A practical guide to patent trial discovery

The scope and importance of discovery during US patent trials cannot be underestimated. Jack Griem explains how the process works, and highlights the best way to get the most of the system.

The pre-trial discovery phase in US patent litigation is notorious for being time-consuming and expensive. In a typical case, the issues regarding patent infringement, validity, enforceability, and damages require input from technical, business and marketing personnel and internal legal support. Preparing for and managing discovery is, therefore, critical to succeeding in litigation.

This article provides practical advice useful in pursuing discovery intelligently in patent litigation, focusing on pharmaceuticals and biotechnology litigation. As with most things, planning – as opposed to reacting – is key. Comprehensive pre-suit investigations provide counsel with the best possible understanding of the facts, which results in more focused and efficient discovery efforts. Counsel and client should work together to utilize both traditional discovery tools, including document requests, interrogatories, depositions, subpoenas, and expert disclosures, as well as informal sources, such as public libraries, the Internet, and government sources.

US law also provides an often-overlooked avenue to obtain discovery in aid of a proceeding outside the US. This avenue should always be considered where one of the parties is resident in the US.

Advance planning is critical

In all cases, the pre-suit investigation should include a thorough review and understanding of the patents at issue, prosecution histories and other relevant evidence (such as the prior art cited during the patent application process). This pre-suit investigation, as well as the litigation management and coordination, is best accomplished by a dedicated group of people who can provide assistance to the legal team and coordinate and manage activities. Members of this group might include in-house and outside lawyers as well as in-house technical, business and marketing personnel. Such a team composition will assist in coordinating activities between any related litigations (in the US and abroad), help minimize disruptions within the company, resolve litigation-related issues as needed, and at the same time assure that in-house assistance is timely and efficiently provided.

One task which the litigation team should address early is identification and retention of outside experts for non-testifying and testifying roles. These in-house and outside technical experts will assist in making determinations regarding what, if any, testing to conduct and when it should be conducted. Early involvement of counsel also permits the client to take full advantage of exceptions to the US discovery requirements for work performed under the direction of counsel (which is protected from disclosure under the work-product doctrine).

An early understanding of the patents, prior art and products at issue is even more critical in pharmaceutical cases that might be brought under the Hatch-Waxman Act, given the disclosure requirements and relatively short time period for bringing suit. This Act requires a party to notify the owner of patents covering a branded pioneer drug within twenty days of filing an Abbreviated New Drug Application (ANDA) with the United States Food & Drug Administration (the FDA) seeking approval to market a generic product before the patents expire. The Act provides that the patentee must initiate suit within forty-five days of receiving notification of the ANDA filing in order to take advantage of a 30 month stay in approval of the ANDA.

Strategic use of traditional discovery tools

The scope of discovery in the US, in comparison to other countries, is generally speaking very broad. The Federal Rules of Civil Procedure allow discovery into any unprivileged matter which is relevant to the claim or defense of any party. Discovery is not limited to information admissible at trial. A party can obtain discovery of information if it appears "reasonably calculated" to lead to admissible evidence. Because discovery is linked to the asserted claims and defenses, parties should consider discovery issues when crafting initial pleading documents, including whether to provide more detail than is required to give legally adequate notice of the claims being asserted.

