

Adli Law Group P.C.

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California Labor Laws: Changes in 2012

Beginning in the new year of 2012, about two-dozen new California labor laws are set to take effect. According to experts, many of these laws are designed to protect California workers, and in turn will put additional burdens on employers at a time when the job market is not very favorable. Some of these newly imposed...

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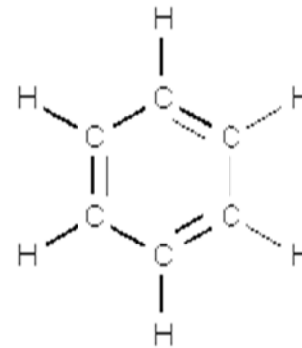


Successive 30-Month Stays Still Feasible Under a Post-MMA Framework

**Michael Rothwell
Attorney**

Traditionally, a patent holder could submit patent information for listing in the Food and Drug Administration's ("the FDA") *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book") at any time and still expect to obtain a 30-month stay of regulatory approval of a generic competitor's Abbreviated New Drug Application ("ANDA"). The practice of "late listing" patents in the Orange Book allowed for a patent holder to add patents to the Orange Book both incrementally and after the onset of ANDA litigation in order to obtain successive 30-month stays. Where a patent was late-listed after the filing of an ANDA by a competitor, another 30-month stay of approval was potentially triggered. The net effect was a litigation-derived delay of the regulatory approval of generic pharmaceuticals. In December of 2003, however, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("the MMA") was enacted and sought to address, in part, the practice of late-listing patents in the Orange Book. After the MMA, only those patents submitted to the FDA by the NDA holder before the submission of ANDA could serve as a foundation for a 30-month stay. As such, the practice of obtaining successive 30-month stays by virtue of late-listing patents was terminated by the new legislation.

Despite the enactment of the MMA, however, the FDA has demonstrated that, under certain circumstances, the obtainment of successive 30-month stays is still feasible. This article explores the circumstances under which successive stays may occur.



I. Boniva®

In an ANDA dispute between Hoffman-La Roche Inc. ("Roche") and Orchid Healthcare regarding the drug product Boniva (ibandronate sodium), the FDA was asked to confront, in response to a Citizen Petition filed by Roche, whether successive 30-stays still held any validity post-MMA. In its Citizen Petition, Roche specifically asked the FDA to consider whether it was entitled to a successive 30-month stay when Orchid had amended a paragraph III certification, initially filed in conjunction with a paragraph IV certification that thus gave rise to the initial 30-month stay, to a paragraph IV certification after a significant patent term extension had been awarded. The FDA reasoned that because the MMA did not extinguish successive stays entirely, and instead merely foreclosed the possibility of successive stays where patent information was submitted to the Orange Book after the filing of the ANDA, any amendment that otherwise comported with the requirements of the FDA and Cosmetic Act gave rise to a successive stay. Stated differently, where a patent is timely filed in the Orange Book, any paragraph IV certification involving that patent will give rise to a 30-month stay—irrespective of whether an earlier stay had already been granted or that the patent was first subject of a paragraph III certification before being identified as paragraph IV.

In practical application, amendments by ANDA filer from paragraph III to paragraph IV are relatively uncommon. However, any litigant involved in an ANDA litigation pertaining to a New Chemical Entity (“NCE”) should be wary of the possibility of such amendments. This is attributable to the fact that patents protecting NCEs are often subject to significant patent term extensions. In some instances, the patent term extension may be awarded after the filing of the ANDA, thus necessitating a potential amendment of certification from paragraph III to paragraph IV. Where this occurs, the patent holder, provided that the patent information had been timely submitted to the Orange Book, is thus eligible for a second 30-month stay.

