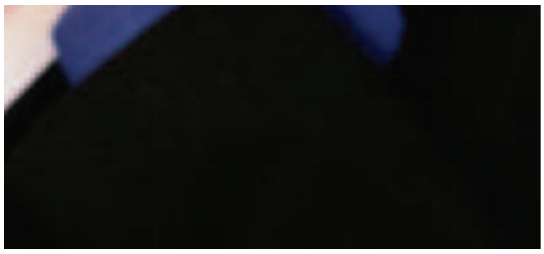
ideas on intellectual property law



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CARR
Intellectual Property Law

Protecting Your Share of the Marketplace.®

CARR LLP
670 Founders Square
900 Jackson Street
Dallas, Texas 75202
www.CarrIP.com
214.760.3000

Declaring dependence

Dependent patent claims and the doctrine of equivalents

You don't have to literally infringe a patent claim to be liable for patent infringement. You can also infringe a patent with an "equivalent." How does this work when the patent application starts out with independent and dependent patent claims? An important decision sorted this out.

WHAT'S THE DIFFERENCE?

There are two kinds of patent claims: independent and dependent. An independent claim contains all the ingredients of the claimed invention expressly, such as, "A gadget comprising an A, a B, and a C." A dependent claim also includes all the ingredients of the claimed invention, but not expressly. Some ingredients are incorporated by reference to some other claim, such as, "A gadget as in claim 1, further comprising a D."

The independent claim, which is incorporated by reference, is the "parent" of the dependent claims. A dependent claim, by its nature, consists of all the features of its parent claim, plus one or more additional features that make it narrower than the parent claim.

WHY USE DEPENDENT CLAIMS?

Why do patent attorneys employ dependent claims? For two laborsaving reasons. First it saves time writing. A patent attorney doesn't have to repeat the parent claim's words over again in a narrower claim. It's easier and faster simply to incorporate them by reference from a broader (parent) claim. And second, it saves the patent examiner a tremendous amount of time reading. It's immediately apparent exactly how the narrower dependent claim differs in scope from the broader parent claim, without having to compare them word by tedious word.

If the Patent and Trademark Office (PTO) examiner rejects the parent claim as too broad — and the attorney cannot overcome the rejection — it's standard practice for the attorney to cancel the broader parent claim and settle for the narrower dependent claim.

DOES AMENDMENT CHANGE SCOPE?

To be complete, however, every dependent claim has to have an independent claim as its ultimate parent. So you can't simply cancel the independent parent claim and leave the dependent claim sitting there in dependent form. You have to amend the broadest remaining dependent claim to expressly include the features of the now canceled parent claim. In other words, you must amend the broadest remaining dependent claim to make it an independent claim, to take the place of the broader, but canceled, parent claim.

When you amend a dependent claim to expressly incorporate the parent claim's features — instead of merely by reference — does that change the amended claim's scope? No, because the features expressly added by the amendment were always there, except that previously they were incorporated only by reference. Nothing changes except the mode of expression. It's merely a change of form — not of substance.

But, while the scope of that particular claim hasn't changed, the scope of the patent application as a whole has indeed changed, because the broader canceled parent claim is replaced by the narrower previously dependent claim. In effect, the patent attorney agrees to narrow the patent application's scope by replacing a broader claim with a narrower one.

WHAT IS THE IMPACT OF THE DOCTRINE OF EQUIVALENTS?

This distinction is important because of the doctrine of prosecution history estoppel. You can infringe a patent claim two ways: 1) literal infringement by an accused device or process that meets the terms of the claim exactly, or 2) infringement by an accused device or process that's equivalent to a claim term, although not meeting it exactly. The second way is referred to as the doctrine of equivalents.

But the doctrine of equivalents isn't available to a patentee if during the application's prosecution it was originally broad enough to encompass the accused device or process literally, and was later narrowed by amendment so that it no longer literally covers it. That is called the doctrine of prosecution history estoppel.

This estoppel doctrine has been around a long time. But in recent years it has been made more formidable by the Supreme Court's decision in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* The Court stated that any narrowing amendment is *presumed* to invoke an estoppel, unless the patentee can prove otherwise, which isn't easy to do. Therefore it's crucial to determine when a claim amendment is or is not a narrowing one.

