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BRADLEY ARANT BOULT CUMMINGS

Innovator Liability For Injuries Resulting From Generic Version of a Drug

In *Conte v. Wyeth*, 168 Cal. App. 4th 89 (Cal. Ct. App. 2008), the California Court of Appeals recognized that brand named innovators and manufacturers could, in some circumstances, be liable for injuries resulting from the generic versions of their drugs. In most states, innovators and manufacturers of brand named drugs are not liable for injuries that result from taking a generic version of a drug. *See Foster v. Am. Home Prods.*, 29 F.3d 165 (4th Cir. 1994) (holding that "because generic drugs are required by federal law to be equivalent to their name brand counterparts," the brand-name manufacturer was not liable for the generic manufacturer's labeling omissions or representations). However, in *Conte*, the California court held that a brand-name manufacturer can be liable for injuries resulting from a generic drug if it is foreseeable that a doctor will reasonably rely on the name-brand product information when prescribing the generic drug. *Conte*, 168 Cal. App. 4th at 94-95 & 144.

Conte is an important decision for drug manufacturers and innovators, because it extends their liability in California and encourages similar arguments in other states. For those disputes that arise in California, brand-name manufacturers and innovators may now be liable for injuries caused by a generic drug. For those disputes arising in other states, encouraged by *Conte*, plaintiffs are increasing claiming that brand named drug manufacturers and innovators are liable for injuries caused by taking a generic version of a drug. *See, e.g.*, *See,e.g., Mensing v. Wyeth, Inc.*, 588 F.3d 603, 613-14 (8th Cir. 2009); *Moretti v. Wyeth, Inc.*, No. 08-CV-396, 2009 WL 749532, at *4 (D.Nev. March 20, 2009); *Finnicum v. Wyeth, Inc.*, --- F.Supp. 2d ----, 2010 WL 1718204 (E.D.Tex. April 28, 2010); *Hardy v. Wyeth, Inc.*, No. 9:09-cv-152, 2010 WL 1049588, at *2-*5 (E.D.Tex. March 8, 2010) (report and recommendation); *Burke v. Wyeth, Inc.*, No. G-09-82, 2009 WL 3698480, at *2-*3 (S.D.Tex. Oct. 29, 2009); *Howe v. Wyeth, Inc.*, No. 8:09-cv-610, 2010 WL 1708857, at *3 (M.D.Fla. April 26, 2010); *Levine v. Wyeth, Inc.*, --- F.Supp. 2d ----, No. 8:09-cv-854, 2010 WL 456773, at *4-*5 (M.D.Fla. Feb. 10, 2010); *Dietrich v. Wyeth, Inc.*, 2009 WL 4924722 (Fla. Cir. Ct. Dec. 21, 2009); *Meade v. Parsley*, No. 2:09-cv-00388, 2009 WL 3806716, at *3 (S.D.W.Va. Nov. 13, 2009). While courts outside of California have yet to adopt this theory of liability, it is likely that brand-name drug manufacturers and innovators will be faced with this argument and will be forced to argue that *Conte* does not apply to their particular case.

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Therapeutic Discovery Project Program

Last Friday, the IRS released Notice 2010-45, which provides the guidelines that small companies can use to have their research projects certified as eligible to participate in the government's Therapeutic Discovery Project Program, under I.R.C. § 48D. The program is designed to spur medical research by providing an income tax credit to companies that are selected to participate in the program.

The tax credit, which will be available for investments made in 2009 and 2010, will cover up to 50 percent of the cost of qualifying biomedical research, up to a maximum credit of $5 million per business. The credit is only available to companies with fewer than 250 employees and has an overall cap of $1 billion. Selection will be targeted toward projects that show significant potential to produce new therapies, address unmet medical needs, reduce the long-term growth of health care costs, and advance the goal of curing cancer within the next 30 years.

Companies interested in participating in the program must act quickly. They may begin submitting applications for certification beginning on June 21, 2010, but all applications must be received by July 21, 2010. As part of the review process, the Health and Human Services Department will evaluate each project for its potential to produce new therapies or reduce health care costs. The allocation decisions will also consider which projects show the greatest potential to create and sustain high quality, high-paying jobs

in the United States. Only projects that show a reasonable potential to meet these goals will be certified as eligible for the tax credit. Decisions on qualifying projects will be issued by October 29, 2010.

