THOMPSON HINE

Business Law Update

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General Corporate

Enhancing Enterprise Value: Protecting Your Intellectual Property

By Donald H. Messinger & Steve Elleman

Occasionally businesses overlook relatively simple means of adding value – and revenue – to their enterprises. Also, it sometimes helps to have an understanding of the interplay, and differences, among patent protection, trademark (or service mark) protection, business name protection and copyright protection. The following are actual experiences that prompted this article.

- **Utilizing Manufacturing Waste Materials** – One client developed a methodology to recover the waste material from its manufacturing operations, planning to sell it in a new line of business. The client was able to obtain patent protection for its propriety methods. The marketing of its new product was enhanced by the selection, and federal registration, of a trademark under which the new product was sold. The new line of business was instantly profitable. Previously, the waste material had been dumped into an onsite landfill.

- **Enhancing Software Sales** – Another client developed proprietary software that it utilized in its own operations. Internally, the client had a shorthand way of referencing its software (its "eureka" moment). A company employee then saw the same "shorthand term" used by another company to market an unrelated consumer product, which resulted in a second "eureka" moment. The shorthand term was so clever that our client decided to register the shorthand term as a trademark for its software, thereby enhancing its ability to market the software to others.

- **Creating a Patent Portfolio** – Over the years, a privately-owned manufacturer had developed several proprietary products and processes. Because it sold its products to a stable customer base, the owners never were willing to seek patent protection for the company's intellectual property. Then, the owners decided to sell

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For more details on any of the topics covered in this *Business Law Update*, please contact the authors via the links at the end of each article or David R. Valz, editor-in-chief. For information on our Corporate Transactions & Securities practice, please contact Frank D. Chaiken, practice group leader.

the business. The intellectual property was quickly evaluated, patent applications were filed for eligible inventions, and the resultant "patent portfolio" became a major asset of the company, thereby enabling the owners to obtain full value for the business.

- **Protecting the Company Name** – A client opened a new restaurant under a "new, unique concept." Before doing so, we recommended a national clearance, or "right to use" search, and, based on the results, the client selected a trademark for the restaurant that was different than the client's corporate name. The client then obtained federal registration of its new trademark. Several things happened. The restaurant was spectacularly successful and expansion opportunities (including franchising) followed. Because of trademark registrations, the client was able to expand geographically relatively quickly with no "conflicting name" issues.

- **Capitalizing on Creativity of Volunteers** – A small nonprofit decided to gather family recipes from its corps of volunteers and to publish the recipes in a book distributed to its donors. Fortunately, the nonprofit obtained copyright protection for the book. Subsequently, a major for-profit company copied the recipes word-for-word and published its own book of recipes for sale to the general public (perhaps thinking the nonprofit wouldn't care or notice). We brought the copyright infringement to the attention of the for-profit company, which resulted in a very nice contribution to the nonprofit and its charitable mission.

In each of these instances, the client did not initially realize the ways in which intellectual property assets could be used to create value and enhance revenue. Moreover, the clients were unsure of what type(s) of intellectual property protections were available and what action steps would be needed. Consequently, we have prepared this short introduction to "IP 101."

Patent Protection

Patents in the United States are issued by the U.S. Patent and Trademark Office (PTO) for inventions that, among other requirements, are "novel" and "non-obvious." Commonly, patent protection is available for new and useful machines, processes, methods of production and compositions of matter. Under federal law amendments effective in early 2013, the United States now has a "first inventor to file" system, so timely filing of patent applications is increasingly vital.

Generally, the patent protection process involves several steps, including an (optional) search of the public record to determine whether the invention is unique (and to distinguish any "prior art"), the drafting of the patent application (including the so-called "patent claims"), filing the application with the PTO, waiting for the application to be reviewed by the PTO examiner and responding to any issues raised by the examiner. Once approved by the examiner and published by the PTO, and assuming no successful challenges by third parties, a patent will be issued by the PTO. The issuance of the patent will typically give the owner 20 years of protection from the filing date of the application, during which time the owner will have the right to exclude others from practicing the invention (absent a license) and to seek damages and/or injunctions from any unauthorized users of the invention.

This protection will extend throughout the United States and may be (and often is) sought to be extended internationally to one degree or another based on various treaties and conventions.

Trademark and Service Mark Protection

A trademark is a word, name, symbol or device that is used to indicate the source of a particular product or item; a service mark carries the same meaning for the source of a service. Both types of marks may be registered with the PTO and/or with individual states.