HOW DOES ESTOPPEL AFFECT PREVIOUSLY DEPENDENT CLAIMS?

So, for estoppel purposes, how should we treat a dependent claim that is amended to make it independent, while its former parent claim is canceled? This question was raised by the Federal Circuit Court of Appeals in *Honeywell International Inc. v. Hamilton Sundstrand Corp.* Because of its importance, this decision was handed down by the full court of 12 judges instead of the usual panel of three.

The court ruled that the fact that a rewritten claim's scope has remained unchanged won't prevent the application of prosecution history estoppel because, by canceling the original independent claim and rewriting the dependent claims into independent form, the scope of the broadest subject matter claimed is narrowed to secure the patent. As a result of this decision, any accused device that falls between the scope of the canceled independent claim and the scope of the previously dependent claim is presumed *not* to infringe the amended claim under the doctrine of equivalents, absent a contrary showing.

WHAT DOES THE FUTURE HOLD?

This decision will no doubt cause quite a change in the way patent attorneys write and apply for patents. It may even open the door for more contentious litigation because insignificant changes in the wording of claim limitations that would have been incorporated by reference may now be reason for litigation.

An unforeseeable new rule?

One of the 12 judges dissented in Honeywell, saying the court's holding in effect means that restating a dependent claim in independent form is a "narrowing amendment" even though the claim was never rejected, amended or narrowed. This judge believes this new rule will cause patent applicants to use more independent claims, instead of the accepted protocol of presenting successively narrowed dependent claims for examination.

As a result, the dissenting judge believes this decision will increase the cost of patent applications because independent claims have a higher fee than dependent ones. In addition, examination will probably take longer because the use of dependent claims adds organization to the claims and makes them easier to understand. Most troubling, she believes, by adding presumptive estoppel to elements and limitations that were never a basis of rejection and never narrowed during examination, the court is eroding inventors' ability to protect their inventions.

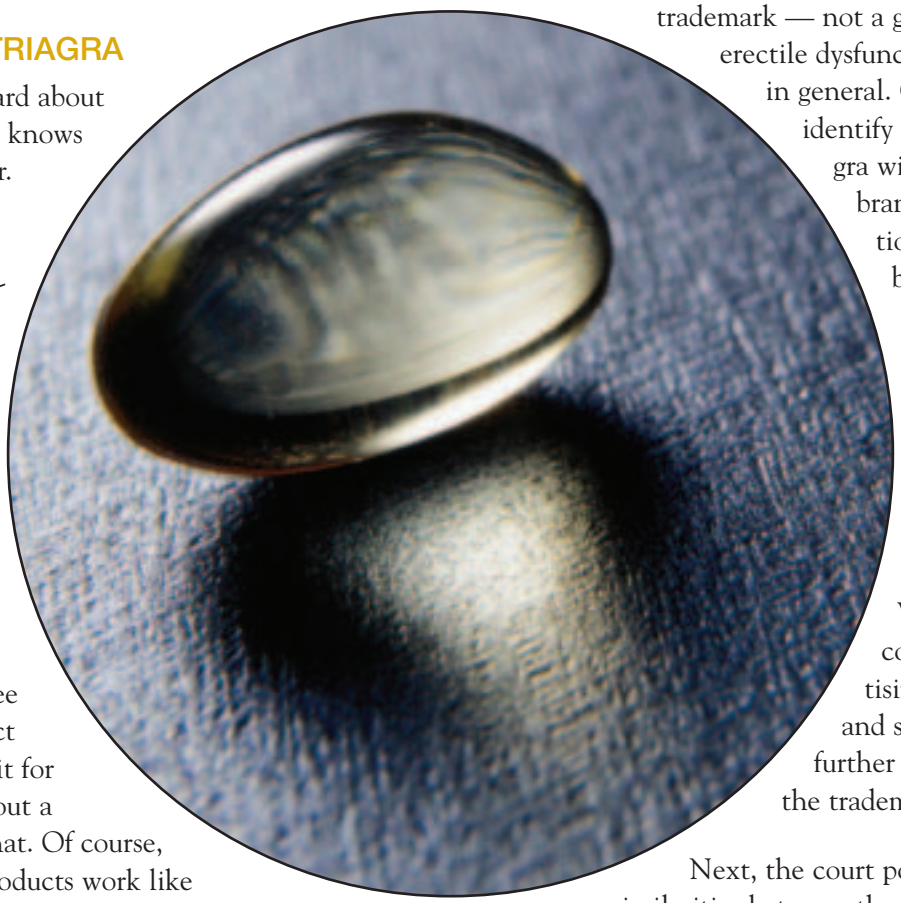
What's in a name?

