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# Two Recent Decisions Involving The Hatch-Waxman Act

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Chemical Group Luncheon

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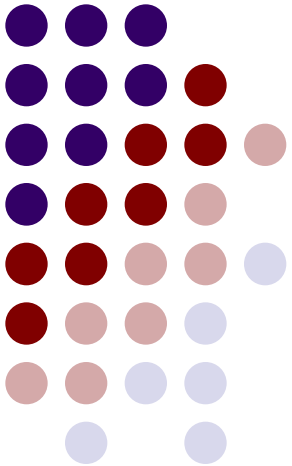


# *Sunovion v. Teva*

*Sunovion Pharmaceuticals, Inc.*

*v.*

*Teva Pharmaceuticals USA, Inc.*,

108 USPQ2d 1486 (Fed. Cir. 2013)

# *Sunovion v. Teva*

The Federal Circuit's recent decision in *Sunovion v. Teva* is significant in the common scenario in which a branded drug company asserts patent infringement against a defendant which is seeking FDA approval to sell a generic version of the branded drug. These patent infringement cases are usually brought under the Hatch-Waxman Act.

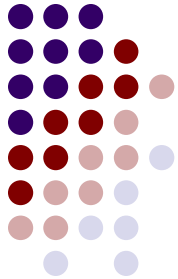
In this case, Teva Pharmaceuticals and Dr. Reddy's Laboratories filed an ANDA under the Hatch-Waxman Act, certifying that their proposed product did not infringe claims of Sunovion's U.S. Patent No. 6,444,673.

# *The Hatch-Waxman Act*

The Hatch-Waxman Act established a framework which was designed to facilitate the approval of new generic drugs, while at the same time ensuring that companies can enforce any patents that they have on those drugs.

The Hatch-Waxman Act provides for applications to sell generic versions of drugs which the FDA has already approved for use in the U.S. without incurring the expense of running their own clinical trials. This is done by filing an Abbreviated New Drug Application, otherwise known as an ANDA. The ANDA must establish, among other things, that the proposed generic product is “bioequivalent” to the existing branded product.

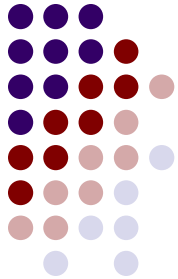
# *The Hatch-Waxman Act*



The idea is that by establishing bioequivalency, the generic applicant will have thus demonstrated that its product has the same effectiveness and safety that were shown in the clinical trials of the branded drug.

By avoiding the expense of developing the drug from scratch and running clinical trials, the generic manufacturer will usually be able to sell its product at a much lower price than the originator company.

# *The Hatch-Waxman Act*



If there are patents associated with the branded product and the generic manufacturer wants to launch its product before the patents expire, it must certify that its proposed product does not infringe any valid patent covering the branded product.

If the seller of the branded drug disagrees with that certification, it may file a patent infringement suit to prevent FDA approval of the generic drug until after patent expiration.

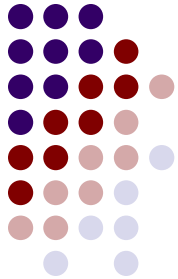
# *The Hatch-Waxman Act*

Generic drug companies filing ANDAs have to deal with competing considerations.

On the regulatory side, they want to make their product seem as similar as possible to the branded product in order to demonstrate bioequivalence and facilitate FDA approval.

However, on the litigation side, they often want to make their product seem different from the patent claims covering the branded drug so that they can argue non-infringement.

# *The Hatch-Waxman Act*



Generic manufacturers sometimes copy all or part of the labeling used for the branded product into their ANDA to facilitate FDA approval.

They then sometimes argue to the courts that, in order to avoid infringement, they intend to use a formulation which differs from the formulation recited in the ANDA when they actually manufacture their product.

As we will see, that approach no longer will work after the Federal Circuit's decision in *Sunovion v. Teva*.

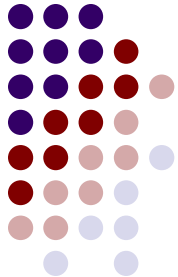
# *Sunovion v. Teva*

*Sunovion v. Teva* address a frequently disputed issue regarding how to determine infringement in Hatch-Waxman cases.

Hatch-Waxman cases differ from most other patent infringement cases because the patentee files suit before the defendant has begun selling its product. Therefore, instead of focusing on a product that is already on the market, the Hatch-Waxman infringement analysis must focus on the product that the defendant would sell if it were to obtain FDA approval.

A question unique to Hatch-Waxman cases is: what sources of information should a court consider in order to determine what the defendant will sell if it obtains FDA approval?

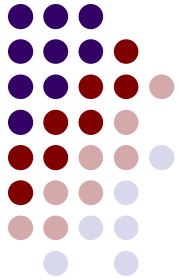
# *Sunovion v. Teva*



*Sunovion* held that if the ANDA describes an aspect of the defendant's product which is determinative of infringement, then the ANDA's description of the product controls. The defendant may not use extrinsic evidence to argue non-infringement.

