

The Next Wave of Wage and Hour Litigation

Pharmaceutical Product Representatives Seek Overtime

In recent years, class and collective actions filed under the Fair Labor Standards Act (FLSA) and state wage and hour laws have swept across entire industries, including retail, insurance, and financial services. The filing of one or two high-profile or high-exposure cases has caused the plaintiffs' bar to bring a host of copycat cases against most of the major employers in these industries. Much of the recent wage and hour litigation has focused on relatively highly compensated jobs that have long been considered exempt from overtime pay, such as insurance agents, claims adjusters, loan officers, underwriters, and stockbrokers.

These cases have led to costly settlements and verdicts for employers in these industries. In January 2005, an insurance company settled a wage and hour class action brought by its California claims adjusters for approximately \$135 million. In February 2006, a financial services company agreed to pay up to \$89 million to settle wage and hour litigation relating to its stockbrokers. And in March 2006, a court awarded \$33.2 million to store managers of a retail chain.

Class-Based Wage and Hour Litigation Comes to Life Sciences

Recent wage and hour lawsuits suggest that the plaintiffs' bar is now focusing on the pharmaceutical industry and mounting an industrywide challenge to the overtime-exempt status of pharmaceutical product representatives. Nine major pharmaceutical

companies have been sued this year in class and collective actions challenging the exempt status of their product representatives. Most of the cases have been brought by the same attorneys, who have targeted the industry, and who are using a website to recruit potential plaintiffs. In one of these cases, the plaintiffs contend that they and the other current and former product representatives of the company are owed more than \$200 million.

The courts have not yet ruled on whether these cases may proceed as class or collective actions or whether the product representatives are exempt from overtime. There are compelling reasons why the overtime claims of product representatives cannot and should not proceed on a class or collective action basis. In addition, there are several exemptions from overtime that are potentially applicable to product representatives depending upon the facts pertaining to each individual. Two such exemptions, the "outside salesperson" and "administrative employee" exemptions, are discussed briefly below.

Outside Salesperson Exemption

The FLSA exempts from overtime "any employee employed ... in the capacity of outside salesman." 29 U.S.C. § 213(a)(1). In the decision in *Olivo v. GMAC Mortgage Corp.*, 374 F. Supp. 2d 545 (E.D. Mich. 2004), a case handled by Morgan Lewis, the court concluded that loan officers were exempt as outside salespersons based on the following:

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(1) loan officers were made aware of the fact that they were joining a “sales force” when they commenced employment, (2) loan officers participated in a sales incentive program, and (3) loan officers solicited and promoted new business and had a considerable amount of flexibility to configure their workdays.

Administrative Employee Exemption

The FLSA and its regulations exempt from overtime any employee whose primary duty (1) is the performance of office or nonmanual work directly related to the management or general business operations of the employer or the employer’s customers, and (2) includes the exercise of discretion and

independent judgment with respect to matters of significance. 29 C.F.R. § 541.200.

In *Cote v. Burroughs Welcome Co.*, 558 F. Supp. 883 (E.D. Pa. 1982), the court ruled that the plaintiff, who was employed as a “Professional Representative” or “detail person,” was exempt as an administrative employee.

This job required the plaintiff to “call regularly on physicians, hospitals, and pharmacies and to increase the sale of Burroughs’ products by ‘detailing’ the recommended indications of these drugs to potential prescribers and retailers.”

The court granted summary judgment in favor of the employer, ruling that the plaintiff was exempt under the administrative exemption even though the representatives were provided with “an extensive set of selling tools,” and even though the plaintiff “had only mechanically to apply specified procedures in setting up her physician visit schedule.” The court found “ample” evidence of the exercise of independent judgment and discretion because the plaintiff had been commended for her initiative in increasing sales, and the plaintiff was expected to “use a wide degree of discretion in deciding how to encourage the use of the product.”

Another case that may support the exempt status of product representatives as administrative employees is *Reich v. John Alden Life Ins. Co.*, 126 F.3d 1 (1st Cir. 1997). In that case, the First Circuit Court of Appeals found that “marketing representatives” of an insurance company, whose primary duty was to cultivate sales of the company’s insurance products by independent insurance agents, were exempt “administrative” employees. The court found that the marketing representatives exercised substantial independent judgment and that their activities were only ancillary to the employer’s principal production activity – the creation of insurance policies.