Triagra loses battle for trademark rights

Some trademark infringement seems so obvious that you wonder why the competitor even tried to get away with using a confusingly similar name. Proving a likelihood of confusion — the benchmark of trademark infringement — isn't so tough when the competitor picks a name for its competing product that varies by only two letters. As an example, a recent case was an open and shut winner for Viagra.

VIAGRA VS. TRIAGRA

Everyone has heard about Viagra. Everyone knows what Viagra is for. Viagra is a trademark for Pfizer's brand of prescription drug. Yet everyone who uses e-mail has received advertisements for "generic Viagra," or some similar wording. These e-mails suggest that anyone is free to name a product Viagra and offer it for sale — and without a prescription at that. Of course, whether these products work like Viagra is another story.



In one case, Y2K Shipping & Trading Inc. decided to sell an herbal nonprescription product as a cure for erectile dysfunction. Y2K didn't call its product Viagra, or generic Viagra. It called its product by a completely different name: Triagra! Y2K met the issue of the product's effectiveness head-on by advertising that Triagra was "clinically proven," was FDA-approved, and had a 100% success rate — even though Y2K had no evidence to support any of those claims.

Pfizer promptly sued Y2K for infringement of its Viagra trademark. The court granted Pfizer summary judgment.

INFRINGEMENT

The court first noted that Viagra is a strong trademark — not a generic term for erectile dysfunction remedies in general. Consumers identify the name Viagra with a particular brand of prescription drug. Also, because Viagra is a coined word, it has no descriptive or suggestive qualities that would detract from its strength. Viagra's media coverage, advertising, promotion and sales success further demonstrated the trademark's strength.

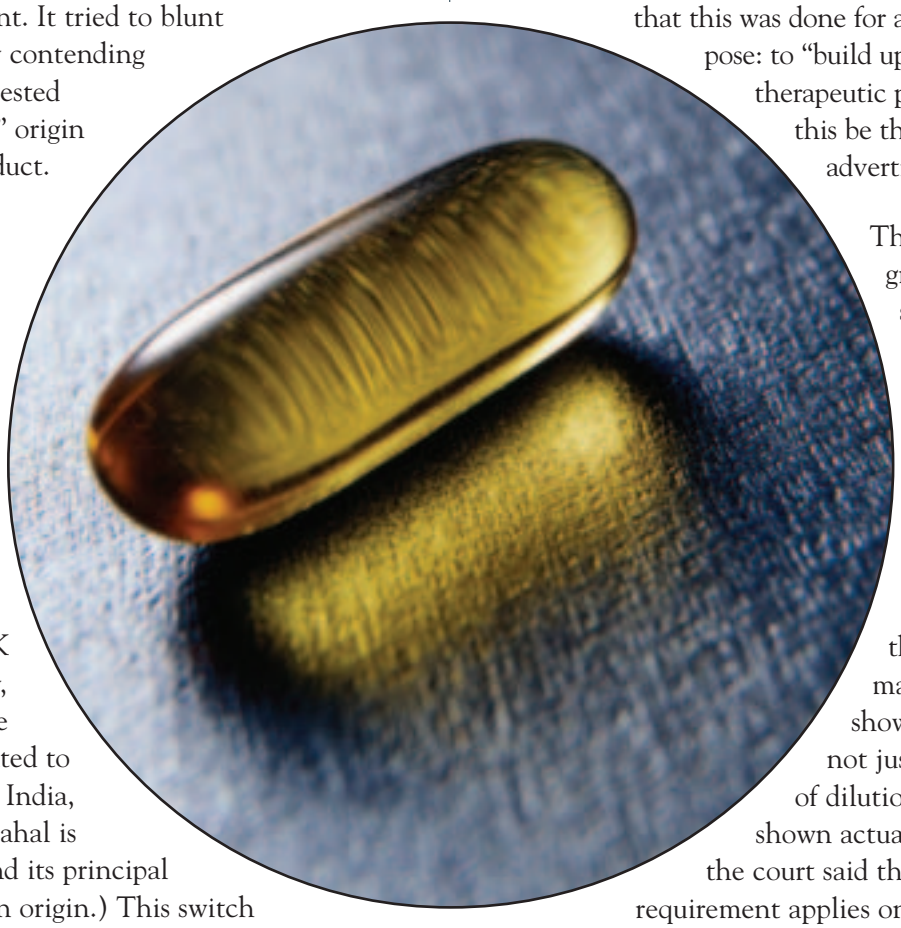
Next, the court pointed out the similarities between the marks Viagra and Triagra:

- They differ only in the substitution of "TR" for the "V" in Viagra.
- Both feature the sounds "I" and "AGRA."
- The letters "IAGRA" are the dominant visual feature of each mark.

Did it matter that Triagra is an herbal nonprescription product and Viagra a prescription-only chemical pharmaceutical? No. The court noted that the parties' products were in direct competition for the erectile dysfunction market, so the argument that the differences between the products would mitigate confusion didn't have a great deal of force.

SUSPICIOUS SIMILARITY

The court put a lot of emphasis on Y2K's choice of such a similar mark, which seemed *intended* to cause confusion in the marketplace. Y2K admitted to being aware of the Viagra mark at the time it selected the name Triagra for its herbal supplement. It tried to blunt this argument by contending that Triagra suggested the "agricultural" origin of its herbal product. Y2K said the resemblance between the marks "was coincidental and in good faith."



But the court wasn't buying this. And later in the court proceedings, Y2K changed its story, claiming that the term Triagra related to the city of Agra, India, where the Taj Mahal is located. (Y2K and its principal are of East Indian origin.) This switch came too late, and the court, in its skepticism, refused to admit the new story when it was submitted after a pretrial deadline.

Y2K had argued that doctors are too sophisticated to confuse Triagra with Viagra. True, said the court, but Triagra's target market for its nonprescription product is ordinary consumers, not doctors. And these consumers don't have a medical education to arm them against confusion.

For all these reasons, the court found that Triagra infringed the Viagra trademark and took the unusual step of granting Pfizer summary judgment to that effect.

FALSE ADVERTISING AND DILUTION CLAIMS

In addition to suing for trademark infringement, Pfizer also sued Y2K for false advertising and trademark dilution. The court granted summary judgment to Pfizer on its false advertising claim too. Y2K submitted absolutely no evidence of Triagra's effectiveness, its supposed clinical trials, FDA approval or the claimed 100% success rate. Indeed, Y2K admitted that they "exaggerated," but said that this was done for a laudable purpose: to "build up confidence for therapeutic purposes." Could this be the placebo advertising effect?

The court also granted Pfizer summary judgment on its trademark dilution claim. But what about the recently imposed requirement that the trademark owner must show actual harm, not just a likelihood of dilution? Pfizer hadn't shown actual dilution. But the court said the actual harm requirement applies only to federal dilution law. Pfizer had wisely withdrawn its federal dilution claim, and thereafter relied solely on New York state law for its dilution claim. New York law doesn't require a showing of actual dilution, so Pfizer's state dilution claim survived.

NOT THREE TIMES AS GOOD

Ultimately Pfizer succeeded on all of its claims against Y2K. Obviously, Y2K's trademark wasn't three times as good.

Get Reddy

Extending pharmaceutical patents

The Food and Drug Administration (FDA) withholds drugs from the market pending lengthy clinical trials and approval. A drug patent owner used to lose time from the patent's term while waiting for the FDA process to end. So Congress passed the Hatch-Waxman Act, which can extend a drug patent's term when it is consumed by the regulatory approval process. But does this extension apply equally to all patents? A recent case tackled this issue.

GENERIC MANUFACTURERS BENEFITED

To balance the effect of patent term restoration on the pharmaceutical market, the act contained additional provisions giving generic-drug manufacturers freedom from infringement liability during production and testing of generic counterparts intended for sale after patent expiration. It also gave generic producers the right to rely on a drug patentee's FDA clinical trial data to support regulatory approval of their generic counterparts.

