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401(k) Fiduciary - Are You Protected From The Risks?

By Robert J. D'Anniballe, Jr. Esq. and Erica M. Yacoviello Esq.

Providing at least one named fiduciary is a required component of every employee benefit plan. Pursuant to federal law, any fiduciary of an employee benefit plan is personally liable to the plan for any losses resulting from a breach of fiduciary duties (ERISA § 409).

A fiduciary is a person who exercises any discretionary authority or control regarding the management of an employee benefit plan or exercises control in the disposition of its assets. Fiduciaries include those that provide investment advice for a fee and have discretionary authority or responsibility in the administration of the employee benefit plan (ERISA § 3(21)).

In carrying out duties with respect to an employee benefit plan, a fiduciary is held to a specific standard of care. These fiduciary duties include (ERISA § 404(a)(1):

- Discharging all duties for the exclusive benefit of plan participants and their beneficiaries, including defraying reasonable expenses of administering the plan;
- Acting with the care, skill, prudence, and diligence of a prudent person in a like capacity;
- Diversifying the investments of the plan while minimizing the risk of substantial losses, unless it is not prudent to do so; and
- Performing in accordance with the plan documents, unless the same are inconsistent with ERISA

Any plan loss that is caused by a breach of these fiduciary duties makes the fiduciary personally liable for such losses.

A separate ERISA provision requires that every plan fiduciary, and any other person handling plan funds or property, be bonded (ERISA § 412). The purpose of Section 412 bonds is to protect plan funds against losses resulting from fraud or dishonesty. Although required by law, a bond does not provide protection to a fiduciary for losses associated with a breach of fiduciary duties. A bond specifically provides protection for losses associated with fraud or dishonesty or, more simply put – losses resulting from theft. Moreover, a bond is typically limited to $500,000; thus, plan losses exceeding that value, whether resulting from theft or from a breach of fiduciary duties, leave plan participants seeking other avenues by which to recover their losses. In many cases, plan participants will eventually seek recourse from the fiduciary. Thus, plan fiduciaries remain exposed to personal liability. This is especially true where there is a combination of a theft of plan assets that was facilitated by a breach of fiduciary duty.

Though not required by law, fiduciary liability insurance coverage provides protection that is absolutely necessary. With almost 90 million participants in defined contribution retirement plans, the vast majority of which are 401(k) plans, and approximately five trillion dollars in plan assets, plan fiduciaries are exposed to a substantial amount of risk. Insurance protection is available to provide coverage for these risks, and any plan fiduciary must consider obtaining that protection. Such an approach not only protects the fiduciaries from personal liability exposure, but also provides additional resources to remedy fiduciary breaches.

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Employers Must Begin to Act: Long-Awaited Updates to White Collar Overtime Regulations Published

By Jennifer R. Russell, Esq. and Shelly R. Pagac, Esq.

On May 23, 2016, the U.S. Department of Labor (DOL) published its long awaited Final Rule updating the Fair Labor Standards Act's (FLSA) regulations relating to the "white collar" executive, administrative and professional exemptions from overtime compensation (29 C.F.R. Part 541). The Final Rule is not effective until December 1, 2016. Once implemented, the Final Rule means that employees paid on a salary basis earning less than $47,476 per year can no longer be treated as exempt employees, and will now be entitled to overtime compensation for hours worked in excess of 40 per week.

In order for employees to fall within the FLSA's white collar exemptions and not be entitled to overtime pay, employees must **(1)** be paid on a salary basis, **(2)** be paid more than the threshold amount set by the DOL; and **(3)** perform duties that are primarily executive, administrative or professional, as defined by the regulations. Although the Final Rule does not change the duties test, it significantly increases the salary level required for the exemptions and adds additional types of compensation that may be included in certain employees' salaries to reach the newly-updated threshold. Employers should keep in mind that an employee must meet *both* the salary test and duties test to be considered exempt from overtime pay obligations. This new rule *only* modifies the salary portion of the test, but does not in any way modify the duties test.

For the first time since 2004, the salary level threshold was increased – indeed, more than doubled - from $455 per week ($23,660 per year) to $913 per week ($47,476 per year). The calculation is based upon the 40th percentile of weekly earnings of full-time, salaried workers in the lowest-wage U.S. Census Region (currently the South). For highly-compensated employees, the amount was increased from $100,000 per year to $134,004 per year, which is based upon the annual earnings for the 90th percentile of earnings of full-time, salaried workers across the nation. The DOL estimates that approximately 4.2 million workers will join the over 22.5 million workers currently entitled to receive overtime compensation. Automatic updates will be made to the threshold amounts every three years starting January 1, 2020, at which time the white collar salary threshold is expected to exceed $50,000, so employers should budget for these increases.