The patent in *Sunovion* covered compositions of a drug which included less than 0.25 percent of a levorotatory isomer of eszopiclone. The defendant's ANDA sought approval to sell a product with between "0.0-0.6 percent eszopiclone.

# *Sunovion v. Teva*



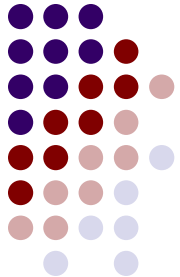
The defendant argued non-infringement by submitting a declaration vowing that the product to be marketed would always be outside of the range covered by the claims, alleging that the product to be marketed would contain 0.3-0.6 percent of the levorotatory isomer of eszopiclone, whereas the patent covered less than 0.25 percent.

The defendant also submitted internal manufacturing guidelines, which allegedly showed that the product would “contains at least 0.3 percent of levorotatory isomer.”

# *Sunovion v. Teva*

The Federal Circuit rejected these arguments and found infringement as a matter of law. The court explained that the defendant's evidence was irrelevant, stating that "What [the defendant] Reddy has asked the FDA to approve as a regulatory matter is the subject matter that determine whether infringement will occur, and the fact that Reddy either tells the court that its manufacturing guidelines will keep it outside the scope of the claims or has even filed a declaration in the court stating that it will stay outside the scope of the claims does not overcome the basic fact that it has asked the FDA to approve, and hopes to receive from the FDA, approval to market a product within the scope of the issued claims."

# *Sunovion v. Teva*



"Reddy's request for approval of levorotatory amounts from 0.0-0.6% is within the scope of the "less than 0.25%" limitation of the '673 patent claims."

The court observed that the defendant's pledge was unenforceable.

The court also remarked that, if the defendant really had no intent to infringe, it should not have requested approval to market a product within the scope of the patent claims.

# *Sunovion v. Teva*

The court rejected the defendant's suggestion that, if some batches of the generic product turned out to fall within the patent, then any harm could be addressed in a later infringement suit. The court explained that "it would be practically impossible for Sunovion, the FDA, or any court to monitor Reddy's compliance."

The court further indicated that such an approach would be inconsistent with the Hatch-Waxman Act, which is designed to achieve early resolution of patent issues before a generic manufacturer is permitted to begin selling its product.

# *Galderma v. Tolmar*

*Galderma Laboratories, LP*

*v.*

*Tolmar, Inc.,*

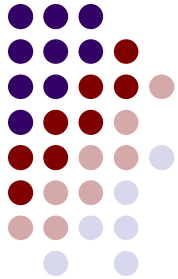
108 USPQ2d 1929 (Fed. Cir. 2013)

# *Galderma v. Tolmar*

This is a Hatch-Waxman case, based on Tolmar's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of Differin® Gel, 0.3%, which is a topical medication containing 0.3% by weight adapalene, approved for the treatment of acne.

Galderma sued Tolmar in the U.S. District Court for the District of Delaware, alleging that the product described in Tolmar's ANDA infringed Galderma's patents. The district court ruled in favor of Galderma. This appeal is from the district court's ruling on Tolmar's obviousness defense.

# *Galderma v. Tolmar*



At the time of the Tolmar invention, adapalene was a known compound. Certain prior art patents, referred to as the Shroot patents, disclosed topical adapalene compositions for the purpose of treating acne in a preferred range of 0.01%-1%. The asserted claims are directed to 0.3% topical adapalene compositions for the treatment of acne. This falls within the concentration range disclosed in the Shroot patents.

The CAFC indicated that "the Shroot patents disclose all of the limitations of the asserted claims, except for a precise teaching of 0.3% adapalene and the specific inactive ingredients of the asserted claims." The inactive ingredients of the asserted claims were, however, taught by an ancillary reference.

# *Galderma v. Tolmar*

On appeal, the sole dispute between the parties was whether it was obvious to use a composition containing a 0.3% adapalene concentration for the treatment of acne.

Tolmar argued that the asserted claims are obvious because they claim nothing more than the use of an old compound for a known purpose in a concentration that falls within a range disclosed in the prior art as preferred for that purpose.

# *Galderma v. Tolmar*

Tolmar's evidence in support of its obviousness argument included:

- A reference which used a lotion containing 0.3% adapalene in an animal model to determine that adapalene was particularly suitable for the treatment of acne.
- Prior art showing that 0.03% and 0.1% adapalene products were suitable for the treatment of acne.
- Prior art indicating that dermatologists want to have available to them acne treatments which come in varying concentrations.

# *Galderma v. Tolmar*

The district court did not agree with Tolmar that the patent claims were obvious.

The district court relied on evidence showing that increasing the dose of adapalene was likely to increase the incidence of certain side effects and evidence showing that 0.1% was considered the optimal adapalene concentration for the treatment of acne.

Also, the district court held that at least two secondary considerations – unexpected results and commercial success – additionally supported the determination that the asserted claims were not invalid due to obviousness.