Trademark and service mark registration follows essentially the same process as patent protection, but the legal effect of federal trademark/service mark protection is somewhat different. For example, duration of the registration is potentially infinite so long as the mark, in the form registered, does not materially change, maintenance and renewal fees are paid, and the mark is used in commerce. Furthermore, enhanced damages, as well as injunctive relief, may be available from an infringing party (namely, one who uses a mark that is "likely to cause confusion" in the relevant market as to the source of the goods or services).

As in the case of patents, one may seek to extend trademark and service mark protection internationally in many cases.

Business Name Protection

Businesses conduct business under a name that denotes that business. Normally, the business name is the name of the corporation, partnership, LLC or individual. In Ohio and in most states, the name of a business entity must be distinguishable from the name of any other business registered with the state. Sometimes, a business will do business under an assumed name. For example, the Subway restaurants are actually operated or licensed by a corporation named "Doctor's Associates Inc." Thus, Doctor's Associates Inc. is registered with both its corporate name and with the Subway trade name.

Business name protection, commonly referred to as "trade name protection," is secured on a state-by-state basis. Consequently, businesses often will register names or qualify to do business in adjacent or different states before they are legally required to do so merely to protect their business/trade names. Of course, as in the case of trademarks, it is prudent to do a name search before selecting a business/trade name in order to ascertain any potential conflicts. The first business to register in a state is usually the first to have rights to use the particular name. For this reason, a business will often examine whether its trade name is also used in a manner that connotes the source of its products or services and, thus, is entitled to federal registration with the PTO, as described above. The only common right to challenge a prior-in-time registrant of a business/trade name in a particular state is to demonstrate that the prior registrant is guilty of "unfair competition," namely trying to usurp the good will of the challenging business.

Copyright Protection

A copyright protects "original works of authorship" that are "fixed" in a tangible medium of expression (e.g., text written on a page or stored in a computer, recorded sounds, etc.). Copyright does not protect ideas or facts per se, but can protect the manner of expression of those ideas or facts.

Unlike the other intellectual property protections described above, there is no requirement of a particular registration to obtain copyright protection. Rather, copyright exists automatically when the work is created and "fixed." Use of the traditional copyright notice (the word "copyright" or the symbol "©," the year and the name of the owner) is often helpful in giving others notice of the copyright and thereby discouraging infringement. Furthermore, registration with the federal Copyright Office of the Library of Congress is required before a lawsuit can be filed in an enforcement action seeking damages and/or injunctive relief from an infringer. Such registration can also enable the owner to collect enhanced monetary damages. Generally, a copyright will last for 70 years after the author's death (or, in the case of works made for hire, the longer of 120 years after creation or 95 years from publication).

Conclusion

Utilization of one or more of the foregoing means of protecting intellectual property can be relatively inexpensive, particularly in view of the value of the rights being protected. Keeping these opportunities in the forefront of business activities can result in tangible value to any commercial enterprise.

With any questions, please contact Don Messinger or Steve Elleman.

Ohio Changes Duty Requirements for Limited Liability Companies

By Marcie Hunnicutt & David A. Neuhardt

Until recently, Ohio law, as modified in 2012, imposed on each member of a limited liability company (LLC) a duty of care and a duty of loyalty. The duty of loyalty comprised three obligations: (1) the duty to account to the LLC any property, profit or benefit derived by the member, including from the appropriation of an LLC opportunity, (2) the duty to refrain from dealing with the LLC as or on behalf of a party having an interest adverse to the LLC, and (3) the duty to refrain from competing with the LLC in the conduct of the LLC's business. The duty of care imposed an obligation to refrain from engaging in grossly negligent or reckless conduct, intentional misconduct or a knowing violation of law. While a member would not violate a duty or obligation to the LLC "merely because the member's conduct furthers the member's own interest," both duties included an obligation to standards of good faith and fair dealing. While standards for complying with those duties could be set forth in the LLC's operating agreement, the law did not permit the duties to be waived or eliminated.

