the 1960s. Starting then, and into the 1970s, franchises began popping up all over the United States. Not only did the franchise business model take off, but so did the horror stories about franchisors stealing the life savings of "mom and pop" franchisees through fraud, precipitous terminations and other unfair conduct. Some skeptics, in fact, viewed franchising as little more than a scheme to take advantage of unsophisticated investors. It was not long before franchisees began taking their place alongside widows and sailors as individuals needing special protection by legislatures. California took the lead in passing laws regulating franchising, followed closely by Minnesota and a number of other jurisdictions. Not long after, the federal government stepped in with a law of its own.

franchise

Forty years and thousands of franchises later, franchising has proven itself a legitimate method of distributing goods and services. But it remains today the same as it was in the 1970s—an industry that is regulated through a combination of disclosure and relationship laws at both the state and federal level.

At the federal level, Congress passed a law in 1979 called the "FTC Trade Regulation Rule: Disclosure Requirements and Prohibitions Concerning Franchising and Business Opportunity Ventures." See 16

C.F.R. 436 (1979). The Federal Trade Commission (FTC) Rule identifies a number of disclosures that must be made by a franchisor to a prospective franchisee in a written document, ranging from the history of the franchisor to the

identity of other franchisees to the details of any "earnings claim." Fortunately for the "unsuspecting franchisor," the FTC Rule does not create a private cause of action as enforcement lies with the FTC alone. The "unsuspecting franchisor" doing business in the 18 states that have enacted laws similar to the FTC Rule, however, is subject to lawsuits by franchisees. These states give franchisees the right to sue the franchisor for damages. In addition, potential franchisors are subject to significant damages in the 16 states with franchise relationship laws that punish "franchisors" for terminating franchisees without cause or failing to give proper notice and an opportunity to cure.

#### The Definition of a Franchise: The Devil's in the Details

As Mitsubishi learned in *To-Am Equipment*, franchising is not about labels and it is not about feelings. Parties to a transaction cannot waive the protections of the franchise laws. It therefore does not matter whether the parties call their relationship a "franchise," a "license," or a "distributorship," or "feel" like they are in a franchise relationship. Nor does it matter whether the licensee is big or small or otherwise needs the protection of the franchise laws. The existence of a franchise is a matter of definition, pure and simple.

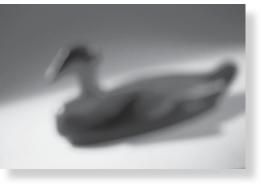
Courts will find that a transaction is a "franchise" if three elements are present: (1) the grant or licensing of a right to use a trademark or trade name; (2) the payment of a "franchise fee" for the use of the mark

or name; and (3) some variant of a community of interest, m a r k e t i n g plan, control, or assistance. See 16 C.F.R. 436.2(a)(1)-(2). The definition seems simple enough. For a company trying to avoid being

declared a franchise by a court or the FTC, however, the only part of the definition which provides certain protection is the first part—the licensing of a mark or name. As long as it is not somehow permitting a third party to use a mark or name, a company is not offering a "franchise." As the FTC states in its "Interpretive Guides to Franchising and Business Opportunity Ventures Trade Regulation Rule":

> The Commission does not intend to cover package or product franchises in which no mark is involved. If a mark is not necessary to a particular distribution arrangement, the supplier may avoid coverage under the rule by expressly prohibiting the use of its mark by the distributor.

Anytime a company authorizes anyone to use its mark or name and expects to control and be paid for it, that opportunity may well be the proverbial duck, regardless of how it looks, walks or talks.



# The Third Element is a Given

Under the FTC Rule, the third element of a franchise is some sort of "control or assistance" on the part of the supposed franchisor. Alleged franchisors, therefore, rarely are successful in claiming that they do not offer a marketing plan or have a community of interest or somehow "control" the alleged franchisee At its simplest, any control by a franchisor over a franchisee and any assistance to a franchisee will qualify as "control" as long as the FTC believes it is "significant"-and it does not take much to be significant. Training programs, operation manuals, and establishing methods of operation all meet the test.

Some states (Minnesota, New Jersey, and Wisconsin, for example) require a "community of interest" between franchisor and franchisee. Courts applying the laws of these states rarely fail to find a community of interest in even the most basic forms of product and service distribution relationship. California requires the presence of a "marketing plan or system" before labeling a relationship a franchise, and courts there have found that oral or implied and optional or suggested plans and systems meet the test. In short, prudent companies do not count on the third element to save them from being branded a "franchisor."

#### It's All About the Fee

Ultimately, disputes over the existence of a franchise turn on the existence of a franchise fee. Upfront payments for a right to do business under a particular name or mark and ongoing royalty payments are obvious examples of franchise fees. But almost any payment might qualify as a franchise fee. The Interpretive Guides say that the "required payment" element of the definition of a franchise is designed "to capture all sources of revenue which the franchisee must pay to the franchisor or its affiliate for the right to associate with the franchisor and market its goods or services." Interpretive Guides, 44 Fed. Reg. 49,966-49,992 (Aug. 24, 1979). According to the FTC.

a franchise fee may be found in initial franchise fees as well as those for rent, advertising assistance, required equipment and supplies including those from third parties where the franchisor or its affiliate receives payment as a result of such purchase—training, security deposits, escrow deposits, nonrefundable bookkeeping charges, promotional literature, payments for services of persons to be established in business, equipment rental, and continuing royalties on sales.