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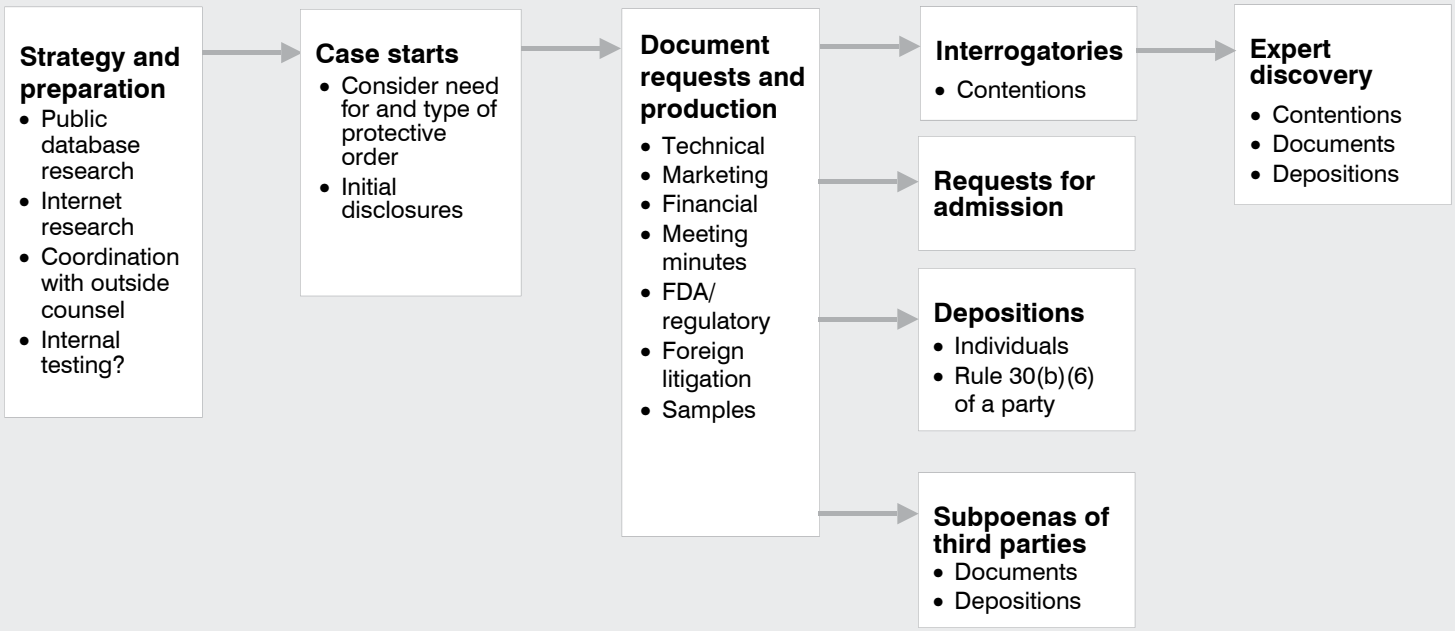
As shown in the box overleaf, the Federal Rules allow discovery regarding any unprivileged matter which is relevant to the claim or defense of any party. Accordingly, parties can obtain documents and information which may at first appear only tangentially related to the action. For example, documents relating to other projects manufactured by the parties which use the same active or inactive ingredients as the products at issue, while not strictly necessary to proving whether the product at issue does or does not infringe, may provide information useful for understanding the formulation of the product. The parties may agree to limit the scope of discovery. Barring an agreement, a party may attempt to understand the breadth of discovery permitted by a particular court by filing a well-founded motion for a protective order early in the case.

The usual path of discovery



In pharmaceutical or other cases involving government regulated products, the parties should request FDA submissions relating to the products covered or alleged to be covered by the patents at issue, as well as any internal company records like log books and correspondence with the FDA. These documents provide information on composition, manufacturing, formulation, which addresses ingredient characteristics as well as submissions of technical expert reports which address issues in the lawsuit. To remain aware of changes impacting the litigation, updates should be requested pursuant to the continuing obligation to supplement discovery responses throughout the litigation.

Parties can also obtain critical information from meeting minutes. Meeting minutes and periodic reports may provide identification of the personnel involved with a project over time and also information concerning what was considered during development of the product or process at issue.

Parties should be sure to specifically request all rulings, pleadings and supporting documentation from any related foreign proceedings, including court and patent office litigations, oppositions and patent prosecutions. This information often provides a strategic preview of the opposing party's presentation of critical subject matter in the case, including key prior art and test results. These documents

The discovery process – A step-by-step guide to patent trial discovery.

- **Before discovery begins: guard any trade and business secrets from public disclosure through a protective order.** As soon as the complaint is filed, the parties should begin discussing an appropriate protective order to safeguard trade secrets and other confidential business information. Compliance with discovery obligations may require a party to provide the other parties – often competitors – with sensitive scientific, technical and business information, including internal scientific studies and reports, marketing reports, sales data and forecasts, manufacturing protocols and procedures, and company policies. In some cases, a "two-tier" protective order is appropriate. Such an order limits access to the most critical company secrets of other parties to a smaller group of people at the company, while permitting a slightly larger group to access less sensitive materials.
- **A hint at what lies ahead: initial disclosures.** Before any formal discovery demands are made, the Federal Rules require that the parties exchange initial disclosures. These disclosures generally identify the type and locations of relevant documents and witnesses with knowledge regarding the subject matter of the action. If not provided already, regulatory documents relating to the patents and products at issue can be exchanged at this time. Because the rules specify the information to be disclosed, they do not provide any real opportunity for discovery advantage.
- **The main tool: document requests.** Document production is generally the main method for obtaining essential information from an opposing party. Under the Federal Rules, these requests encompass any information or item that exists in tangible form, including paper, electronic data and samples. The Federal Rules do not restrict the number of document requests.
- **Getting the other side's position in writing: interrogatories and requests for admission.** Under the Federal Rules, interrogatories are afforded the same broad discovery scope permitted for the other discovery mechanisms. Interrogatories are written questions posed to the other party which are then answered by their attorneys. However, the Federal Rules limit the number of interrogatory requests as of right to 25, and local rules may further limit their use. Therefore, interrogatories should be used regarding key issues and contentions only. Requests for admission are not limited in number. Subject to any objections from the other party, the parties are required to admit or deny the requests, or set forth reasons why the request cannot be admitted or denied. Requests for admission are an excellent device for limiting areas of contention, and better defining disputed issues.
- **Face-to-face discovery: depositions.** The Federal Rules permit a party to depose persons related to the case. A deposition is an examination of a person under oath. An attorney from the party requesting the deposition asks questions, and in most