# *Galderma v. Tolmar*

The district court found that the comparable tolerability of 0.1% and 0.3% adapalene was unexpected in view of the prior art, since a POSITA would have expected that tripling the concentration of adapalene from 0.1% to 0.3% would have resulted in a clinically significant increase in side effects.

The CAFC agreed that this result was unexpected, but held that it does not constitute an unexpected result that is probative of non-obviousness. The CAFC indicated that "where an unexpected increase in efficacy is measured by a small percentage, … the result constitutes a difference in degree, not kind. So too, where an increase by a percentage is expected but not found, that result is also likely only a difference in degree." 108 USPQ2d at 1934.

# *Galderma v. Tolmar*

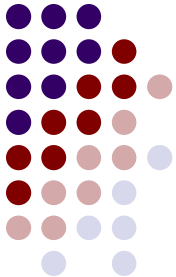
The CAFC held that, in this case, the expected result was an increase, by some percentage, in the prevalence of certain side effects. The failure of that percent increase to materialize, although unexpected, constitutes only a difference in degree from the prior art results. According to the CAFC, therefore, the comparable tolerability of 0.1% and 0.3% adapalene – that is, the failure of the higher dose to cause side effects not caused by the lower dose – did not indicate that the asserted claims are non-obvious.

# *Galderma v. Tolmar*

Regarding commercial success, the CAFC indicated that evidence of commercial success is only significant if there is a direct connection between the claimed invention and the commercial success.

In this case, the district court had made two findings in its holding as to commercial success. First, that Differin® 0.3%, Galderma's commercial embodiment of the claims, "quickly gained and maintained market share - even in the face of an overall declining market and decreasing promotional expenditures, and while facing competition from generic 0.1% adapalene formulations." Second, that, according to the district court, "Tolmar … seeks to enter the market precisely because Differin® 0.3% has been commercially successful."

# *Galderma v. Tolmar*



The CAFC indicated that the mere fact that generic pharmaceutical companies seek approval to market a generic version of a drug, without more, is not evidence of commercial success relevant to the non-obviousness of patent claims. The CAFC noted that Tolmar believes that it can make a profit selling a generic version of the claimed invention. “This is likely true in all Hatch-Waxman cases, if not all patent cases generally.” However, the CAFC said, that fact reveals very little about the level of commercial success of the patented invention relative to the prior art – or the extent to which the commercial success of the branded drug is due to the merits of the claimed invention beyond what was readily available in the prior art. Accordingly, the CAFC held that the commercial success in this case does not support a finding of non-obviousness.

# *Galderma v. Tolmar*

The CAFC indicated that, in general, “Commercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art.”

However, the CAFC cautioned that where market entry by others was precluded due to blocking patents, the inference of non-obviousness of asserted claims based on evidence of commercial success is weak. In this case, the Shroot patents had blocked the market entry of 0.3% adapalene products until their expiration in 2010. Therefore, no one could have successfully brought to 0.3% to market prior to 2010.

# *Galderma v. Tolmar*

Dissent by Judge Newman, who summarized the district courts' findings as follows:

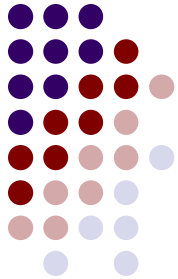
The district court found that Galderma's Differin® 0.3% gel quickly gained and maintained market share a crowded market for treatment of acne. The district court agreed with Galderma that Tolmar seeks to sell the 0.3% formulation precisely because that formulation is preferred by consumers over the 0.1% formulation. The district court found that the availability of cheaper generic 0.1% adapalene after the expiration of the Shroot patents did not appear to have affected consumer demand for the Differin® 0.3% product, whose market share and revenue were not explained by promotional activity, since marketing expenditures for Differin® 0.3% had actually decreased.

# *Galderma v. Tolmar*

Judge Newman noted that her colleagues had discount the factor of commercial success, arguing that the entry of 0.3% adapalene products, by Tolmar or others, had previously been blocked by the Shroot patents.

She made the point, however, that the evidence in the district court was that the 0.3% product was successful against the 0.1% product and other acne medications. Judge Newman contended that the district court did not err in including evidence of commercial success in its evaluation of the question of obviousness.

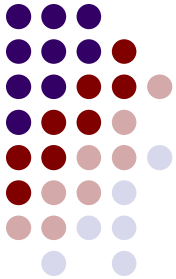
# *The Hatch-Waxman Act*



*Galderma* holds that the fact that a generic pharmaceutical company has filed an ANDA seeking approval to market a generic version of a drug is not in itself evidence of commercial success relevant to the non-obviousness of patent claims, and that commercial success is not probative of non-obviousness when it could be attributed to the expiration of patents rather than to the invention itself. *Galderma* also holds that unexpected results of low magnitude may not be probative of non-obviousness.

*Sunovion* holds that infringement under the Hatch-Waxman Act is determined by the language of the ANDA application, and not by what the defendant alleges that it will actually be manufacturing.

# *The Hatch-Waxman Act*



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