The To-Am Equipment case provides a startling illustration of how courts have construed this type of language against franchisors. The Seventh Circuit found that Mitsubishi charged a franchise fee because the forklift distributor purchased more than \$500 worth of sales and service manuals over an 8-year relationship in order to satisfy the manufacturer's requirement of an adequate supply of manuals. *To-Am Equip. Co., Inc.*, 152 F.3d at 663.

Despite the seemingly broad reach of the franchise laws, the FTC Rule and various state statutes create some exemptions from the existence of a fee. The FTC rule excludes from the definition of a franchise fee payments of less than \$500 made before or within six months of the opening a business. See 16 C.F.R. 436, 2(a)(iii). A number of states have a similar exclusion, although the amount may vary. Under FTC rules and the laws of several states, monies paid for a reasonable quantity of goods at a bona fide wholesale price purchased from the "franchisor" for resale are also exempted from the definition. See Bus. Franchise Guide (CCH) ¶ 380 (citing 15 U.S.C. § 57a(g)).

#### **A Few Safe Harbors**

The FTC Rule and most states exclude a number of relationships from their definition of a franchise. For example, a business opportunity that will constitute merely a part of a company's existing business falls within the "fractional franchise" safe harbor. The FTC Rule, however, allows the exemption only when

# The FTC Rule and most states exclude a number of relationships from their definition of a franchise.

the franchisee has more than two years of prior management experience in the business represented by the franchise and where the parties anticipate that sales under the franchise will represent no more than 20% of the dollar volume of the franchisee's projected gross sales. See 16 C.F.R. 436.2(a)(i); 436.2(h). Rhode Island and Wisconsin exclude sales to purchasers with a high net worth or a high income, and several states (California and New York are the main examples) exempt sales by large franchisors from the registration requirement. Isolated sales are exempted by the FTC and a few states.

#### **Mistakes Can Be Costly**

The FTC Rule applies to franchise opportunities in each of the 50 states. Thus, a company offering an investment that qualifies as a franchise under the FTC Rule must present a prospective franchisee with an offering circular containing specific and detailed information about the franchisor and the opportunity. Although a franchisee wronged by the failure to disclose may not have a private right of action, the FTC can bring enforcement proceedings against the franchisor. In states with their own disclosure laws, a failure to disclose at all. or an incomplete or misleading disclosure, allows a franchisee to seek equitable relief and sometimes damages. In some states, the failure to make an accurate disclosure carries the additional risk of exemplary damages, criminal penalties, and fines.

Perhaps most troublesome, however, are the relationship laws adopted in various states. Some of these make it unlawful for franchisors to discriminate among franchisees, restrict the ability of franchisors to profit from the sale of goods to franchisees, and otherwise regulate the ongoing relationship between franchisor and franchisee. Almost all of these states allow franchisors to terminate only for cause before the end of the term of the agreement, and then only after providing the franchisee with notice of default and an opportunity to cure. At least two states (Wisconsin and New Jersev) make franchisee agreements "evergreen," that is, terminable only for cause without regard to their stated term. Thus, a relationship that otherwise looks terminable at will may, in fact, constitute a franchise that may not be terminated except for cause. No one knows better than Mitsubishi just how costly mischaracterization of the relationship can be.

#### The Moral

The prudent distributor of a product or service under a mark or name errs on the side of following the franchise laws, including the use of an offering circular. A licensor still wishing to avoid the burden of preparing an offering circular and the risk of liability under various franchise laws must exercise great caution to avoid charging a franchise fee and becoming a proverbial franchise duck.

# firm news

#### **Eleven New Partners Admitted**

Faegre & Benson has admitted 11 associates to partnership effective January 1, 2007. The six men and five women practice in a diverse array of litigation and transactional areas—including corporate, business and regulatory litigation, health care and non-profit organizations, intellectual property, and real estate. Four of the new partners practice in the Minneapolis office, six in the firm's Colorado offices and one in the London office.

"Admission to our partnership represents a milestone—for these lawyers and for our firm," said Tom Morgan, chairman of Faegre & Benson's Management Committee. "As individuals, each of these lawyers is outstanding in his or her field. As a group, they bring a diversity of backgrounds and expertise which allows us to tailor our services even more acutely to



Nathaniel G. Ford

the specific needs of our clients."

**Nathaniel G. Ford** practices corporate law in the Denver office, where he concentrates his practice on venture capital financings, public securities offerings, securities law compliance, private equity and mergers and acquisitions. He is a graduate of Princeton University (A.B., *cum laude*, 1993) and the University of Colorado (J.D., 1999).

**Gina M. Kastel** practices in the area of nonprofit and tax-exempt organizations and health care law in the Minneapolis office. Gina graduated from the University of Notre Dame (B.A., *with highest honors, Phi Beta Kappa*, 1992) and Harvard University (J.D., *magna cum laude*, 1999).



Gina M. Kastel



Steven G. Lentz

**Steven G. Lentz** practices corporate law in the Minneapolis office, where he focuses on investment management. He is a graduate of the University of Notre Dame (B.A., *with highest honors, Phi Beta Kappa*, 1987) and the University of Minnesota (J.D., *cum laude*, 1990). He served as a judicial law clerk to the Honorable Frank J. Magill, United States Court of Appeals, Eighth Circuit.

