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The authors provide advice to in-house counsel to prepare for patent litigation under Hatch-Waxman.

The Challenger Is Prepared, Are You? Strategies for Preparing to Enforce Patents Covering Pharmaceutical Products

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Your company's new product is doing very well, and sales are increasing. Management is looking to you, the chief IP counsel, for guidance on how to use the company's patents to protect the market for this important product. Data exclusivity may not exist or may be ending soon. You are sure that someone will try to sell a generic version and you want to be prepared to enforce your company's hard-won patents.

If your company's product is a small molecule product subject to a Hatch-Waxman Act challenge, your company will have only 45 days to decide whether to file a patent infringement action against the challenger in order to obtain the 30-month stay of Food and Drug Administration approval provided by the act. This deadline makes it especially important to be prepared if any challenge can be anticipated.

How do you figure out what potential challengers are doing? What issues are likely to come up in litigation? Set out below are a few key steps you can take to prepare management and key personnel for litigation that may determine the fate of this product.

Whether the litigation is triggered by the challenger's patent notice required by the Hatch-Waxman Act, or by potential competition from a similar biologic product in the same class as your company's product, one key to long-term success is thorough and effective early preparation.

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Do Your Homework to Find and Assess Potential Challengers

The first place to start is making sure you have good information available on potential challengers. There are many good sources of market intelligence. Patents, published patent applications, and prosecution histories can yield particularly useful information about the direction a generic challenger is taking. You also can research potential challengers using press releases, corporate financial statements, and regulatory information such as clinical trial reports and FDA reports on Drug Master File, or DMF, applications.

Analyst reports are another fruitful source of information. A structured program to monitor various sources of publicly available information can be very effective in piecing together disparate bits of information into a useful picture of the competitive landscape.

For example, bioequivalence clinical trial information can reveal the status of efforts to show that a potential competitor is ready for commercial sale. However, bioequivalence clinical trial information is often sketchy. For example, a trial may be identified only by a drug number code, without stating what the active pharmaceutical ingredient is. But this code may be mentioned in corporate news reports, financial statements, or publicly available articles and presentations. Drug codes may also be mentioned in patent applications and/or prosecution histories.

In addition, DMF applications will reveal which companies are planning to introduce an active pharmaceutical ingredient in the United States, long before a formulation is finalized. DMFs are listed on the FDA's website and updated frequently. When combined with information from private market research and sales people in the field, it is possible to make good guesses as to which competitors are planning to challenge your patents, and when. Often, a competitor will begin selling a formulation outside the United States, perhaps in India or Eastern Europe, which can signal a potential U.S. challenge.

If there are other brand drugs in the same class as your company's product, it would also make sense to monitor public information about challenges to those drugs, such as DMF filings, Abbreviated New Drug Applications, and associated FDA approvals, whether they are tentative or final. Challenges to related brand drugs are often made by the same generic company, and its processes to make the related brand drugs may be very similar. Consequently, a challenge to a related brand drug may provide some insight into potential challenges to your company's product.

Preparing to Defend Your Hard-Won Patents From Infringement

Now that you've determined a challenge is likely, researched potential challengers, and hopefully obtained some information on likely generic formulations, the next step is to consider the defenses and claims that are likely to be raised. It may make sense at this point to line up outside counsel, clear conflicts, and set a budget to permit them to come up to speed on the key facts and to assist in considering the legal issues.

If the Hatch-Waxman Act applies to your company's product, it would make sense at this time to reconsider whether all of the right patents have been listed in the Orange Book. Orange Book listing decisions are important because under the Hatch-Waxman Act, a generic challenger that wants to sell a competing product before the patents expire must certify that any listed patent is either not infringed, invalid, or unenforceable. The patent owner can then sue for infringement and, if it declines to file suit, the challenger may be able to seek a declaratory judgment.

In either case, litigation may be imminent. It is therefore better to consider listing decisions well in advance, rather than after a litigation is imminent or has been instituted. It is generally not necessary to list process patents but they can be asserted in litigation, so they should be considered in any pre-suit analysis. Use patents can be listed in certain circumstances, and should also be considered in analyzing which patents are listed in the Orange Book, as well as any infringement analysis.

There are many useful steps you can take in assessing how a litigation is likely to proceed. You should start by stepping back and considering what evidence will be necessary to prove infringement, and what potential validity challenges might be raised.

A first step might be to ensure a prior art search has been performed on any applicable patents and think about what related invalidity arguments are likely to be made. You can look at the prosecution history of the patents with a critical eye. What arguments would you make if you were the challenger, trying to limit or invalidate the patents? Consider whether you have doctrine of equivalents limitations, or whether you can assert a broad scope of equivalents. If such exercises are performed sufficiently in advance, they may reveal flaws in patent protection that can be corrected before litigation ultimately commences. For example, it may be possible to seek and obtain a patent continuation, reexamination, or reissue that can fix a gap in coverage or a potential invalidity issue.