The Final Rule also includes a new provision allowing up to 10 percent of non-highly compensated employees' salaries to be comprised of non-discretionary bonuses, incentive payments and commissions. These payments must be made at least quarterly, and employers are permitted to make a quarterly "catch-up" payment when an employee's actual salary plus bonus, incentive payment or commission does not reach the required threshold. Employers, therefore, may consider structuring some employees' compensation arrangements to include these forms of compensation in order to reach the newly-increased exemption threshold.

Employers can respond to the increased threshold by **(1)** increasing salaries of employees who meet the duties and salary basis tests in order to maintain their exempt status *or* paying those employees overtime in lieu of raising salaries; **(2)** reducing or eliminating overtime hours; **(3)** reducing the amount of pay allocated to base salary (not below minimum wage), and adding pay to account for overtime for hours worked over 40 in a workweek, to hold total weekly pay constant; **(4)** restructuring compensation arrangements; or **(5)** using some combination of these responses.

The changes will have a notable effect upon businesses that cannot afford to raise salaries, including small businesses and non-profits. If salaries cannot be raised for currently-exempt employees, employers will need to reclassify such employees as non-exempt, but may choose to restrict their hours to 40 hours per week or otherwise manage overtime to minimize cost. Reclassification may be viewed as a demotion by reclassified employees, who will now have to track their hours, and could result in higher employee turnover rates. The need to track hours may also require employers to reexamine telecommuting and mobile device policies, and other flexible work arrangements, as they apply to non-exempt workers. Despite these potential downsides, however, employers now have a unique opportunity to study their workforce and correct any potentially-improper misclassifications which may otherwise raise a red flag with the DOL. Accordingly, employers should ensure that positions classified as exempt that already meet the salary threshold also comply with the duties test.

In order to make appropriate changes, employers will need to identify all current exempt positions with compensation below $50,000 and determine whether compensation can be increased above the new salary threshold, or whether to reclassify such positions as non-exempt. For

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The Best Lawyers in America

William Pietragallo, II, Mark Gordon, Gaetan J. Alfano, and **Marc S. Raspanti** lead the list of firm attorneys who have received *The Best Lawyers in America*© 2017 award. It is the oldest and most highly-respected peer review guide to the legal profession worldwide, coming into its 23rd Edition.




William Pietragallo received this recognition for the 25th year in the areas of Bet-The-Company Litigation, Commercial Litigation and Personal Injury Litigation - Defense; **Mark Gordon**, 20th year for Workers' Compensation Law - Employers; **Gaetan Alfano**, 5th year for Commercial Litigation; and **Marc Raspanti**, 10th year for Health Care Law.

In addition to the four name partners, the following firm lawyers were acknowledged by the publication as well: **Francis E. Pipak, Jr.,** 20th year on the *Best Lawyers* list for Workers' Compensation Law - Employers**; Alan G. Towner,** 5th year on the *Best Lawyers* list for Copyright Law, Litigation - Intellectual Property, Litigation - Patent, Patent Law, and Trademark Law; **Clem C. Trischler**, 5th year on the *Best Lawyers* list for Commercial Litigation, Product Liability Litigation - Defendants; and **Paul K. Vey**, 5th year on the *Best Lawyers* list for Medical Malpractice Law - Employers.

Since its inception in 1983, *The Best Lawyers in America* has become universally regarded as the definitive guide to legal excellence. Inclusion in *Best Lawyers* is based entirely on peer-review. The methodology is designed to capture, as accurately as possible, the consensus opinion of leading lawyers about the professional abilities of their colleagues within the same geographical area and legal practice area.

Pietragallo Welcomes New Attorneys

The Pittsburgh office of Pietragallo has welcomed **James J. Buldas** as a Senior Associate in the Litigation Practice Group. Mr. Buldas is working primarily in construction, commercial, and insurance coverage disputes. He has been practicing for seven years, and has handled numerous arbitration hearings, jury trials through verdict, and arguments before the Superior Court of Pennsylvania.