**Richard A. Nakashima** practices in the area of biotechnologyrelated intellectual property in the Boulder office. He graduated from the University of California, Santa Cruz (B.A., 1975), the University of California, Davis (M.A., 1978), the Medical College of Ohio (Ph.D., 1983), the Johns Hopkins University (Post-Doctoral, 1988) and Texas Tech University (J.D., \_\_\_\_\_\_\_\_\_ summa cum laude, Order of the Coif, 1996).



Richard A. Nakashima



Heather Carson Perkins

**Heather Carson Perkins** practices in the commercial litigation area with the Denver business litigation practice, focusing on franchise advising and litigation and antitrust, trade secret, and insurance litigation. She is a graduate of the University of Colorado (B.S., *cum laude*, 1993; J.D., *Order of the Coif*, 1998). Heather served as a judicial law clerk to the Honorable Edward W. Nottingham, United States District Court for the District of Colorado.

Lisa R. Pugh is a member of the corporate practice in the Minneapolis office, where she focuses on federal and state tax law. Lisa is a graduate of the University of Minnesota (B.A., *summa cum laude, Phi Beta Kappa*, 1992) and the University of Virginia (M.A., 1993; J.D., 1998, *Order of the Coif*).



Lisa R. Pugh



Adam H. Sher Adam H. Sher is resident in our Boulder office, where he represents a wide variety of national, regional and local clients in connection with U.S. and international commercial real estate and private equity transactions with a focus on acquisitions, development, financing, leasing, dispositions and joint venture arrangements. He is a graduate of Wesleyan University (B.A., 1986) and Fordham University (J.D., cum laude, Order of the Coif, 1996).

Jennifer L. Sullivan practices business litigation in the Boulder office, where she focuses on complex commercial litigation and construction litigation. She is a graduate of Case Western Reserve University (B.A., cum laude, 1996) and Duke University (J.D., 1999). She served as a judicial law clerk to the Honorable W. Royal Furgeson, United States District Court for the Western



District of Texas.

Aaron D. Van Oort Aaron D. Van Oort is a member of the business litigation practice in the Minneapolis office, where he focuses on class action litigation,

consumer fraud and antitrust, and appellate litigation. Aaron is a graduate of the University of Minnesota, Morris (B.A., with high distinction, with honors, 1996) and the University of Chicago (J.D., with high honors, Order of the Coif, 1999). He served as a judicial law clerk to the Honorable Richard A. Posner,

United States Court of Appeals, Seventh Circuit and the Honorable Antonin Scalia, United States Supreme Court.

Melanie Wadsworth practices corporate law in the London office, where she focuses on securities offerings and mergers & acquisitions. Melanie is a



Melanie Wadsworth

Ezekiel (Zeke) J.

Williams

graduate of Aston University, Birmingham (B.Sc., with honours, 1992) and the College of Law, Chester (Common Professional Examination, 1993; Legal Practice Course, with commendation, 1994).

Ezekiel (Zeke) J. Williams practices natural resources, oil and gas, and environmental law in the Denver office. He is a graduate of Montana State University (B.A., 1987) and the University of Denver (J.D., Order of St. Ives, 1994). He served as a judicial law clerk to the Honorable Bobby R. Baldock, United States Court of Appeals, Tenth Circuit. 🖪

#### Faegre & Benson Adds Senior Patent and Litigation Partners



Scott M. Alter

Scott M. Alter has joined the firm's Colorado intellectual property practice bringing nearly 20 years experience developing and implementing IP strategies for companies in the high-tech sector, including software, electronics, Internet, telecommunications, e-commerce, and semiconductor technologies.

Scott received his J.D. from the George Washington University Law School, and a B.S. in computer science and a B.A. in physics from Emory University. Prior to attending law school, Scott was employed by IBM as a LAN systems

developer and computer programmer.



Will Stute has joined the firm's Minneapolis office as a partner in business litigation. His practice will focus on litigation matters, in particular those involving commercial fraud, including securities fraud; shareholder class action, financial institution litigation; and other complex business litigation. He received his J.D., cum laude, from the William Mitchell College of Law in 1997.

Prior to joining Faegre & Benson, Stute practiced at Lindquist & Vennum for eight years, where he chaired the Securities Litigation Group.

Ī

news

# firm news

#### Former U.S. Attorney Joins Faegre & Benson

Former Colorado United States Attorney **William J. Leone** joined the firm as a partner in the Denver office on December 4, 2006. He served in the United States Attorney's Office in Denver for five years as First Assistant and, most recently, as United States Attorney.



William J. Leone

Leone was appointed to serve as United States Attorney by Attorney General Alberto Gonzales and was later named United States Attorney by the judges of the United States District Court. During his tenure, the United States Attorney's Office focused on corporate fraud and gang violence. Bill personally handled the investigation of Qwest Communications and obtained convictions of four former executives, including the chief financial officer. He also sought and obtained the indictment of the former CEO on 42 counts of insider trading. Last year, under Leone's leadership, federal prosecutors brought major cases

against the notorious GKI street gang and Thompson drug trafficking organization.

Leone is a 25-year veteran trial lawyer and complex case civil litigator. Prior to joining the United States Attorney's Office, Leone was a partner in the Silicon Valley based technology law firm Cooley Godward LLP and handled major civil cases, including securities and accounting fraud, large contract disputes, and antitrust and unfair competition matters.