Effective July 6, 2016, Ohio LLC law was changed to allow greater flexibility to the members of an LLC when defining the duties of the LLC's members, managers and officers. Specifically, the General Assembly stated an intent to give maximum effect to the principle of contract and to the enforceability of operating agreements. While Ohio law continues to require the members of an LLC to adhere to both the duty of care and the duty of loyalty, it imposes on its officers, if any are elected, fiduciary duties. The law now also provides that a written agreement, including an LLC operating agreement, that modifies, waives or eliminates the duty of loyalty, the duty of care, or both, for members, managers and/or officers, will be recognized and given effect. As a result, any of the "default" duties in the Ohio LLC law pertaining to the rights and obligations of the members, managers and officers of a limited liability company now may be modified.

In addition, the amendments also changed the statutory duty of loyalty of the members. As amended, the duty to refrain from competing with the LLC was removed from Ohio law. This change addressed the concerns of parties who may wish to transact business as an Ohio LLC but have no intent to restrict competition amongst the LLC members.

Next, the law was amended to expressly provide that no officers are required for an LLC, but added default fiduciary duties in the event that officers are elected and the officers' duties are not addressed in its operating agreement. The statutory duties require, at a minimum, that an officer must perform his or her duties in good faith and in a way that the officer reasonably believes to be in or not opposed to the best interests of the company, using the care of an ordinarily prudent person under similar circumstances. As noted above, these duties may be eliminated, waived or modified in the LLC's operating agreement.

Last, the law now expressly states that all members, managers and officers must act in a manner that fully discloses material facts and provides a fair opportunity for the LLC or its disinterested members to approve any act which would be adverse to the LLC. This requirement is consistent with the duties imposed under Ohio partnership and corporation law and may also be modified by the operating agreement.

Thus, when there is no operating agreement or it is silent as to the duties of the members, managers or officers (if any), the current statutory duties will apply. Therefore, it is particularly important when drafting the operating agreement or any other written agreement pertaining to rights and duties of members, managers or officers that the agreement address whether and to what extent these default duties should apply.

With the changes to the law governing LLCs, freedom of contract reigns supreme in Ohio, at least with respect to the governance of LLCs. This new-found flexibility should eliminate concerns previously exposed regarding the use of LLCs organized under Ohio.

With any questions, please contact Marcie Hunnicutt or Dave Neuhardt.

Mergers & Acquisitions

Tips for a Successful Working Capital Adjustment

By Tony Kuhel & Jim Brown

While most purchase agreement provisions will not be read after the closing of an M&A transaction, there is one provision that is sure to be revisited: the working capital adjustment. The purpose of a working capital adjustment is to ensure that the target company has an agreed upon level of working capital at closing and to discourage the sellers from manipulating working capital prior to closing. Here are a few tips that will help avoid ambiguity, and reduce the likelihood of a dispute, when it comes time to conduct the working capital adjustment in your next transaction.

Accounting Principles

The first step toward creating an unambiguous working capital adjustment mechanism is to clearly define what constitutes working capital. All too often, a purchase agreement will simply define working capital as “current assets” minus “current liabilities” and refer to generally accepted accounting principles (GAAP) to define these terms. Very few businesses, however, actually think of their working capital in such simple terms. In addition, GAAP often presents options that can result in differences in how working capital is calculated. A working capital provision should establish an agreed upon set of accounting principles, included as a schedule or exhibit to the purchase agreement and created with input from the parties’ accountants, that clearly defines how the various components of working

capital will be calculated. This schedule or exhibit can even include a sample working capital calculation (used for illustrative purposes only) based on the target’s most recent interim financial statements (or a closing balance sheet, if available). Lastly, for stock transactions in particular, as many are consummated on a debt-free/cash-free basis, the parties should consider how they wish to define and treat cash in defining working capital.

Pre-Closing Estimate

In a two-step transaction (i.e., when the signing and closing do not occur simultaneously), we often recommend that the parties prepare an estimate of working capital (usually a few days before closing) and make an adjustment to the purchase price at closing based on any differences between the working capital estimate and the previously agreed to working capital target. The standard post-closing adjustment mechanism then becomes a way to true-up the purchase price adjustment that occurred at closing. While this construct adds some additional legwork before closing, a pre-closing estimate reduces the likelihood of a substantial post-closing purchase price adjustment (especially when there is an extended period of time between signing and closing) and also serves as an ideal sample working capital calculation for purposes of the post-closing true-up.