may also contain critical admissions or statements contrary to the positions taken in the US litigation. Although courts generally find that a party's positions on foreign legal matters are irrelevant and do not constitute judicial estoppel, these materials can still provide party admissions and powerful impeachment material. In coordinating related litigation worldwide, parties should always keep in mind that documents not discoverable outside the US may be subject to discovery in US Proceedings.

Parties should also request all documentation relating to any samples provided during discovery to ensure that they were manufactured in the ordinary course. At minimum, all testing relating to the samples should be requested, along with supporting material specifications, manufacturing protocols and conditions, and shipping conditions. When using testing based on samples to address infringement, issues of admissibility and representativeness should be addressed up front. Anticipating and planning to overcome challenges regarding the relevance, reliability and representativeness of any testing should be done before and during testing – not after its completion.

It is usually a good practice to obtain substantial document discovery before taking many depositions. The documents will help define the issues, identify deponents and permit a more focused and in-depth deposition.

In face-to-face discovery (see box for details), the Federal Rules limit the grounds for instructing a witness not to answer questions during a deposition. A defending attorney generally may instruct the person being deposed not to answer if the answer would divulge attorney-client privileged or attorney work product information. While an attorney can object to questions on the basis of his opinion of the relevance of the question, in many cases the attorney may not instruct a witness not to answer the question on that basis. In addition, a party may obtain a protective order by motion if the deposition is being conducted in bad faith or to annoy, embarrass or oppress the deponent or the party.

In light of the broad scope of questions that must be answered, depositions also provide an excellent opportunity for obtaining information concerning collateral matters, including matters primarily useful for impeachment. In litigation involving a common subject matter and multiple defendants, for example, plaintiffs can ask one defendant's expert his opinion concerning another defendant's expert's positions and opinions.

The Federal Rules also provide a mechanism for taking the deposition of a company, and requiring the company to produce a witness who has investigated the company's knowledge regarding topics related to the litigation. During these depositions, known as Rule 30(b)(6) depositions, the person's testimony becomes the position of the corporation as a whole. The employee does not need to have personal knowledge of the matter under enquiry. Rule 30(b)(6) depositions can be a good way to obtain testimony binding on the company regarding key issues, and also to get a second chance to ask questions previously directed to a particular individual witness. Rule 30(b)(6) depositions can also be used to authenticate documents for use at trial, and to determine whether the other party has complied with its document discovery production obligations.

Plaintiffs can ask one defendant's expert his opinion concerning another defendant's expert's positions and opinions

A testifying expert must disclose all information considered, even attorney work product documents prepared by an attorney for the attorney's use in preparing for trial. Moreover, all communications, even oral communications, between the testifying expert and any person, including the client, other technicians, other experts, or attorneys, are discoverable. In addition, email correspondence between a testifying expert and an attorney is discoverable. Parties should also keep in mind that any preliminary or preparatory work performed on behalf of the testifying expert, such as determining proper settings and conditions for the expert testing, may be similarly viewed as having been considered by the testifying expert – even if this work is performed under the direction of counsel.

instances, an attorney from the party aligned with the person being deposed defends the deposition by interposing objections to the form of questions and, where appropriate, instructing the witness not to answer a question. The questions, answers, objections and instructions are transcribed, and may also be videotaped. Depositions provide an excellent mechanism for obtaining factual information, often referred to as an investigatory deposition, and for preparing for a cross-examination at trial.