"We are thrilled to have attracted Bill Leone to our firm and know that his diverse experience with 'bet the company' legal problems will help us better serve our clients," said Michael S. McCarthy, a member of Faegre & Benson's Management Committee. "We conducted a national search for someone with Bill's background and experience, only to find that we had the perfect resource in Denver," said Tom Morgan, Chairman of Faegre & Benson's Management Committee.

#### Faegre & Benson Adds 14 New Associates

In addition to all of the new partners, Faegre & Benson has recently added 13 associates to its Colorado offices and one to its Des Moines office.

"Client demand continues to grow in all areas of our firm, but is particularly strong in our Colorado offices," said Michael McCarthy, a Colorado business litigation partner and member of the firm's Management Committee. "We're excited to be able to add such a talented group of new associates to meet the needs of our clients."

#### Denver

www.taegre.com

**Anne Gasperini DeMarco** joined the corporate practice. Anne earned her J.D., with honors, in 2006 from the University of Texas School of Law. She received her B.A., magna cum laude, in 2001 from Colorado College where she majored in English.

**Sarah A. Mastalir** joined the litigation practice. She received her J.D. from the University of Colorado School of Law in 2006. She received her B.A., cum laude, in 2003 from Wake Forest University where she graduated with honors in economics.

**Lyndall S. McLetchie** joined the health care/nonprofit organizations practice. Lyndall received her J.D. from University of Denver College of Law in 2004. She received her B.A., with honors, in 1999 from Colby College where she majored in government.

**Linda M. Michael** joined the health care/nonprofit organizations practice. Linda received her J.D. in 2006 from the University of Denver where she was a member of the Order of St. Ives and Senior Staff Editor for the *Law Review*. In 1998, she received her Professional in Human Resources (PHR) certification. She earned her M.S. from the University of Nebraska at Omaha in 1992 and her B.A., magna cum laude, from Doane College in 2002.

Adam Platt joined the intellectual property practice. Adam received his J.D., summa cum laude, from the University of Kentucky College of Law in 2006 where he was a member of the Order of the Coif. He earned his B.A. in 1999 from Middlebury College where he majored in international studies.

**Sarah Radunsky** joined the health care/nonprofit organizations practice. Sarah received her J.D., cum laude, from Suffolk University Law School in 2006, where she earned a Health and Biomedical Law Concentration Certificate, with distinction. She received her B.S. in 2003 from the University of Colorado where she majored in business administration.

**Kathy Schaeffer** joined the litigation practice. Kathy received her J.D. from the University of Denver College of Law in 2006. She earned her B.A. in biology in 2000 from Cornell University.

**Stephen A. Wichern** joined the construction practice. Stephen received his J.D. from the University of Denver College of Law in 2006. He received his B.S., with honors, in 1997 from Queen's University where he majored in civil engineering.

**Megan Andersen Yahr** joined the real estate practice. Megan received her J.D. from the University of Denver Sturm College of Law in 2006. She received her B.B.A. in 2000 from the University of Texas where she majored in international business.

#### Boulder

**Laura Hutchings** joined the litigation group. Laura received her J.D., magna cum laude, in 2006 from Boston University School of Law. She received her B.A., summa cum laude, in 2002 from the University of Pittsburgh where she majored in English literature and anthropology.

**Rita P. Sanzgiri** joined the intellectual property group. Rita received her J.D. from the University of Colorado School of Law in 2006. She earned her Ph.D. in Genetics in 1998 from Iowa State University. She received her M.S. in biotechnology in 1990 from the University of Poona in Pune, India. Rita earned a B.S. in chemistry from the University of Bombay in Mumbai, India in 1988.

**Peter C. Schaub** joined the real estate group. Peter received his Master of Laws in Environmental and Natural Resources Law and Policy from the University of Denver College of Law in 2006. He received his J.D., summa cum laude, in 2005 from Thomas M. Cooley Law School. Peter earned his B.A. in biology in 1993 from Western State College of Colorado.

**Matt Stamski** joined the corporate group. Matt received his J.D. from the University of Colorado School of Law in 2006. He received his AB, cum laude, in 1996 from Harvard University where he majored in social anthropology.

#### **Des Moines**

**Stuart A. Ruddy** joined the firm's real estate practice in the Des Moines office. He received his J.D. from the Georgetown University Law Center in 2001. He earned his B.A., magna cum laude, in 1994 from Loras College.

#### Faegre & Benson Inaugurates Joe Montano Scholarship Fund



Joe Montano with current University of Denver law students

Faegre & Benson and the Sturm College of Law at the University of Denver have joined together to honor former Faegre & Benson partner Joe Montano through a scholarship for students of underrepresented ethnic backgrounds. In addition to the firm's gift of \$100,000 to establish the Joe Montano Scholarship, Faegre and Benson lawyers also pledged individual contributions exceeding \$30,000. More than 100 students, faculty and administrators, and Faegre & Benson lawyers gathered with Joe at the Sturm College of Law on September 26, 2006 for a ceremony honoring him.

"Joe Montano was the first Hispanic

partner of a large downtown Denver law firm," said Faegre partner John Shively. "In creating this scholarship, Faegre & Benson honors not only Joe's excellent lawyering, but his perseverance in overcoming the social barriers which prevented earlier generations of Hispanic lawyers from reaching partnership. He has been an inspiration to an entire generation of Denver lawyers."