Dispute Resolution

The buyer and the sellers typically agree to refer any working capital adjustment disputes that they are not able to resolve to an arbitrator (usually an accounting firm) for final resolution. While the parties may agree to defer the selection of the arbitrator until the time that a dispute actually arises (at which point the parties may be in a contentious mood), we recommend selecting the arbitrator in advance (when the parties are in the mindset to agree). The purchase agreement should also clearly outline the procedures for the arbitration (e.g., presentation of positions, timing, allocation of costs and expenses, etc.). Most notably, the parties can stipulate whether the arbitrator (1) may make an independent calculation of the disputed elements of working capital, (2) must calculate each of the disputed items within the range presented by the buyer and the sellers, or (3) must select the calculation of working capital submitted by the buyer or the sellers in its entirety without any combination of the positions taken by the parties on the disputed items (referred to as baseball arbitration). While there are pros and cons to each of these options, the conventional wisdom is that baseball arbitration incentivizes the parties to take reasonable positions, since an unreasonable position is more likely to cause the arbitrator to take the side of the other party. Baseball arbitration is also arguably (and ironically) more likely to cause the parties to settle their dispute (rather than proceed to arbitration) since each side runs the risk of losing the entire dispute with no mechanism for the arbitrator to split the difference on the disputed items.

Working Capital Escrow

In the sale of a typical private company, the sellers may remain key members of the target's management team after closing or they may sail into the sunset after a successful exit. Either case creates collection risk for the buyer if there is a downward working capital adjustment. Creating a separate working capital escrow at closing is a way to provide security for the buyer. While the seller would like to maximize the amount of cash received at closing, a separate escrow may actually provide comfort to the sellers in a situation where there is a disparate group of sellers and they feel that there is collection risk among the seller group if there is a downward adjustment. In this way, a working capital escrow can relieve collection risk for the buyer and the sellers in connection with a downward working capital adjustment.

A well-drafted working capital provision will help ensure that the post-closing working capital adjustment process does not evolve into anything more than the routine matter you intended at the outset of the transaction.

If you have any questions, please contact Tony Kuhel or Jim Brown.

Thompson Hine Earns First-Tier Rankings in *Chambers USA*

Thompson Hine LLP has been recognized for the 14th year in a row as a leading law firm in *Chambers USA: America's Leading Lawyers for Business*, which ranks lawyers according to technical legal ability, professional conduct, customer service, commercial awareness, diligence and commitment, based on interviews with clients and peers.

In the 2016 edition, Thompson Hine is named a top firm in 12 practice areas, four of which are ranked nationally:

- Banking & Finance
- Bankruptcy/Restructuring
- Construction*
- Corporate/M&A
- Employee Benefits & Executive Compensation
- Intellectual Property
- Litigation: General Commercial
- Natural Resources & Environment
- Real Estate
- Transportation: Aviation (Regulatory)*
- Transportation: Rail (for Shippers)*
- Transportation: Road (Carriage/Commercial)*

*National ranking

Employee Benefits

Is Your Company's Group Health Plan Required to Cover Gender Transition Services Next Year?

By Peggy Baron

The Department of Health and Human Services issued final regulations under Section 1557, the nondiscrimination provision of the Affordable Care Act (ACA), on May 13, 2016. The final regulations prohibit certain health plans and policies from imposing a categorical coverage exclusion or limitation on health services related to gender transition.

The final HHS rules apply to health insurance policies purchased through an ACA Marketplace, as well as to non-Marketplace policies issued by Marketplace insurers. In other words, if an insurance company offers policies for sale through an ACA Marketplace, all health insurance policies issued by that insurance company must comply with the rules.

In addition, the rules apply to health coverage offered by certain employers. If an employer purchases a group insurance policy to pay benefits under its health plan, and if the insurance company providing the policy is subject to the final HHS rules, then the policy must comply with the rules.

Otherwise, an employer's health plan would be subject to the rules only if (i) the employer operates a health program or activity, and (ii) any part of that health program or activity receives federal financial assistance from HHS.

Obvious examples of employers that operate a health program or activity include hospitals, health clinics, physicians, skilled nursing facilities, hospices, organ procurement centers and home health agencies. However, a group health plan is also considered a health program or activity. Therefore, if an employer sponsors a health plan for its employees, and if that health plan receives federal financial assistance from HHS, the employer's health plan must comply with the rules.

What Is Federal Financial Assistance?

Federal financial assistance generally includes any grant, loan, credit, subsidy, contract (other than a procurement contract but including a contract of insurance), or other arrangement by which HHS makes available funds, property or services of federal personnel. For example, the Medicare Part D retiree drug subsidy is federal financial assistance. An employer that receives the Medicare Part D retiree drug subsidy in connection with its health plan would be required to comply with the final HHS rules.