Christopher J. Owens has joined the Pittsburgh office as an Associate in the Intellectual Property Practice Group. He handles matters such as patent searches, preparation and prosecution of U.S. patent and trademark applications, and oppositions of U.S. trademark applications. Mr. Owens earned his J.D., *cum laude*, at the University of Pittsburgh School of Law where he served as an Associate Editor for the Journal of Law and Commerce.

Employers Must Begin to Act : Long-Awaited Updates to White Collar Overtime Regulations Published continued from page 2

employees who may need to be reclassified, employers should determine the tasks they perform and begin to track how many hours they usually work. In order to assess the impact and cost of any changes, employers will need to obtain a good understanding of the number of hours these employees work per week. It may be that the employees do not work more than 40 hours per week and, thus, their salaries can remain the same, and the employees may simply be reclassified as non-exempt. However, if these employees work overtime, employers should consider whether tasks can be assigned to other employees, including managers and others who are exempt, and consider the option of hiring part-time or temporary employees to reduce and spread out such employees' workloads. Employers must also develop an employee communications plan, required by the DOL, announcing the new regulations and the changes they have necessitated.

Pietragallo's Employment & Labor Practice Group is available to counsel employers as to what they need to do to comply with these changes.

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Recent Successes

Robert J. D'Anniballe, Jr., assisted by **Erica M. Yacoviello**, successfully argued on behalf of a gaming corporation's casino facility in front of the Supreme Court of Appeals of West Virginia regarding three certified questions from the United States District Court for the Northern District of West Virginia. The questions were presented after motions to dismiss were filed in federal court for failure to state a claim. The plaintiff in this matter alleged that her deceased husband had become addicted to gambling due to the negligent and intentional acts of the casino and the video lottery terminal manufacturer, leading to his embezzlement of millions of dollars and eventual suicide. The Supreme Court of Appeals of West Virginia held that video lottery terminals are approved, owned, and controlled by the state, and that the regulatory scheme of West Virginia, promulgated by the legislature, does not permit a compulsive gambler to recover for his or her gambling habits. Thus, it has now been established under West Virginia law that there is no duty of care by a casino or a video lottery terminal manufacturer to protect users from compulsively gambling.

Bryan S. Neft and **Jeanette H. Ho** were successful in appealing an adverse summary judgment ruling to the Commonwealth Court of Pennsylvania before the commencement of trial. The appeal involves an issue of first impression as to whether a political subdivision – in this case, a local school district – can be held liable for injuries suffered by a school teacher as a result of alleged work-related exposure to asbestos. Because the teacher last worked for the school district in 1959, the Workers' Compensation Act did not prevent her from bringing a lawsuit against her former employer. The Commonwealth Court accepted the pending case for interlocutory review less than one month after the trial court denied the school district's motion for summary judgment. The question that will be decided is whether the teacher's claim against the school district falls within an exception to governmental immunity. It is expected that the Commonwealth Court will hear argument on this matter later this year.

Biotech's Patent Eligibility Problem: The Stringent U.S. Patent Eligibility Standard May be in Violation of International Treaties


By Alicia M. Passerin, Esq. and Charles M. Yeomans, Esq.

The viability of many diagnostic method patents is in serious question after the recent Federal Circuit decision, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.,* 788 F.3d 1371 (Fed. Cir. 2015). There are four threshold requirements that must be established by a potential patentee in order to establish his or her right to a patent: **(1)** the invention must be directed to patent-eligible subject matter; **(2)** the disclosure must enable one of skill in the art to make and use the invention; **(3)** the invention must be novel; and **(4)** the invention must be non-obvious. While the focus of most patent practitioners has traditionally been on the latter two requirements, patent eligibility has become more difficult to establish in view of recent Supreme Court precedent. This article considers the state of the law for patent eligibility of diagnostic methods and compares patent eligibility in the U.S. under *Ariosa* to patent eligibility required under the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"). The article further explores the movement towards international patent harmonization and whether patent eligibility in the U.S. under *Ariosa* is in accordance with the requirements of TRIPS.

It has become increasingly difficult for the biotech industry to establish the patentability of diagnostic methods in view of the Supreme Court's *Mayo* and *Alice* decisions. Specifically, *Alice* further defined *Mayo*'s standard for patent eligibility in announcing a two-part test: **(1)** determine whether the claims are directed to a patent-ineligible concept such as a law of nature, natural phenomenon or abstract idea; and **(2)** determine whether the claim's other elements, considered both individually and as an ordered combination, transform the nature of the claims into a patent-eligible application, such that they are directed to an inventive concept.