#### Faegre & Benson Ranked #4 in Technology

A national survey of mid-level associates has ranked Faegre & Benson #4 in "technology overall" among the law firms surveyed. The survey results, published in the November 2006 issue of *The American Lawyer* magazine, also ranked Faegre #4 in technology training and #5 in technology support.



#### **Faegre & Benson Sponsors Chinese Association of Iowa**



Faegre & Benson has become a gold-level sponsor of the Chinese Association of Iowa (CAI), a nonprofit organization created to educate and advocate on issues of vital interest to Chinese Americans in the state of Iowa. As part of the sponsorship, lawyers in the Des Moines office work as pro bono legal counsel to the CAI. According to the 2000 U.S. census, there were nearly 2,600 Chinese living in the Des Moines/Ames area, and central Iowa has seen a significant increase in the Chinese population since 1990.

# When "Obvious" is Not Obvious: The Supreme Court Reviews a Key Legal Test for Patentability

#### By Lee M. Pulju



Lee Pulju (lpulju@faegre.com) is an associate in the firm's Minneapolis office and practices in the area of intellectual property law.

The notion that patents will not be granted for "obvious" inventions appears at first glance to be, well, obvious. Determining which inventions meet the legal standard for obviousness, however, is far from simple. The analysis is highly fact-intensive and requires consideration of many factors. Moreover, the test for determining obviousness has recently come under attack in the wake of the U.S. Supreme Court's decision to grant certiorari in KSR v. Teleflex, an appeal that challenges the test for obviousness created by the Court of Appeals for the Federal Circuit. Recent decisions coming out of the Federal Circuit have attempted to defend and clarify the test ahead of the Supreme Court's review. This article will examine the current legal definitions and tests for "obviousness," the challenge posed in KSR v. Teleflex, and the possible implications of the Supreme Court's review.

#### The Supreme Court's Graham Factors

Under 35 U.S.C. § 103, a patent claim is obvious when the differences between the claimed invention and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." When discussing the requirements for obviousness under § 103, the landmark case is *Graham v. John Deere Co.*, 383 U.S. 1 (1966). In the Graham case, the Supreme Court established factors to be considered when making an obviousness determination: (1) the scope and content of the prior art; (2) the level of skill of a person of ordinary skill in the art; (3) the differences between the claimed invention and the teachings of the prior art; and (4) the extent of any objective indicia of non-obviousness. 383 U.S. at 17-18.

#### The Federal Circuit's "TSM" Test

The Federal Circuit has further fleshed out the requirements for obviousness by establishing the so-called Teaching, Suggestion, Motivation ("TSM") test. When a claim of obviousness is made based on multiple pieces of prior art, the TSM test (as the name indicates) requires some teaching, suggestion, or motivation that would have led a person of ordinary skill in the art to combine the prior art references in the matter claimed in the patent. According to the Federal Circuit, the TSM test is intended to prevent "statutorily proscribed hindsight reasoning when determining the obviousness of an invention." Alza Corp. v. Mylan Labs., Inc., 464 F.3d 1286, 1290 (Fed. Cir. 2006). In other words, some inventions-like putting together a puzzle—only appear obvious with the benefit of hindsight. The TSM test is intended to combat this type of retrospective analysis by prohibiting one from picking and choosing, using the advantage of hindsight, elements of the patented invention from various sources of prior art. Instead, the TSM test states that there must be some teaching, suggestion, or motivation to combine the various pieces of prior art. Furthermore, the general understanding for some time has been that the teaching, suggestion, or motivation to combine must be *explicitly* contained in the prior art.

#### KSR v. Teleflex—The Supreme Court Reviews the TSM Test

The Federal Circuit's TSM test has now come under the Supreme Court's scrutiny in the KSR v. Teleflex case. This case involves a patent relating to an adjustable pedal assembly for use with automobiles having electronic throttle control. The district court granted summary judgment, holding that both adjustable gas pedals and electronic sensors were well known in the art, and that it would have been obvious to combine them. The Federal Circuit, in an unpublished opinion, vacated and remanded the district court's judgment and held that the district court failed to correctly apply the TSM test. Although the district court did acknowledge the TSM test in its order, the Federal Circuit found the analysis to be incomplete because the district court did not make specific findings as to whether there was a teaching, suggestion, or motivation to combine the prior art in the particular manner claimed by the patent.

The Supreme Court granted certiorari in June 2006 to consider the Federal Circuit's TSM test for the first time ever. The patent community has been extremely interested in the case, and numerous amicus curie briefs have been filed, which both support and attack the TSM test. Notable supporters of the TSM test include the major patent bar associations, General Electric, 3M, and Proctor & Gamble. Notable detractors include Intel, Cisco, Microsoft, and many academics. Even more noteworthy, however, is the degree to which the Federal Circuit itself appears to be interested in the Supreme Court's review of its TSM test.

In several recent opinions, the Federal Circuit has defended its TSM test in advance of the Supreme Court's review and refuted the common understanding that an explicit teaching, suggestion, or motivation to combine must be found within the prior art. See In re Kahn, 441 F.3d 977 (Fed. Cir. 2006); Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299 (Fed. Cir. 2006); Alza Corp. v. Mylan Labs., Inc., 464 F.3d 1286 (Fed. Cir. 2006); Dystar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356 (Fed. Cir. 2006). The Federal Circuit has even gone so far as to specifically address its critics, stating that "[i]n contrast to the characterization of some commentators, the suggestion test is not a rigid categorical rule. ... '[T]here is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention." Dystar, 464 F.3d at 1361 (quoting Motorola, Inc. v. Interdigital Tech. Corp., 121 F.3d 1461, 1472 (Fed. Cir. 1997)).