II. Hectoral®

In another ANDA dispute, this time between Genzyme Corp. (“Genzyme”) and Cobrek Pharmaceuticals, Inc. (“Cobrek) regarding the drug Hectoral (doxercalciferol), the FDA was again asked via Citizen Petition to consider the statutory sufficiency of a successive 30-month stay, albeit under dissimilar circumstances. Here, the FDA sought to determine whether a singular patent, already the subject of an ANDA litigation and an initial 30-month stay, could be used again to initiate a second, successive stay where there had been approval of a supplemental NDA (“sNDA”) for a newly-formulated version of the same drug product and the generic competitor had thus filed an amended ANDA targeting the same patent in a new paragraph IV certification. Specifically, Genzyme first received approval of its NDA for its initial formulation in 2000. Its patent information regarding the technology subject of the NDA was submitted to the FDA in the same year. In 2007, Cobrek submitted an ANDA regarding the initial formulation of Hectoral; the Genzyme patent was certified under paragraph IV. Genzyme then initiated a lawsuit for, *e.g.*, patent infringement, triggering the initial 30-month stay.

Later, in 2008, the FDA approved Genzyme’s follow-on formulation for the same drug and the patent listing information was again submitted to the Orange Book in the same year. Cobrek then reformulated its product to match Genzyme’s follow-on formulation and, in 2009, amended its ANDA to reflect the new specification. Per the FDA’s requirements, Cobrek had to then re-certify the Genzyme patent after submitting its amended ANDA. Not surprisingly, the Genzyme patent was again certified under paragraph IV and a second lawsuit was initiated to address generic version of the follow-on formulation. Genzyme then requested that the FDA grant it a successive 30-month stay given that Cobrek had filed a second paragraph IV certification.

Employing the reasoning articulated in *Boniva*, the FDA declared that the MMA did not enact an outright prohibition on all successive stays—instead, only those stays that relied on patents filed after the submission of the ANDA were impermissible. Given that the patent subject of the second certification was listed in the Orange Book pre-amended ANDA, the requirements of the Federal Food, Drug, and Cosmetic Act were met. According to the FDA, these requirements were not altered, colored, or otherwise undermined by the fact that the same Genzyme patent was involved in both stays, or that a follow-on sNDA for a reformulation of the same technology gave rise to an amended ANDA.

III. Conclusion

As these examples illustrate, the FDA’s handling of successive 30-month stays in a post-MMA framework has been relatively straightforward. Where the requirements of the Federal Food, Drug, and Cosmetic Act have been met, and the patent information has been listed by the NDA holder in the Orange Book prior to the submission of the ANDA, the FDA has been apt to grant successive stays—the varying procedural configurations leading to such a result notwithstanding.



**Crocs Design Patent
vs. Third Party
Designs**

**Payam Moradian
Patent Attorney**

There are two types of patents, design patents and utility patents. Design patents cover as their name implies, the overall design of a product. Design patents do not cover functional elements of a product because functional (utilitarian) elements are not considered design elements. Design patents can be used to cover the overall design of many different products, including jewelry, shoes, tools, and even cell phones. Recently Crocs asserted its design patent (D517,789) to the Crocs shoe that we are all familiar with, and accused several manufacturers of infringing this design patent.

According to the court, an ordinary observer, familiar with shoe designs, would be deceived into believing the accused products are the same as the patented design. One of the overall effects of the design is the interaction between the strap and the base portion of the shoes where the strap is attached to the base. Multiple major design lines and curves converge at that point creating a focal point attracting the eye of the ordinary observer when viewing the overall effect of the design. Another overall effect of the design is a visual theme of rounded curves and ellipses throughout the design, including the strap forming a sort of continuation of the sidewall of the base to create a visually continuous ring encircling the entire shoe. Other examples of rounded curves or ellipses in the design are the ellipses formed by the strap and the foot opening in the base. Both the claimed design and the accused designs have these overall effects. In conclusion, the federal appeals court found that the accused products embody the overall

effect of the Crocs design in sufficient detail and clarity to cause market confusion.