Future guidance may apply the nondiscrimination requirements to entities that receive financial assistance from other governmental entities. For now, however, the rules apply only when financial assistance is provided by HHS.

What Do the Final HHS Rules Require?

The final HHS rules require covered entities to take a number of steps to ensure that they are not discriminating against individuals on the basis of race, color, national origin, sex, age or disability. This article focuses on just one of those requirements – the elimination of any categorical exclusions or limitations on coverage of all health services relating to gender transition. For example, a covered plan or policy could not place an annual dollar limit on the gender transition services covered under the plan.

HHS has clarified that health plans and policies are not required to cover all types of gender transition services in all cases. For example, a health plan could deny coverage for certain transition services that were not medically necessary for an individual. The plan would need to ensure, however, that the medical necessity criteria were being applied in a nondiscriminatory manner.

When Must Covered Entities Make Plan Changes?

If a covered health plan or policy currently imposes a categorical coverage exclusion or limitation on health services related to gender transition, changes will need to be made to comply with the final HHS rules by the first day of the plan or policy year that begins on or after January 1, 2017.

Other Potentially Applicable Factors

The rules under Section 1557 are in addition to similar rules that apply to federal contractors under guidance recently issued by the Office of Federal Contract Compliance Programs. Further, the Equal Employment Opportunity Commission has made it clear that it interprets existing federal nondiscrimination laws to prohibit discrimination on the basis of gender identity, change of sex and/or transgender status. Even if your company is not subject to the 1557 rules, it should proceed with caution in maintaining a group health plan that imposes a categorical coverage exclusion or limitation on health services related to gender transition, or in maintaining any other plan designs that might be viewed as discriminating on the basis of gender identity.

For more information, please contact Peggy Baron.

WHAT THE MARKET SAYS ABOUT THOMPSON HINE

Thompson Hine Recognized by Corporate Counsel as Innovation Leader for Fourth Year

Thompson Hine LLP has again been honored in every category for game-changing innovation in *The BTI Brand Elite: Client Perceptions of the Best-Branded Law Firms.* The firm was ranked among the top seven law firms nationwide in the category "Innovation: Client Service Strategists" – those making changes other firms are not to improve the client experience. In addition, Thompson Hine was named one of the leading firms nationwide in the category "Innovation: Movers & Shakers" – firms delivering new and valuable services that others are not. Thompson Hine is one of only 29 firms nationwide recognized in all innovation categories.

Investment Management

Mutual Funds Receive Temporary Relief to Auditor Independence Dilemma

By Christopher A. Moore & Michael V. Wible

On June 20, 2016, the investment and accounting industries each breathed a sigh of relief as the Securities and Exchange Commission (SEC) released a no-action letter that provided a temporary reprieve to mutual funds and accounting firms who found themselves in an unexpected independence quagmire. This no-action letter addresses what is known as the "Loan Rule," which regulates financial connections between mutual funds and their auditors, and will, at least for the moment, keep a significant number of mutual funds from having to replace their auditors.

The Loan Rule

Under federal law, auditors are required to be independent of their clients. The Loan Rule is contained in Rule 2-01(c)(1)(ii)(A) of Regulation S-X, an SEC rule regulating auditor independence that was implemented to ensure that auditors are qualified and independent of their audit clients – "both in fact and in appearance." The Loan Rule makes clear that an auditor is not considered independent if the firm has "[a]ny loan … to or from an audit client, or an audit client's officers, directors, or record or beneficial owners of more than ten percent of the audit client's equity securities." In practical terms, this means that an auditor is not independent of its client (and any of the client's affiliates) if a bank or other company that has loaned money to the auditor owns ten percent of more of the audit client. Violations of the auditor independent rules could force a company or fund to find new auditors or even required previously issued financial statements to be reexamined by a new accounting firm.

The Issue and Request for Relief

Mutual fund shares are often held by bank-owned brokerages that hold the shares in omnibus accounts for the benefit of their customers. This arrangement creates a situation where banks often appear to be the record owners of a large percentage of a mutual fund. These same banks also may have loaned money to the auditor of the mutual fund (or any of its affiliates, including advisers), therefore creating a technical independence issue under the Loan Rule. Audit firms have claimed that this relationship doesn't compromise the firm's objectivity or impartiality and that this application is not a fair representation of the rule's intention. When this issue was first identified in March 2016, the accounting and mutual fund industries requested that the SEC provide clarification on the rule to help guide the industries' response.