Analyze the Exempt Status of Product Representatives Before Litigation Hits

Given the trend of industrywide wage and hour litigation in the retail, insurance, and financial services industries, FLSA collective

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actions and state law class actions are likely to be filed against other employers in the life sciences industry that have a substantial number of product representatives. Such companies are well advised to carefully consider with legal counsel the exemption status of their own product representatives well before litigation ensues. This will position the company most favorably should they become targets of an overtime challenge by product representatives.

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life sciences

Recent Victory

Morgan Lewis Assists in Obtaining Patent for Subject Matter of Nobel Prize

Morgan Lewis attorneys led by senior counsel Paul Kokulis represented the Carnegie Institution of Washington before the U.S. Patent and Trademark office in obtaining U.S. Patent 6,506,559, which claims the subject matter awarded the Nobel Prize in Medicine for 2006. Andrew Fire, a scientist who discovered RNAi, or RNA interference, while at the Carnegie Institution’s Department of Embryology, along with Craig C. Mello of the University of Massachusetts Medical School, were awarded the Nobel Prize in Medicine in October 2006. The Fire-Mello discovery that double-stranded RNA can quash the activity of specific genes is an important breakthrough in modern molecular biology. RNAi is now being widely used both as a research tool and for the development of products that could combat diseases such as cancer and HIV. U.S. Patent 6,506,559 and corresponding foreign patents and pending applications have been licensed on a nonexclusive basis by the Carnegie Institution of Washington and the University of Massachusetts (joint owners) to more than 50 pharmaceutical, biotechnology, and agricultural companies.

For more information, visit www.morganlewis.com

Update on Parallel Trade in the European Union

The debate over the acceptability of the parallel trade in medicinal products in the EU has long been controversial, with lengthy battles and much money being spent by both its supporters and detractors in an attempt to defend their rights. For many years, the majority of rulings were in favor of parallel trade, but the EU pharmaceutical industry is currently more encouraged following [two] recent rulings in favor of GlaxoSmithKline's (GSK's) steps to prevent parallel trade, which have given the industry hope that the EU's position on parallel trade may be about to turn in their favor.

Parallel trade of medicinal products in the EU is possible because EU Member States retain their own pricing laws for medicinal products. As a result, wholesalers of medicinal products are able to buy drugs that are priced cheaply in one EU country, resell them at a higher price in other EU countries at prices lower than those prevailing for the originator's own products in that country, and make a margin for themselves.

As far back as the 1970s, wholesalers began fighting a war in favor of parallel trade that, for the most part, was highly successful. As a result, over the years, parallel traders have won the right to repackage medicinal products for resale in different countries, successfully argued that patents and trademarks should not be an obstacle to parallel trade, and altered trademarks when repackaging products intended for parallel trade.

Supporters of parallel trade argue that it benefits patients by keeping down the costs of medicines in the EU and promoting competition, while the pharmaceutical industry has always maintained that it affects the safety of products, encourages counterfeiting, and deprives the industry of income that would otherwise be put toward research. The imposition of free trade principles on a system in which prices are controlled is unfair and unbalancing, the industry says. The arguments on both sides of the parallel trade debate remain strong. However, in recent years,

more questions are being asked about how much of the economic benefit of parallel trade is being passed on to patients or to national healthcare systems, and whether the practice is endangering patients in countries with lower prices due to an increased risk of stock shortages.

When faced with parallel trade activity, a recent response of the pharmaceutical industry has been to restrict supplies of medicinal products to the wholesalers in question, a practice that has been attacked as anticompetitive on multiple occasions.

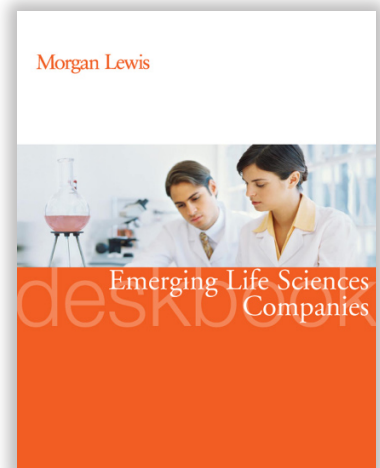
However, in more recent years, a number of national rulings that such practices are not anticompetitive have provided a glimmer of hope to the pharmaceutical industry. Although there were several promising national decisions before it, the *Bayer/Adalat* case of 2004 is credited with being perhaps the first decision by the European Court of Justice (ECJ) that the pharmaceutical industry could use in its war against parallel trade. The key issues in the case were that Bayer was not in a dominant position in relation to the disputed product and was found by the court not to have an agreement with its distributors. The ECJ ruled that a nondominant company could unilaterally limit the supply of its products to wholesalers in one EU Member State in order to prevent them from reselling the products in another Member State, provided this practice did not become a part of the agreement the company had with its wholesaler. Accordingly, the specific and limited nature of the ruling prevented it from providing definitive help to the pharmaceutical industry, although the case could clearly be of assistance to companies in a nondominant position vis-à-vis their product.

