

Waxman-Hatch litigation strategies for generic and brand companies

The Waxman-Hatch Act offers opportunities to manufacturers of both brand and generic drugs in terms of market entry and exclusivity periods. A canny and fluid litigation strategy can help parties to take best advantage of the provisions available

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The Drug Price Competition Act and Patent Term Restoration Act of 1984, commonly known as the Waxman-Hatch Act, created a streamlined procedure for the approval and marketing of generic drugs through the filing of an abbreviated new drug application (ANDA). Before the enactment of Waxman-Hatch, the Food and Drug Administration (FDA) approved drugs only pursuant to a new drug application (NDA), which required that the applicant prove the safety and efficacy of its drug through extensive clinical testing. Waxman-Hatch allows an ANDA applicant to document the therapeutic equivalence of its generic product to the approved brand-name drug and rely on the data provided for the branded drug's proof of safety and efficacy. By obviating the need for expensive clinical testing, Waxman-Hatch greatly facilitates the entry of lower-priced generic drugs into the market. In return, owners of branded drugs are granted protection against generic competition for a fixed period (marketing exclusivity), and the regulatory scheme is designed to expedite the resolution of patent disputes before the marketing of the generic drug.

Regulatory framework

Under Waxman-Hatch, the FDA publishes a list of patents claiming the brand drug or its method

of use in the so-called Orange Book (published as an actual book with an orange cover, the Orange Book is now maintained on the FDA's website at www.accessdata.fda.gov/scripts/cder/ob/default.cfm). It is important that NDA holders list all relevant patents with the FDA in a timely and proper fashion, as without such a listing the statutory triggers for Waxman-Hatch litigation will not be set in motion. An ANDA applicant is required to file a certification regarding each Orange Book patent, stating one of the following:

- The patent has expired.
- Marketing approval is not being sought until the patent expires (a Paragraph III certification).
- The patent is invalid, unenforceable or would not be infringed by marketing of the ANDA product (a Paragraph IV certification).

A Paragraph IV filing is considered to be a technical act of patent infringement and gives the innovator company the right to initiate a patent infringement suit. The ANDA applicant must notify the owner of the NDA and the owner of any listed patent for which a Paragraph IV certification was made that the ANDA and certification have been filed. The notice must be accompanied by a detailed statement of the factual and legal bases for the applicant's opinion that the patent is invalid, is unenforceable or has not been infringed. If the owner of a listed patent sues for patent infringement within 45 days of receipt of notice, the FDA is barred from approving the ANDA for 30 months. The availability of this automatic stay provides an incentive for the patent owner to litigate.

Conversely, Waxman-Hatch also provides an incentive to challenge invalid or

unenforceable patents or patents that would not be infringed by marketing of the generic drug by rewarding the first ANDA applicant to file a Paragraph IV certification with an extremely valuable 180 days of generic exclusivity if the first filer prevails in litigation. This generic exclusivity prevents the FDA from approving another ANDA containing a Paragraph IV certification for six months after the earlier of the date of the first commercial marketing of the first ANDA product or the date of a court decision holding the relevant patent invalid, unenforceable or not infringed.

Generic exclusivity can be forfeited if the ANDA is not approved within 30 months of filing or if the applicant fails to market its approved product within 75 days of certain triggering events, including approval of the application and a final adjudication of all patents to which a Paragraph IV certification was filed.

Litigation strategies for generic and brand companies

Whether to file a Paragraph IV certification

When the listed patent is a method-of-use patent and the drug is approved for more than one use (or indication), an ANDA applicant can submit a statement of unapproved use in lieu of a certification. The statement asserts that the claims of the listed patent do not cover a use for which the applicant is seeking approval. One of the first elements of the generic strategy is to decide whether to file a Paragraph IV certification or a statement of unapproved use regarding listed method-of-use patents. In contrast to a Paragraph IV certification, a statement of unapproved use does not require the patent owner and NDA holder to be served notice. If such method patents are the only patents listed, the patent owner/NDA holder will not know that an ANDA containing only statements of unapproved use has been filed and will be unable to sue. Moreover, because the 30-month stay applies only to an ANDA containing a Paragraph IV certification, even if the patent owner were aware of the ANDA containing no Paragraph IV certifications, it would not be entitled to the lucrative stay of approval.