In the Crocs case, the Crocs patent was relatively strong because most of the elements of the shoe were ornamental rather than functional. The Crocs case is *Crocs Inc. v. International Trade Commission*, decided by the Federal Circuit on Feb. 24, 2010. The Crocs Patent No. is D517,789.

*The summary of the Crocs case has been simplified and should not be relied on for legal advice or taking any action.



**Centillion Data
Systems, LLC v. Qwest
Communications
Intern.**

James Ahn, Attorney

The Federal Circuit's recent decision in *Centillion Data Systems, LLC v. Qwest Communications Intern., Inc.*, 631 F.3d 1279 (Fed. Cir. 2011) addressed, for the first time, the question of infringement for "use" of a system claim that includes elements in the possession of more than one actor. Centillion's asserted claims against Qwest require a system for presenting information to a user comprising: storage means for storing transaction records, data processing means for generating summary reports as specified by a user from the transaction records, transferring means for transferring the transaction records and summary reports to a user, and personal computer data processing means adapted to perform additional processing on the transaction records. The parties did not dispute that the first three claim elements constituted the "back-end" of the system, while the fourth claim element constituted the "front-end." Qwest's billing systems accused of infringing the patent-in-suit included Qwest's back office systems and front-end client applications that a user may install on a personal computer.

The district court applied the standard of "use" defined by *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282 (Fed. Cir. 1995), which required that a party must put the invention into service, i.e., control the system as a whole and obtain benefit from it. Citing *BMC Resources Inc. v. Paymentech, L.P.*, 498 F.3d 1373 (Fed. Cir. 2007) and *Cross Medical Products v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293 (Fed. Cir. 2005), the court also held that direct infringement required that an accused infringer must either practice every element or control or direct the actions of another that practices the element in question such that the accused infringer should be vicariously liable for the actions of another. In doing so, the court found no infringement based on the determination that no

single party practices all of the limitations of the asserted claims. Specifically, the court held that Qwest did not "use" the entire system because Qwest did not control claim element 4, the front-end of the system. The court also held that Qwest's customers did not "use" the entire system because the customers did not control claim element 2, the back-end of the system.

The Federal Circuit held that while the district court was correct in determining that the standard of "use" as defined by *NTP* was applicable, the district court misapplied that standard by requiring that a party must exercise *physical or direct* control over each element of the system. The Centillion court found that the "control" contemplated by *NTP* is the ability to place the system as a whole into service and did not require direct, physical control. Accordingly, the court held that Qwest's customers exercised sufficient control over the entire system, including the back end, by initiating the demand for the service. In its reasoning, the court stated that, but for the customer's actions, the entire system would never have been put into service.

With respect to Qwest, the Centillion court agreed with the district court, holding that, as a matter of law, Qwest did not "use" the entire system because it never puts into service the front-end of the system. The court held that making and supplying the software for the customer to use is not the same as using the system. Thus, the only way Centillion can establish "use" by Qwest is if Qwest is vicariously liable for the actions of its customers, i.e. if Qwest controls or directs its customers to practice all limitations of the asserted claim through an agency relationship or other contractual obligation. In this case, because the "use" of the system was entirely at the discretion of the customers, and the customers were not obligated to "use" the system as an agent or by contract, the court held that Qwest was not vicariously liable for the "use" by its customers.



Breaking News!!!

California Employment-Related Laws: Changes in 2012

Beginning in the new year of 2012, about two-dozen new California employment laws are set to take effect. According to experts, many of these laws are designed to protect California workers, and in turn will put additional burdens on employers at a time when the job market is not very favorable. Some of these newly imposed requirements include:

-Notices To Non-Exempt Employees.

Employers must provide new notices to all non-exempt employees hired after January 1st. These notices must be in writing and must include:

1. The employee's rate of pay and the basis for such rate (salary, commission, hourly, etc.), including any overtime rates.
2. Allowances claimed as part of minimum wage-including meal or lodging.
3. The correct legal name of the employer and any D/B/A in use.
4. The Physical address of the employer's workers' main office or principal place of business, and a mailing address if different.
5. The employer's telephone number.
6. The name, address and telephone number of the employer's workers' compensation insurance carrier.
7. Any "other information" the Labor Commissioner deems material and necessary.