In the Dystar case, the jury found that the patent at issue was infringed and not invalid as anticipated or obvious. On appeal, the Federal Circuit reversed, holding the patent to be obvious. The Federal Circuit declared that the patentee (and certain commentators) had misunderstood its TSM test in arguing that it required the cited references themselves to explicitly contain a teaching, suggestion, or motivation to combine. Instead, the Federal Circuit stated that "evidence of a motivation to combine need not be found in the prior art references themselves, but rather may be found in the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. . . When not from the prior art references, the 'evidence' of motive will likely consist of an explanation of the well-known principle or problemPatent practitioners everywhere will be watching to see how the Supreme Court treats the Federal Circuit's TSM test. Any change in the wellestablished test would have a major impact on both patent prosecution and litigation—opening the door to scores of challenges to existing patents.

solving strategy to be applied." *Dystar*, 464 F.3d at 1366 (quotations omitted). The Federal Circuit further appeared to vent its frustration, stating:

It is difficult to see how our suggestion test could be seen as rigid and categorical given the myriad cases over several decades in which panels of this court have applied the suggestion test flexibly. Obviousness is a complicated subject requiring sophisticated analysis, and no single case lays out all facets of the legal test. Dystar's argument and the above-cited commentary highlight the danger inherent in focusing on isolated dicta rather than gleaning the law of a particular area from careful reading of the full text of a group of related precedents for all they say that is dispositive and for what they hold. When parties like Dystar do not engage in such careful, candid and complete legal analysis, much confusion about the law arises and, through time, can be compounded.

Id. at 1367.

Oral argument before the Supreme Court in the KSR v. Teleflex case was held on November 28, 2006. During the argument, the justices appeared to be critical of the TSM test as the exclusive means for determining obviousness. Several justices appeared to find the Federal Circuit's TSM test to be particularly confusing. Indeed, Justice Brever complained that "I just don't understand what is meant by the term 'motivation,'" Justice Scalia referred to the test as "gobbledygook" and Chief Justice Roberts contended that it is "worse than meaningless." Some justices also appeared to be critical of the Federal Circuit's recent attempts to clarify its TSM test. Justice Scalia, for example, contended that "in the last year or so, after we granted cert in this case after these decades of thinking about [the TSM test], [the Federal Circuit] suddenly decides to polish it up."

Patent practitioners everywhere will be watching to see how the Supreme Court treats the Federal Circuit's TSM test. Any change in the well-established test would have a major impact on both patent prosecution and litigation—opening the door to scores of challenges to existing patents. The Supreme Court's opinion is expected sometime before the end of the Court's term in June 2007.

# **Global Employment Law Update**

#### By Greg Campbell



Greg Campbell (gcampbell@faegre.com) is a partner in the firm's London office practicing in the area of labor and employment law.

#### UNITED KINGDOM

#### Age Discrimination Update



On October 1, 2006, the

Employment Equality (Age) Regulations 2006 (the "Regulations"), came into effect. The Regulations apply to employers, partnerships, providers of vocational trainers and trade associations (but not providers of goods and services). Unlike the model in many US states, all discrimination based on age will be unlawful, not merely discrimination against older workers. The application of the Regulations is therefore expected to bring an equal number of claims from younger workers alleging that they have been retired prematurely.

The Regulations provide that both direct and indirect age discrimination can be lawful (unusual for discrimination legislation), provided the employer can show that the discrimination is objectively justifiable-i.e., it is targeted at a legitimate business need and does no more than is necessary to satisfy that need. In the draft regulations published earlier in the year, the UK government gave some guidance as to when discrimination might be justified. However, the guidance to the final Regulations contains no examples of justifiable discrimination, so this is likely to be an area of intense litigation over the coming years, as the courts are left to crystallise the issues.

On the two largest elements of age-related discrimination—benefits related to length of service and retirement—the government has introduced compromises. Forcible retirement is the most obvious example of

age discrimination, and the Regulations confirm that forced retirement at age 65 remains completely lawful. Instead of outlawing forced retirement, the government has inserted a right for employees to request to work beyond age 65. This is, however, a meaningless right. Employers are under an obligation to facilitate the making of the request and to consider the request. But provided certain



procedural formalities are followed, an employee has no right to pursue an employer for refusing the request.

The Regulations expressly permit different levels of benefits based on length of service, despite the fact that such a process indirectly discriminates against younger workers. The Regulations provide that, where the increased benefit relates to more than five years' service, the employer must show that it "reasonably appears" that the provision of the benefit satisfies a business need. This is likely to be a fertile area for litigation—most particularly in connection with schemes that provide enhanced benefits upon retirement, which could be argued to operate to the detriment of younger employees.

#### UNITED STATES

#### Supervisor Status



A person who is a supervisor as defined in the National Labor

Relations Act (NLRA) is not entitled to union representation or to engage in activities in support of a union. Furthermore, an employer has the right to demand complete support from supervisors in the employer's relationships or conflicts with unions.