An ANDA applicant that expects its ANDA to be the first filed may choose to submit a

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Paragraph IV certification with the hope that subsequent applicants will do the same and will be blocked by its exclusivity. However, even if the ANDA is first, its Paragraph IV certification will not block subsequent applicants that file a statement of unapproved use. Moreover, if the applicant is not first, filing a Paragraph IV certification as opposed to a statement of unapproved use may subject it to the first applicant's exclusivity. Sometimes there is as much litigation between competing generic manufacturers on entitlement to exclusivity as between ANDA applicants and the brand company.

Time considerations

In ANDA litigations, time is generally the friend of the patentee/NDA holder and the foe of the ANDA applicant. Every day that the ANDA applicant is not on the market is another day of monopoly pricing and profits for the patentee/NDA holder and another opportunity for it to switch the market to a reformulated product with which the ANDA product will not be interchangeable or a second-generation drug (eg, a prodrug or enantiomer of the original drug). Thus, during the 30-month stay of FDA approval, the ANDA applicant generally tries to hurry the resolution of the suit, while the brand company seeks to slow down resolution to take maximum advantage of the 30-month period.

After the 30-month period expires, the

roles may be suddenly reversed. With the ANDA applicant now free to market the generic drug, the brand company often moves quickly to prevent or restrict competition through one or more of the following measures:

- Seeking a preliminary injunction or even a temporary restraining order.
- Changing the formulation and/or prescribing information of its drug to mirror the claim language of a newly issued patent.
- Marketing a different product containing a different active ingredient.
- Marketing an authorised generic sold under the FDA's approval of the NDA, but with a generic name and at a lower price.

Whereas motions by a defendant to dismiss a suit for having been brought in an inappropriate jurisdiction or to transfer to a different jurisdiction are common in patent

litigation, they are less common in ANDA litigation. The importance of celerity to the ANDA applicant means that the value in potentially having the suit dismissed or obtaining a preferable forum must be balanced against the time it takes to resolve it. Again in the interest of expediency, an answer to the complaint in an ANDA patent litigation is apt to be short and contain relatively few counterclaims, other than counterclaims for declarations of invalidity, non-infringement or unenforceability.

When there is more than one listed patent

When faced with multiple listed patents, especially with widely differing expiration dates, the ANDA applicant must decide when to file its application and which patents to challenge. If the ANDA applicant decides not to challenge some early expiring patents and to file Paragraph III certifications, litigation on the Paragraph IV certified patents may conclude before the Paragraph III patents have expired, resulting in forfeiture of the generic exclusivity. If the ANDA applicant decides to wait until the first patents are about to expire, another applicant may be the first to file and thus be the recipient of exclusivity. In a recent case the ANDA applicant took the first course of action, then successfully moved the district court to stay the action for five years, thus preventing forfeiture.

Discovery

Discovery is expensive and time consuming. The ANDA applicant must balance the plaintiff's need for discovery and the cost and burden of responding to the plaintiff's requests against the delay which will likely ensue if the parties cannot agree on a discovery plan or if defendants are forced to compel discovery from the plaintiff. The Waxman-Hatch Act potentially provides some relief: if a court finds that a party has been dilatory in discovery, it may shorten or lengthen the 30-month stay of approval of an ANDA application accordingly.

Expert testimony

ANDA litigation typically entails complicated technical and legal issues, making the retention of experts in the relevant technology

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or practice a necessity. Here, the NDA holder/patentee is at an advantage because it will have retained many technical experts in the course of developing its drug product and gaining approval for the NDA. In contrast, the generic company may lack internal expertise in certain technical areas relating to the patent. Because of additional difficulties in finding experts in the United States who are not conflicted from assisting their client, counsel for the ANDA defendant should begin an early search for the best experts available even before the complaint is filed and the detailed statement of factual and legal bases is prepared.