The Labor Commissioner is developing a template to comply with the requirements, but this template has not been published to date. Further, the law requires that written notices of any changes to any of the information listed above be provided to all non-exempt employees within 7 days of the change(s). (AB 469)

-Credit Reports. Most employers will be severely limited in their ability to use credit reports to make employment decisions. For those employers, these reports may only be used with respect to:

1. Managerial positions.
2. Law enforcement.
3. A position where a credit report is required by law.
4. A position where the employee will have access to specified personal or confidential information.
5. A position involving regular access to \$10,000 or more of cash.

-Discrimination (Gender Identity and Genetic Information). Employee handbooks must be updated to reflect that California laws now prohibit discrimination on the basis of "gender identity"; "gender expression" and "genetic information". (AB 887 and SB 559). In addition, health care service plans or insurance policies may not discriminate in coverage between spouses or domestic partners of the same sex. (AB 757)

-Insurance Coverage During Pregnancy Disability Leave. Employers are required to maintain health coverage during a pregnancy disability leave under the same terms and conditions that would have been provided absent the leave. In other words, employers are now obligated to continue to pay the same portion of the health insurance premium during the pregnancy disability leave as had been paid prior to the leave. (SB 299)

-Misclassification of Independent Contractors. This is a HUGE change. The federal and state governments have made no secret over the few years that they are targeting employers that misclassify independent contractors, which they see as a pervasive problem. California law now expressly prohibits "willful misclassification" of independent contractors and authorizes the assessment of civil penalties ranging from \$10,000 to \$25,000 per violation, in addition to other remedies currently available. Further, any employer found to have made a willful misclassification will be subject to an order to prominently display specific information on its company website about the violation having occurred. (SB 459)

-Meal Periods. The California Supreme Court held the long-awaited oral arguments in the Brinker Case, and a decision is expected early next year. Although most observers of the oral arguments believe that the Court is not likely to accept the argument that employers must require employees to take a meal period. Rather, the employer providing the employee with the opportunity to take a meal period appears that it will be enough. However, as a surprise to most employers, the Court appeared to be very focused on whether a meal period must be provided on a rolling 5 hour basis; as opposed to the current understanding of most that a second meal period is required only if the employee works at least 10 hours. The justification of this rule is still ongoing.

The new, restructured laws listed above are just a few of the many labor laws going in effect in 2012. While most of them seem to heavily favor of the employee, it's not all bad news for the employer. According to Kathleen Pender at SFGate.com, a group of five laws supported by the chamber could lower the employer's workers' compensation costs and streamline some notices

and procedures. Depending on which side of the fence you rest on, it may seem like a lopsided victory for the employee, or maybe just old news for an employer that already followed the California labor laws beyond what they were expected of.

For more information, visit the *California Labor website*.

Information courtesy of:

-Kathleen Pender's "2012 Brings New Laws On California Employment" at SFGate.com.

*Please note that the above information is intended for education purposes only and does not constitute legal advice.

Announcements

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Congratulations

Nicolette Hachem-Sawaya

***NAPW* Member of the Month**

January 2012

Nicolette Hachem-Sawaya, Director of Operations at [Adli Law Group P.C.](#), was named the January 2012 Member of the Month by *The National Association of Professional Women*.

The National Association of Professional Women is an exclusive network for professional women to interact, exchange ideas, educate and empower. NAPW members enjoy a wealth of resources, benefits and services dedicated to enhancing their lives and promoting their businesses and careers.

On behalf of Adli Law Group P.C., Dr. Dariush Adli would like to congratulate Mrs. Hachem-Sawaya on a wonderful accomplishment of achieving this well-deserved award.



New Addition
Benjamin Deming
Associate Attorney



New Addition
Michael Rothwell
Associate Attorney