Section 2(11) of the NLRA defines a "supervisor" as:

any individual having authority, in the interest of the employer, to hire, transfer, suspend, lay off, recall, promote, discharge, assign, reward, or discipline other employees, or responsibly to direct them, or to adjust their grievances, or effectively to recommend such action, if in connection with the foregoing the exercise of such authority is not of a merely routine or clerical nature, but requires the use of independent judgment.

In *Oakwood Healthcare*, a recent decision by the National Labor Relations Board (NLRB), new guidelines are provided for determining who falls into the category of supervisor, particularly regarding the meaning of the terms "assign," "responsibly to direct," and "independent judgment":

- "assign" means "designating an employee to a place (such as a location, department, or wing), appointing an employee to a time (such as a shift or overtime period), or giving significant overall duties, i.e., tasks, to an employee."
- "responsibly to direct" means that an individual not only directs the work of employees, but is also accountable for the performance and work product of the employees whose work is directed and the individual has the authority to take corrective action with regard to such employees, if necessary.
- "independent judgment," requires that the individual's judgment is not dictated or controlled by detailed instructions, whether set forth in company policies or rules, the instructions of a higher authority, or in the provisions of a collective bargaining agreement.

#### **Retaliatory Action**

Due to a recent U.S. Supreme Court decision, Burlington Northern & Santa Fe Railway Company v. White, employers must exercise heightened vigilance to ensure that an employee who has lodged a discrimination complaint, either internally or with the Equal Employment Opportunity Commission (EEOC), or who has supported or participated in the investigation of such a complaint, does not suffer adverse consequences at the hands of managers or supervisors because of the complaint, or the employee's activity related to the complaint.

The Supreme Court held that any "materially adverse" action by the employer that "might have dissuaded a reasonable worker" from reporting discrimination may constitute prohibited retaliation under Title VII. Prior to this Supreme Court decision, most employees who had successfully pursued retaliation cases had actually been terminated from their employment. The decision in *Burlington Northern* makes it clear that a court may find there has been unlawful retaliation in connection with lesser, but still adverse, employment actions, such as an unwanted shift change, negative performance evaluation, or undesired change in job duties. The Court emphasized that whether retaliation has occurred must be decided on a case by case basis.

#### GERMANY

#### New Anti-Discrimination Regime



#### On 18 August 2006

Germany (finally) implemented the EU Race and Ethnic Origin Directive 2000 and the Framework Employment Equality Directive 2000. What seemed like a perpetual discussion finally resulted in the General Act of Equal Treatment (the "Equal Treatment Act"), which replaced the few and scattered provisions on antidiscrimination in other German laws.

The Equal Treatment Act outlaws discrimination on the grounds of race or ethnicity, gender, religion or belief, disability, age and sexual orientation. Legislation prohibiting discrimination on the grounds of gender and disability has been in place for several years, but, for the first time, a definition of sexual harassment has been introduced and there is now a new category of age discrimination.

The most heated debate in Germany has been about the impact of the new legislation on dismissals. German law already provides extensive protection against unfair dismissal. In contrast, discrimination has not been a major issue in court so far—perhaps because the additional layer of protection did not seem necessary. Employers have been concerned that the new set of rules on anti-discrimination could lead to additional protection against termination, which would render the termination process even more cumbersome. Therefore, the Equal Treatment Act stipulates that terminations are only subject to the relevant provisions of the Act on Protection against Unfair Dismissal. There is some controversy among legal commentators whether this means that the anti-discrimination laws do not apply to dismissals and, if so, whether this satisfies the minimum standard contained in the directives. If the German law is considered defective, it will be open to challenge before the European Court of Justice.

The provisions of the Equal Treatment Act prohibiting age discrimination have been partially mitigated by a number of exceptions and, again, it remains to be seen whether these exceptions are compliant with the directives. Employers should be careful in making use of any exceptions as there is a risk that one or more of the exceptions will be invalidated by the European Court of Justice. This recently occurred in connection with German provisions on fixed-term contracts for elderly employees.

A further point to be considered by employers is liability for damages caused by discrimination either by the employer itself or any of its staff. The Equal Treatment Act requires the employer to prevent discrimination; this obligation is deemed to be fulfilled by having staff properly trained on discrimination issues. Prudent employers will reduce their potential liability for discrimination by providing anti-discrimination trainings for their staff members. At a minimum, training should become standard for HR staff and executives engaged in the hiring and firing of employees in Germany. Moreover, employers can take the following steps to minimise liability under the new German anti-discrimination laws:

- audit existing individual and collective agreements, collective grants and inhouse practices, job advertisements, etc.
- keep records of job applications and the decision-making process (to the extent permitted by data protection laws)

On October 31, 2006, the Chinese Congress approved the Occupational Safety and Health Convention 1981 ("Convention"). According to the Convention, China should submit an annual report of industrial injuries and occupational diseases to the International Labor Organization and meet other international requirements of labor protection under the Convention.

- make the text of the Equal Treatment Act available to employees
- establish a grievance committee

#### CHINA

#### Labor Union: Wal-Mart Finally Gives In



#### Since its entry into

the China market in 1996, Wal-Mart has been the most high-profile foreign-invested enterprise (FIE) which has refused to recognise labor unions under the PRC Labor Union Law 2001. Wal-Mart is not alone. According to government statistics, 74% of FIEs have not recognised unions for various reasons. The most common excuses for non-compliance are: (1) the union should be recognised only if employees have made a request and no request has been raised; and (2) the enterprise will not recognise a union unless larger companies do first, and the government should not impose different policies on enterprises of different sizes.