Summary judgment motions

Because summary judgment motions can dispose of a case before trial, they are usually not favoured by ANDA plaintiffs. The defendant generic company has a more difficult decision. While summary judgment motions can dispose of some or all issues before trial, they do not necessarily accelerate the final decision, even when successful. A partial summary judgment on some, but not all issues (eg, invalidity or non-infringement of some, but not all of the claims) can reduce the issues for trial, but by requiring the court to take the time to address the motion, may delay the start of the trial. And if the motion is unsuccessful, it will generally delay trial.

A summary judgment motion is generally most effective when brought by the party that does not bear the burden of proving the disputed issue. Thus, because the patentee bears the burden of proving patent infringement, a well-presented motion for summary judgment of non-infringement (brought by the ANDA applicant) may succeed where the only issues genuinely in dispute

relate to claim construction (ie, how the patent should be interpreted), rather than to the chemical composition of the accused product or its use, since the presence of a genuine disputed issue of material fact will defeat the motion. Because the patentee bears the burden of proof, summary judgment of infringement (brought by the patentee) may be more difficult. Finally, because US patents are presumed to be valid and must be proven invalid by clear and convincing evidence, summary judgment of invalidity (brought by the generic applicant) is rare.

Claim construction and Markman hearings

Claim construction – the process of determining the precise meaning of the claim terms and therefore of the overall claims – is sometimes performed at a relatively early stage in the process in a so-called “Markman hearing”. In many cases, the court’s construction of the claims is dispositive of the issue of patent infringement or validity, and is therefore often the pivotal factor in determining whether an ANDA applicant will be allowed to commercialise its product. Consequently, both parties to the litigation must, from an early stage, contemplate claim construction possibilities and develop a strategy for achieving an acceptable claim construction. From the perspective of the ANDA applicant that sets the litigation wheels in motion, it is vital to thoroughly consider, even before filing a Paragraph IV certification, possible claim constructions that may be asserted in likely forthcoming patent infringement litigation.

Because ANDA actions are typically decided by a judge rather than a jury, some judges may not hold a separate hearing, but may consider

claim construction at trial. In either event, claim construction may be the most important single event in the course of an ANDA litigation. Both plaintiff and defendant should therefore put maximum effort into obtaining a favourable claim construction. Extensive discovery should be taken on each issue of claim construction; sufficient deposition time for claim-construction issues should be allotted to experts, inventors and related investigators who may provide evidence of the understanding of one of skill in the art; and trial-like investment should be made at all levels of preparation. Particular emphasis should be placed on drafting briefs that clearly and concisely present the relevant issues, including technical data and the testimony of experts.

Remedies

Remedies for infringement in an ANDA patent litigation are generally limited to those set forth in the Waxman-Hatch Act – namely, delaying FDA approval of an infringing drug product until expiration of the infringed patent or granting an injunction to prevent the commercialisation of an approved product. Monetary damages are available only in exceptional cases where the ANDA product has been approved and marketed prior to trial. In addition, a court may award the prevailing party reasonable attorneys’ fees and/or treble the award of monetary damages in exceptional cases involving wilful infringement, inequitable conduct or litigation misconduct. Because an ANDA filing is only a technical act of infringement, the courts have held that the mere filing of an ANDA application or certification cannot support a finding of wilful infringement and an exceptional case can arise only if accompanied by other factors, such as the defendant’s misconduct during the ensuing litigation. However, the marketing of the ANDA product before final resolution of the case, if later found to be infringing, can support the charge of wilful infringement, the finding that the case is exceptional and the imposition of monetary penalties.

Litigation settlement

Settlement of Waxman-Hatch litigation may terminate the 30-month stay of approval and may provide an agreed timing for entry of the

generic drug into the market. Increasingly, suits are being settled on terms under which the brand pays the allegedly infringing generic manufacturer a substantial sum in exchange for not proceeding with its non-infringement, unenforceability and/or validity challenges of the brand’s patents and delaying market entry of the generic product. These so-called “reverse payment” or “pay-for-delay” settlements have been denounced by the Federal Trade Commission and the Obama administration’s Department of Justice as anti-competitive practices that violate antitrust laws. However, several recent decisions by appellate courts, including the Federal Circuit, have upheld the legality of reverse payment settlements. In light of these court decisions, bills have been introduced to make most such settlements presumptively illegal. *iam*



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