Copyright 101

What are copyrights?

Copyright protects all "original works of authorship" that are "fixed in any tangible medium of expression." In other words, copyright law protects the particular way in which an idea or concept is expressed, but not the idea or concept itself (as opposed to patent law or trade secret law, which might). The work must be original, and it must be embodied in some tangible medium of expression from which it can be perceived, reproduced, or communicated. Protected works can include literary and dramatic works, visual arts, graphics, music, audio/visual works, and computer programs, among others. Copyrights may even apply to more than one aspect of a work; for example, both the source code and the screen displays of a software application would be separate works for copyright purposes.

Copyright generally refers to any one of six exclusive rights, each of which can be separately licensed or assigned: (1) make copies, (2) create derivative works, (3) public distribution, (4) public performance, (5) public display and (6) performance right (for sound recordings). Any exercise of one of those exclusive rights without a license from the owner is copyright infringement.

Copyrights in a work are separate and distinct from the ownership of any particular copy of a work. Thus, the "first sale doctrine" permits the owner of a particular copy to freely dispose of that copy without the copyright owner's consent. For example, an owner of a book can freely resell that particular copy of the book.

Ownership of copyrights

By default, copyrights to a work belong to the individual creator or creators of the work, unless the work is a "work made for hire," in which case the author is deemed to be the employer or commissioning party. A work is a work made for hire ONLY if it means one of these two tests:

(1) the work is created by an employee within the scope of his or her employment ("employee" means employee in the strict sense); or

(2) the parties agree in writing that it is a work made for hire, AND the work falls into one of these categories: (i) contribution to a collective work, (ii) part of an audiovisual work, (iii) a translation, (iv) a supplementary work, (v) a compilation, (vi) an instructional text, (vii) a test, (viii) answers to a test, or (ix) an atlas.

Misapplication of the concept of "work made for hire" is one of the single most common mistakes that companies make with respect to their intellectual property. In most circumstances, works created by non-employees are NOT works made for hire, even if an agreement states that they are. The best approach is to always include a written assignment of all copyrights relating to the work product.

Protecting copyrights

A copyright notice is no longer required under U.S. law, but it is still a good idea, because it may head off potential infringers or eliminate the ability of an infringer to claim that the infringement was "innocent." A proper copyright notice should be placed somewhere where it is reasonably likely to be seen, and should be in the following format: Copyright © [Name of Copyright Owner] [Year or Years of Creation]. All Rights Reserved.

The duration of copyright varies with the year in which the work was first published or registered, and the author of the copyright. Under the current law, works created by an individual known author are protected for the author's life plus 70 years. Works made for hire, and works by unknown individuals, are protected for the earlier of 95 years from the date of first publication or 120 years from the date of creation.

Federal registration is not a requirement for copyright protection, but there are benefits. Registration may allow the owner to recover attorney's fees and statutory damages. Registration also creates a presumption that the copyrights are valid and enforceable. Copyright registration is inexpensive and very easy. The Copyright Office website (www.copyright.gov) has all the necessary forms, clear instructions, and a telephone help line. It is worth the minimal time and effort to register any work of commercial value.

Fair use

Fair use is a defense to a claim of copyright infringement. There are four nonexclusive factors for evaluating whether a particular use is a "fair use":

(1) The purpose and character of the use, including its commercial nature.

(2) The nature of the work itself.

(3) The substantiality of the portion used compared to the work as a whole.

(4) The effect of the use on the market for the work.

These factors are weighed against the interest in protecting the author's exclusive rights to exploit the work. All of the factors are interrelated, although the economic components often dominate. Uses that are "transformative" in nature and have little to no impact on the commercial value of the work are often considered fair use. Examples of fair use could include using a photo of a work of art in a slide presentation to an art class, or quoting a small portion of a literary work for purposes of commentary or criticism.

The value of copyrights

Copyright assets can be valuable, and often overlooked, assets of a business. Web sites, marketing materials, logos, manuals, software, non-functional design elements of

products, checklists, and databases are just some of the many examples of types of assets that can be protected by copyright. The first step is to know what copyright assets exist; our intellectual property attorneys regularly perform intellectual property audits to assist clients with this process. In addition, understanding the basics of copyright law will help companies anticipate and avoid some common pitfalls and to protect those copyright assets that have commercial value to the company.

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