In *Ariosa*, the Federal Circuit had the opportunity to address the patent eligibility of diagnostic method patent claims in view of *Mayo* and *Alice*. See *Ariosa Diagnostics, Inc. v. Sequenom, Inc.,* 788 F.3d 1371 (Fed. Cir. 2015). The invention in *Ariosa* was related to the discovery of cell-free fetal DNA ("cffDNA") in maternal plasma and serum. *Id*. at 1373. The inventors in *Ariosa* isolated cffDNA from the mother's blood to detect paternally inherited cffDNA that allowed them to determine fetal characteristics such as gender. The subject claims were directed to methods for detecting and amplifying paternally inherited nucleic acid from maternal plasma or serum and methods of performing prenatal diagnosis based thereon. *Id*. at 1373-74.

The Federal Circuit affirmed the district court's holding that the claims were directed to patent-ineligible laws of nature and natural phenomenon. *Id*. at 1378. Specifically, applying the two-part framework set forth above, the Federal Circuit found that it was undisputed that the existence of cffDNA in maternal blood is a natural phenomenon, and that "in this case, appending routine, conventional steps to a natural phenomenon, specified at a high-level of generality is not enough to supply an inventive concept. Where claims of a method patent are directed to an application that starts and ends with a naturally occurring phenomenon, the patent fails to disclose patent eligible subject matter if the methods themselves are conventional, routine and well understood applications in the art." *Ariosa* at 1378. The Court further explained that, "The method at issue here amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA. Because the method steps were well-understood, conventional and routine, the method of detecting paternally inherited cffDNA is not new and useful. The only subject matter new and useful as of the date of the application was the discovery of the presence of cffDNA in maternal plasma or serum." *Id*. at 1377.

A petition for rehearing *en banc* was denied by the Federal Circuit. However, two concurrences and one dissent were filed with the order denying the petition that questioned the restrictive *Alice/Mayo* framework. There has been much speculation that the Supreme Court may take up the case to provide further guidance in this area, and a petition to the Supreme Court for a *writ of certiorari* was filed on March 21, 2016.

The major concern for the biotech industry arising from the *Alice/Mayo* framework as applied in *Ariosa* is that many diagnostic method patents are discovery-based inventions. For example, the key to the invention in *Ariosa* was the discovery of cffDNA in maternal blood. That discovery allowed researchers to isolate and analyze cffDNA in a less invasive way than previous methods. However, the existence of cffDNA in a mother's blood is a natural phenomenon, and because the steps of isolating and analyzing the cffDNA were otherwise routine and conventional, the panel concluded that this was patent ineligible subject matter. That has the possible impact of wiping out many diagnostic method patents that are based upon the use of routine and conventional methods in connection with a new biological discovery.

However, the patent eligibility of the corresponding European patent at issue in *Ariosa* was never disputed, and the patent itself was held unobvious in an appeal before the European Patent

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Office ("EPO"). As such, long-term efforts towards patent law harmonization are potentially frustrated by the patent eligibility test in the United States as applied in *Ariosa* as the United States is the only country that uses such a stringent standard. These harmonization efforts date back to the 1883 Paris Convention and, more recently, the development of the World Intellectual Property Organization ("WIPO"). Additionally, at least two *amici* have questioned whether the resulting invalidation of the patent at issue in *Ariosa* conflicts with the 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"). TRIPS is administered by the World Trade Organization ("WTO") and sets down minimum standards for many forms of intellectual property. Article 27.1 of TRIPS provides the requirements for patent eligibility under the Agreement, and it is possible that the *Ariosa* decision is out of line with these minimum requirements at least because of the conflicting results before the EPO.

The *Ariosa* decision also may conflict with congressional intent embodied in the America Invents Act ("AIA"). The AIA was passed in 2011 and is the most significant U.S. patent legislation since the Patent Act of 1952. Congress did not make any changes to the patent eligibility requirements under § 101 other than to explicitly exclude "a human organism" from patent eligible subject matter indicating an intent to maintain the *status quo*. Furthermore, a goal of the AIA was greater patent law harmonization. Both *Mayo* and *Alice* were decided since the enactment of the AIA, and appear to conflict with the intent of global patent law harmonization. As such, the *Ariosa* decision, and the *Mayo* and *Alice* decisions from which it is derived, may not be consistent with congressional intent.