The No-Action Letter

On June 20, 2016, the SEC addressed this issue when it provided Fidelity Management & Research Company with a no-action letter that temporarily shields Fidelity and other mutual funds relying on the letter from SEC enforcement actions related to certain violations of the Loan Rule. Particularly, this letter states that the SEC would not pursue enforcement action where an auditor has a lending relationship with an institution that owns ten or more percent of a mutual fund audit client, as long as the accounting firm's noncompliance with the Loan Rule arose out of that lending relationship, and the accounting firm has concluded that it is objective and impartial with respect to its engagement with the audit client. It also requires that the auditor describe any lending relationships that might impact its independence to the audit client's audit committee, as would generally be required under accounting rules.

This reprieve is only temporary and expires in 18 months. Despite this, the issuance of the no-action letter provides at least temporary relief to the mutual fund industry and hopefully gives the SEC time to develop a proper and fair solution to the issue.

With any questions, please contact Chris Moore or Mike Wible.

Government Contracts

Implied Certification Theory Under the False Claims Act – Approved by the Supreme Court

By Joseph R. Berger

The U.S. Supreme Court, in its decision last summer concerning the False Claims Act (FCA), settled a disagreement among the circuits by holding that, "at least in certain circumstances, the implied false certification theory can be a basis for liability." The unanimous decision in *Universal Health Services v. United States ex rel. Escobar* (June 16, 2016) involved claims to a state Medicaid program that were accompanied by specific payment codes, but the decision highlights the risks for any participant in government contracts, grants, federal funding, and all programs and industries subject to the FCA, including banking, health care and education.

The Court held that "liability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement. In these circumstances, liability may attach if the omission renders those representations misleading."

The Court further held that:

> *False Claims Act liability for failing to disclose violations of legal requirements does not turn upon whether those requirements were expressly designated as conditions of payment. … What matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision.*
>
> *A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act.*

Implied Certification Theory

The implied certification theory has been asserted frequently under the FCA in not only health care cases but also in the context of government contracts, grants and other federal programs. In *Escobar*, the complaint alleged that Universal Health submitted claims to Medicaid that made representations about the services provided by specific types of professionals at one of its treatment facilities, where there were violations of regulations due to unqualified, unlicensed and unsupervised staff.

The Supreme Court reviewed the case to resolve the disagreement among the circuits "over the validity and scope of the implied false certification theory of liability." The Court held first that the implied certification theory can provide a basis of liability "at least in some circumstances," when at least two conditions are satisfied:

> *[F]irst, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.*

Future FCA cases must further interpret this guidance because, in many cases where implied certification is alleged, unlike the facts here, there may be no specific representations in the claims themselves. Government contractors, health care companies and other participants in federal programs must therefore be prepared to continue to defend themselves against allegations of implied certification where the case falls outside of the specific factual circumstances addressed by the Supreme Court in *Escobar*.

Materiality Standard

In *Escobar* the Supreme Court rejected the argument (and standard followed by some circuits) that the implied certification theory was valid only where a requirement was expressly designated as a condition of payment. However, the Court stated that concerns about open-ended liability can be addressed through the FCA's requirements of materiality and *scienter* (or knowledge). The Court focused on the "rigorous" materiality requirement, while noting the FCA's definition of "material" and common-law interpretations of the requirement.

The Court stated that the standard is "demanding" and the FCA is not a "vehicle for punishing garden-variety breaches of contract or regulatory violations." Materiality is not determined solely because the government would have the *option* to decline payment if it knew of the noncompliance, and materiality "cannot be found where noncompliance is minor or insubstantial."

Proof of materiality can include evidence that the defendant knows the government consistently refuses to pay claims in the case of noncompliance with the particular requirement. "Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material."

The Court's guidance thus demonstrates the potential benefits of robust disclosure to the government, as well as robust compliance measures. The Court also noted that the issue of materiality could be dispositive at either the motion to dismiss or summary judgment stage. FCA defendants must, therefore, be prepared to address the issue at the outset of the case and if necessary, through discovery and summary judgment. Following *Escobar*, litigation over the implied certification theory will see continuous new developments in the trial and circuit courts.

Please contact Joe Berger with any questions.