You should also begin at this stage to ascertain the invention story and develop litigation themes supported by internal information that ultimately may be disclosed in discovery. While U.S. discovery can be very wide-ranging, it is usually possible to make reasonable estimates and forecasts about what documents and groups of documents will likely be relevant to the issues in the litigation and to start thinking about what documents will be produced.

It may make sense to conduct an initial review of those documents to anticipate particular issues that might come up. Because of the wide scope of discovery in U.S. cases, litigation and prosecution on related foreign patents often becomes evidence in a U.S. litigation. For that reason, your preparation should include if possible reviewing foreign evidence for statements and arguments that a challenger might assert against you in the United States.

It is usually possible to identify some people who are likely to be the subject of depositions. Certainly, inventors of the patents at issue are likely to be witnesses, if they are available. There may be people who are particularly important from a marketing or business perspective, and so you should consider making contact with those people in order to evaluate them as a potential witnesses.

Often, inventors can be excellent witnesses for the patent owner because they can provide a personal story of invention. Talking with people who have personal knowledge of the invention is also the best way to un-

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cover any potential challenges based on alleged incorrect inventorship or alleged prosecution disclosure misstatements or omissions.

If likely deponents are in another country, it may make sense to think about what the legal requirements are for either bringing them for a deposition in the United States, or holding a deposition in their country of residence. And, of course, likely witnesses may be former employees. You can anticipate that the challenger will seek to contact former employees to determine whether or not they are willing to appear as a witness. It may make sense for you to find out what they will say beforehand, so that you can think about how that information is likely to play out.

In a pharmaceutical patent infringement action, one of the most important aspects of the evidence is expert testimony. Experts are almost always used in addressing validity issues like anticipation and obviousness under 35 U.S.C. §§ 102 and 103. Their testimony will also be necessary on any enablement or description issues under 35 U.S.C. § 112. And of course, experts are also critical for infringement.

Experts can also provide good advice on outside testing laboratories and/or internal testing protocols. So, where you know that a certain patent is likely going to be in litigation, it often makes sense to try to identify and retain relevant outside experts early, even before a suit is filed. Every patent is situated in its own area of technology, and cases can be won or lost based on the quality and preparation of experts.

To check on how strong an expert will be in litigation, it may make sense to review relevant publications authored by a proposed expert, because these will likely be used in cross-examination. Likewise, other cases where the expert has provided an opinion or testimony may come up, and so it may make sense to obtain and review an expert's earlier opinions or testimony, if available.

Infringement is usually proven in part through the testing of samples of the challenger's product. In a Hatch-Waxman action, where the product is not yet on the market, the product to be analyzed for infringement is the product that is likely to be sold if the product is approved.

So, being able to test samples obtained from the challenger which may have been submitted to the FDA is very important. A challenger may provide these samples after its notice letter but before the 45-day deadline to secure a 30-month stay and, depending on the circumstances, you may be expected to have evaluated those samples before filing suit.

This leaves only a narrow window to complete any pre-suit testing, so it may make sense to try and line up relevant testing capability beforehand. That testing can be done by outside experts, outside testing laboratories or, with permission from the challenger, in-house technical experts.

In any event, it will be important to have experts and testing capabilities ready to hit the ground running when a notice letter and samples come in. In fact, it may be possible and desirable to get a head start by obtaining samples of products containing the same active ingredient being sold by the challenger in foreign markets. These foreign samples, while not necessarily the same as U.S. samples, may provide some insight into the issues that will be encountered in a U.S. litigation.

Another important issue to consider is where an action is likely to be brought. Think about where potential defendants are likely to be found, and then what courts would be considered good ones to hear the case. For pharmaceutical patent litigation, the U.S. District Court for the District of New Jersey is a popular place to bring cases because of the number of pharmaceutical companies in that state and the experience of the federal judges in the district. There are other districts that are known for having faster dockets, however, and the speed of the court may be a concern. Other factors to consider in deciding where to bring an action include the location of the likely witnesses, and whether subpoenas will be necessary in order to obtain their testimony at trial.

New Jersey has joined other districts and adopted patent-specific rules that can accelerate Hatch-Waxman patent litigation. These rules require that the generic challenger's Abbreviated New Drug Application be produced very promptly, before the initial scheduling conference, and that infringement and validity contentions be exchanged within two months of the initial scheduling conference.

These rules are similar in that respect to rules in the Eastern District of Texas and the Northern District of California. Preparation is arguably even more important in those courts, where the rules further require a plaintiff to present its claim construction and other key positions quite early in the case.

Conclusion

Even before a specific challenge is received, prudent in-house counsel can do a lot to get ready for challenges to the patents protecting their company's key products. Early research and consultation with outside counsel will make the process smoother and lead to a more effective defense.

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