The *Ariosa* decision may provide a significant blow to diagnostic method patents where the claims recite a naturally occurring phenomenon without any additional steps that are more than routine and conventional. The current state of the law may be out of line with the requirements of international treaties such as TRIPS and the long-standing movement towards global patent harmonization. As such, it may be time for the Supreme Court to act.

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Recent Speaking Engagements

Pittsburgh, PA, July 15, 2016 and Philadelphia, PA, July 21, 2016- **John A. Schwab** and **Christopher A. Iacono** spoke at the Pennsylvania Bar Institute's CLE titled, "Understanding Pennsylvania Grand Jury Practice."

Gettysburg, PA, June 16, 2016- **Mary G. March** spoke at the Pennsylvania Bar Association's Inside-Outside Counsel Summit. She was a panelist discussing, "Time Management for Lawyers – Taking Back Your Life." The event took place at The Gettysburg Hotel.

Philadelphia, PA, June 14, 2016- **Marc S. Raspanti** spoke at Seton Hall Law School's Healthcare Compliance Certification Program on the False Claims Act litigation.

Gettysburg, PA, June 14, 2016- **Michael A. Morse** gave an update on "Health Care Fraud and Abuse" at the Pennsylvania Institute of Certified Public Accountants (PICPA) Health Care Conference at the Wyndham Gettysburg.

Columbia, SC, May 6, 2016- **Marc S. Raspanti** and **Pamela C. Brecht** spoke at the False Claims Act/Qui Tam Whistleblowers Litigation Involving Health Care Providers CLE Program at the South Carolina Bar Conference Center. Mr. Raspanti spoke on "False Claims Act Pleading Issues" and Ms. Brecht discussed "Private Causes of Action Accompanying FCA Qui Tam Cases."

Pittsburgh, PA, April 18, 2016- **Frank E. Pipak** spoke at "Handling the Workers' Compensation Case from Start to Finish" seminar hosted by the National Business Institute. He presented on "Preparing Your Case: Procedures for Claimant and Defendant" and "Settlement Options (Including MSA Considerations)."

Las Vegas, NV, April 17-20, 2016- **Michael A. Morse** and **Pamela C. Brecht** presented at the Healthcare Compliance Association's 20th Annual Compliance Institute at the Aria Resort. Mr. Morse spoke on "False Claims Act Developments" and Ms. Brecht spoke on "Managed Care Fraud: Enforcement and Compliance."

Practice Spotlight: ERISA and Employment Compliance Group

Significant Oversight by the Government of Companies with ERISA Plans and Their Employment Policies and Practices

Government regulators have significantly expanded their oversight of companies. Over the past few years, there has been a proliferation of governmental enforcement activities ranging from audits and investigations to substantial penalties and litigation. The risks are high and the implications enormous, ranging from damaging public relations, personal and corporate liability, as well as substantial monetary and human resource costs in responding to audits and lawsuits. The passage of recent regulations and hiring of DOL investigators is particularly prevalent in the areas of ERISA fiduciary litigation and employment compliance.

Increased Risks, Liabilities, and Potential Loss of Business

Fiduciaries responsible for sponsoring various retirement plans, such as 401k plans, face increased scrutiny from the DOL and the plaintiff's bar. With the recent enactment of the Fiduciary Rule, financial advisors and financial institutions face similar scrutiny and potential liabilities. Companies are also responsible for ensuring that all of their employment-related practices, ranging from hiring decisions to compensation and leave, are fairly and consistently applied. If not, they risk not only audits, investigations, penalties and lawsuits, but also loss of business stemming from current and future federal contracts or subcontracts.

Maintaining or Establishing Compliance to Mitigate Increased Risks and Liabilities

Given this current challenging climate, companies are well advised to take proactive, preventative measures to become and/or remain compliant with the regulations that directly and substantially impact their business. Our attorneys provide counsel to mitigate the prospect of litigation and regulatory challenges. Our team has experience in successfully implementing policies, and navigating compliance audits, training, internal investigations, and litigation for businesses across multiple industries.

Pietragallo Lawyers Experience in Advising and Defending Clients on Compliance-Related Issues

Our team consists of lawyers with substantial knowledge and expertise with ERISA and employment cases, laws, and regulations. Pietragallo attorneys include federal prosecutors who have worked for or with government regulators in order to achieve successful results for their clients. Our lawyers also possess valuable in-house experience that appreciate and understand the significant costs that compliance can bring, and can provide guidance to realigning our clients' compliance programs in an efficient, minimally-intrusive manner.

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