The 2002 decision of the French Competition Council (FCC) in the *Pharma Lab* case is another example of a national ruling in opposition to parallel trade. In that case, Pharma Lab alleged that actions by both GSK and Pfizer

to restrict supplies of certain of their products to it were anticompetitive. However, the FCC rejected the case, as did the Paris Court of Appeal on subsequent appeal, which questioned in its ruling whether the economic benefits of parallel trade were actually being seen by patients and healthcare systems.

These earlier cases have since been substantially bolstered by two recent successes of GSK. The first of these cases, between GSK and a consortium of Greek wholesalers and distributors, dates back to 2000, when the Greek wholesalers filed a complaint to the Hellenic Competition Commission (HCC), alleging that GSK was abusing its dominant position by restricting supplies of three of its medicines (Imigran for migraines, Serevent for asthma, and Lamictal for epilepsy). GSK had stopped supplying the Greek wholesalers with these drugs in November 2000 after they caused shortages in Greece by reexporting the drugs, and began directly supplying hospitals and pharmacists with the drugs instead.

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Randell B. Sunberg • March 14, 2007, New York

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european union life sciences

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Legal Week • Anthony Warnock-Smith • November 2006

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ABA Health Law Section 8th Annual Conference on Emerging Issues on Healthcare Law 2007
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The HCC referred the matter to the ECJ in January 2003, and the EU's Advocate General issued an opinion in GSK's favor in October 2004. However, the ECJ referred the matter back to the HCC in May 2005 without deciding on the merits of the case. Although the ECJ's refusal of the matter on jurisdictional grounds was unfortunate and left key issues moot, then Advocate General Jacobs did provide an opinion in favor of GSK, concluding that the refusal of a dominant company to meet its customers' orders did not automatically amount to an abuse of its dominant position, and such restrictions may be justifiable by such a company as a reasonable means of defending its commercial interests. While the Advocate General's opinion was never reinforced by a judgment from the ECJ, it was a strong sign to the pharmaceutical industry that support for parallel trade in Europe was waning.

Following this, on September 5, 2006, the HCC ruled that GSK was not abusing its dominant position. The ruling will effectively allow GSK and other pharmaceutical companies to prevent parallel importation of drugs to Greece without breaking competition laws. GSK's president reacted to the ruling by saying that the decision "recognizes that parallel trade in the context of the pharmaceutical industry across Europe, where prices are directly or indirectly controlled by EU governments, benefits primarily traders who pass on none or almost none of the price differences to patients and payers."

A second, similar case, also involving GSK and relating to parallel trade in Spain, was heard by the European Court of First Instance on September 27, 2006. In this case, a group of Spanish wholesalers disputed the legality of an agreement that GSK asked them to sign in 1998 that implemented a dual pricing system, effectively distinguishing between prices charged to the wholesalers in the case of domestic resale of reimbursable medicines to pharmacies or hospitals and higher prices charged in the case of exports to other Member States.

On May 8, 2001, the European Commission adopted a decision that GSK had abused its dominant position by entering into such an

agreement. Following an appeal by GSK to the ECJ, the ECJ ruled both for and against the company, offering something to both the supporters and detractors of parallel trade. The decision indicated that while there were some anticompetitive elements to GSK's actions, its dual pricing system was not in itself unlawful. Accordingly, the judgment does not entirely rule out the use of dual pricing systems by the pharmaceutical industry as a means of regulating parallel trade.

Although the pharmaceutical industry has yet to obtain a definitive, recognizable decision in support of its practices of restricting parallel trade that would revolutionize the way parallel trade is conducted in Europe, together these recent judgments paint a much more positive outlook for the pharmaceutical industry. It remains to be seen whether the correct balance between the rights of the industry and the requirements of free circulation will ever be struck; however, in the meantime, the industry finally has some leeway in this area.

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Life Sciences at Morgan Lewis

Our practice is one of the largest in the nation, with more than 200 lawyers whose practice and experience are significantly devoted to the life sciences industry. Additionally, we have more than 60 professionals with advanced scientific degrees in life sciences disciplines.

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