The PRC government and the All China Federation of Trade Unions (ACFTU), which administers unions under the Chinese Communist Party, have made great efforts to pave the way for union recognition in FIEs since 2005, and Wal-Mart has been the top priority. After one year of tough negotiations with the ACFTU, Wal-Mart finally gave in and recognised its first union in July 2006. Agreement was reached with the ACFTU in August that: (1) union relations in Wal-Mart will be supervised by upper level unions and the union in each store will support the lawful administration and management by Wal-Mart; (2) leaders of unions will be elected through secret ballots by employees and the result will be approved by supervising unions; heads or deputy heads of the store and heads of human resources, including their relatives, may not be candidates in the election; and (3) Wal-Mart will assume all responsibilities and obligations under the law and support the recognition and establishment of the union. It is likely that these three principles may become the basic terms and conditions for all labor unions to be established in FIEs in China.

The next targets of the ACFTU are reported to be Foxconn, Kodak, and Dell. The ACFTU has declared that 60% of all FIEs in China should set up labor unions during 2006 under the guidance of the ACFTU.

www.faegre.com

continued on next page



#### Occupational Safety and Health Convention 1981 Approved

On October 31, 2006, the Chinese Congress approved the Occupational Safety and Health Convention 1981 ("Convention"). According to the Convention, China should submit an annual report of industrial injuries and occupational diseases to the International Labor Organization and meet other international requirements of labor protection under the Convention. The Convention will not be applicable to Hong Kong at present, however.

#### Labor Contract Law Delayed

In March 2006, a draft of the Labor Contract Law was published and comments solicited. A revised draft of the law, adopted changes to penalties, and other provisions was produced in July. The revised draft, however, did not pass the second round of deliberation by the Standing Committee of the National People's Congress in October. It remains controversial and it is difficult to say when it will be approved.

24 TRENDS® January 2007

### Last Word: Trusts and Estates

The Pension Protection Act of 2006 (PPA) added new rules effective January 1, 2007, allowing part or all of the benefits payable from a qualified retirement plan, 403(b) program, or governmental 457(b) plan to a non-spouse beneficiary to be transferred in a direct rollover to an "inherited IRA."

The non-spouse beneficiary rollover opportunity is not the same as rollovers by participants, spouse beneficiaries or former spouses who are alternate payees. Unlike a spouse beneficiary, the non-spouse beneficiary will not have the option of delaying distributions from the IRA until he or she reaches age 70 1/2. Instead, the inherited IRA established for a non-spouse beneficiary must make distributions according to the required minimum distribution rules that apply to a non-spouse beneficiary under current law.

Another significant difference is that a non-spouse beneficiary rollover must be transferred in a "direct rollover" from the trustee or custodian of the plan to the trustee or custodian of the IRA. If the non-spouse beneficiary receives a distribution from the plan, he or she cannot then make a rollover to an IRA.

This new rule will help non-spouse beneficiaries under plans that only allow such persons to receive lump sum distributions. The inherited IRA could enable a beneficiary under a lump-sum-only plan to defer taxes by spreading the distributions out either over the five years following the participant's death or over the beneficiary's life or life expectancy. Life installments from the inherited IRA would have to commence by the end of the year following the participant's death.

Given the complexities of the new law and the number of open issues with respect to non-spouse beneficiary rollovers, we recommend that you contact an attorney in our Trusts and Estates Group to discuss your particular situation.



#### USA

#### **MINNEAPOLIS**

2200 Wells Fargo Center 90 South Seventh Street Minneapolis, Minnesota 55402-3901 Phone: 612-766-7000 Fax: 612-766-1600

#### DENVER

3200 Wells Fargo Center 1700 Lincoln Street Denver, Colorado 80203-4532 Phone: 303-607-3500 Fax: 303-607-3600

#### BOULDER

1900 Fifteenth Street Boulder, Colorado 80302-5414 Phone: 303-447-7700 Fax: 303-447-7800

#### DES MOINES

Suite 3100 801 Grand Avenue Des Moines, Iowa 50309-8002 Phone: 515-248-9000 Fax: 515-248-9010

For the latest legal news or copies of any article in this newsletter, visit www.faegre.com

CONTACTING YOUR LAWYERS You may now customize www.faegre.com for easy access to the lawyers with whom you work.

#### INTERNATIONAL Dial 011 before number

#### LONDON

7 Pilgrim Street London, EC4V 6LB England Phone: 44-20-7450-4500 Fax: 44-20-7450-4545

#### FRANKFURT

Main Tower Neue Mainzer Strasse 52-58 Frankfurt am Main, 60311 Germany Phone: 49-69-631-561-0 Fax: 49-69-631-561-11

#### SHANGHAI

Shanghai Centre, Suite 425 1376 Nanjing Road West Shanghai, 200040 China Phone: 86-21-6279-8988 Fax: 86-21-6279-8968



2200 WELLS FARGO CENTER 90 SOUTH SEVENTH STREET MINNEAPOLIS MN 55402-3901

PRSRT STD U.S. Postage PAID Minneapolis, MN Permit No. 27100

# FDA Under Fire: Summaries of the Recent Criticisims See Page 4.