The act gives generic-drug manufacturers freedom from infringement liability during production and testing of generic counterparts intended for sale after patent expiration.

TWO KINDS OF SALT

Pfizer owns a pharmaceutical patent claiming a compound having the common name amlodipine, and its salts. Pfizer obtained FDA approval for use of a drug in which the active ingredient was amlodipine, used in the form of amlodipine's

besylate salt. The company submitted clinical data based on both amlodipine besylate and amlodipine maleate, but chose to market the besylate salt because of its greater ease of tableting.

Pfizer's patent would have expired in 2003, but under the act it was extended until July 2006. Did this extension apply to all forms of amlodipine, or only to the form that Pfizer actually marketed (the *besylate* salt)?

PRODUCT IN COMMERCE

This question became critical when a generic pharmaceutical manufacturer (Dr. Reddy's Laboratories) filed a new drug application proposing to market amlodipine in the form of the *maleate* salt, for the same uses for which Pfizer had obtained approval. Reddy based its application on the same clinical trial data that Pfizer had provided to the FDA. Reddy argued that the patent-term extension applied only to the besylate salt, and therefore the patent was unextended and now expired for the maleate salt.

Pfizer disagreed and sued Reddy for patent infringement, claiming that the extended patent term covered all forms of amlodipine. The trial court agreed with Reddy, and dismissed Pfizer's lawsuit. The trial court reasoned that the patent term extension was limited to amlodipine besylate

because the act limits such extensions to the product's first permitted commercial marketing or use.

On Pfizer's appeal, Reddy argued that, in its request for the extension, Pfizer had identified the approved product as amlodipine besylate, so the extension applied only to the approved product. Pfizer responded that the FDA's approval described the approved product as simply "amlodipine."

Pfizer also claimed that the commercial marketing and use are the same for Reddy's form of amlodipine, and that the choice of salt doesn't affect the active agent — amlodipine. And Pfizer argued that if a change in the salt removes amlodipine from the act's term extension benefit to the patentee, it also removes it from the act's counterpart benefits to the generic producer, so Reddy couldn't rely on Pfizer's clinical trial data.

The appellate court noted that Reddy's FDA application relied on Pfizer's originally submitted data. This included testing of amlodipine as both the maleate and besylate salts. It found that the active ingredient is amlodipine, and therefore the drug is the same whether administered as the besylate salt or the maleate salt.

BALANCE OF EQUITIES

Most important, said the appellate court, the act strikes a balance between preserving the innovation incentive by extending a patent's term, and facilitating generic entry when the extended term expires. So giving the generic manufacturer Reddy the benefit of the act, while denying the corresponding benefit to the patent owner, would defeat the act's intent. The court therefore reversed the dismissal of Pfizer's patent infringement claim.

Working for statutory damages

Because it can be difficult to prove the actual dollar amount of a loss, the federal copyright statute provides that a copyright owner may elect to recover statutory damages — instead of actual damages and profits — for all infringements with respect to any one work. Does that word "work" mean that courts base the amount of statutory damages on the number of the plaintiff's *copyrighted* works that are infringed, or on the number of *infringing* works produced by the defendant? In a recent case that question made a difference of $1.4 million!

The plaintiffs owned copyrights in two songs. They filed a copyright infringement suit against the defendant, alleging that the defendant used the two songs on 16 different albums. They elected to seek statutory damages, rather than try to prove actual damages.

The trial judge decided that the infringement was willful, and awarded $100,000 for each of the 16 infringing albums — a total of $1.6 million in statutory damages. But later, a different trial judge, taking the same statutory damages rate used by the first trial judge ($100,000 per work), applied it to only the two infringed songs instead of the 16 infringing albums, resulting in an award of only $200,000. An appeal followed.

The appellate court agreed with the defendants that courts should base the award on the number of the plaintiff's infringed works, rather than on the number of the defendant's infringing works. But the appellate court didn't simply accept the second trial judge's award. The $100,000-per-work rate set by the first trial judge was discretionary. If the judge had known that the multiplier was only two instead of 16, he may have increased the amount of damages per work. So the appellate court sent the case back to the trial court with instructions to redetermine the amount of statutory damages.