- **Discovery beyond the parties: subpoenas and public databases.** Parties should also consider whether to obtain information from sources besides the parties in the litigation. Formal discovery can be obtained from any third party in the US through Rule 45, which authorizes subpoenas to obtain both documents and deposition testimony. Former employees of the other party and collaborating companies may possess information which the other party does not have or is reluctant to disclose. Moreover, third parties may also provide valuable independent evidence regarding critical issues relating to all aspects of a case, such as damages or the knowledge of one of ordinary skill at the time of the invention. To use the information in court, it must be obtained in a reliable manner such as by formal deposition or in a business record, unless it is a publication that is not reasonably subject to challenge on evidentiary grounds.
- **The key to opinion evidence: expert disclosures.** Special rules apply to experts who will provide opinion testimony at trial. These rules provide another venue to obtain broader discovery than may otherwise be obtained. The Federal Rules require all testifying experts to prepare an expert report containing a complete statement of their opinions, the bases and reasons for these opinions, the information considered in forming these opinions, any exhibits summarizing these opinions, their qualifications, their compensation, and a listing of all trials in which they have testified during the previous four years. Expert discovery and disclosures are usually made after fact discovery are usually made after fact discovery is largely completed. There may be several rounds of expert disclosures, in which the experts from each side further address issues raised by the other party's experts submissions. Testifying expert disclosure obligations only apply to experts retained or specially employed to provide expert testimony. In-house experts and experts retained for consulting – non-testifying – purposes are not required to submit expert reports. Accordingly, a party may be free to use in-house and non-testifying consulting experts to conduct preliminary work product testing under the direction of counsel on the products at issue before the testifying experts conduct their tests. However, parties should be aware that the facts underlying the work product are not similarly protected.

If a testifying expert was retained in a parallel foreign litigation, it may be possible to obtain discovery relating to those foreign litigation opinions, including foreign testing, correspondence and communications with outside attorneys, and draft opinions not produced in the foreign litigation, on the basis that the expert considered this information in reaching an opinion in the US Proceedings.

It may also be important to ensure that production of the information considered by the expert originates from the expert's files and not from the attorney's files. The documents actually considered by the experts may contain notations or highlighting which is absent from the attorney's copies. In addition, review of the documents considered by an expert may reveal that he was provided with incorrect, incomplete or outdated materials. Moreover, where another party's expert has done some testing on samples of products, a party should check to see whether the expert disclosures include all available raw data from any tests conducted by the expert. For example, a party may want to seek production of the underlying raw data and not just manipulated or smoothed data. The expert production requirements apply to any considered information or recorded data, even data from tests which were discarded and not included in the expert's report.

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Once expert disclosures and documents are obtained, the rules provide that the expert's deposition may be taken. A party must weigh the advantages and disadvantages of an expert deposition. It may provide an invaluable opportunity to test various theories, gauge the credibility of the expert and their demeanor, and gather evidence and testimony that will lay the groundwork for cross examination at trial. In addition, admissions during expert depositions can be essential ammunition in motions for summary judgment seeking to win the case without going to trial. On the other hand, the deposition may also permit the expert to expand, tweak and modify opinions without appropriate disclosure in expert reports.

Discovery in aid of foreign proceedings

Even for cases outside the US, US litigation tools may be used to obtain evidence under 28 U.S.C. § 1782(a). This section authorizes US courts to render assistance to foreign courts and foreign litigants by providing a mechanism for permitting discovery from United States residents for use in foreign proceedings. The issuance of such a discovery order is left to the discretion of the district court. Factors to be considered include the nature and attitudes of the government of the country from which the request emanates, and the character of the proceedings in that country. Depending on where the evidence is located in the US, the district court may also consider whether the discovery would be admissible in the foreign court and whether a country grants reciprocal rights to United States courts and litigants.

Of course, every case is different. The use and applicability of the practical tips above will be greatly influenced by the approach of parties and their counsel, and also the judge or magistrate supervising discovery. Seeking to take the fullest possible advantage of the discovery rules may result in disputes that must be resolved by the court. The discovery obtained, however, can be extremely valuable, especially in a high-stakes trial. The right balance can be achieved only by close cooperation between in-house and outside counsel responding to the priorities set by business decision makers for each party.

Tips for gathering data informally

Aside from documents and depositions, other possible sources of useful information include public sources like libraries or the internet, and professional prior art search services.

On the internet, the website www.archive.org grants free access to a vast historical collection, providing an excellent source for locating prior art references or obtaining information no longer available on another party's website. Another valuable internet source is the FDA website, located at www.FDA.gov. This website provides a catalog of different types of approval applications, searchable by drug name and active ingredient. It also provides tracking of other information important in US pharmaceutical patent litigation, like Paragraph IV certifications, Drug Master Files, and OGD suitability.

Also, under the Freedom of Information Act (FOIA), a party may obtain records from any government agency, including the FDA, by filing a request with the particular agency. A list of all US government agency FOIA websites is found at http://www.usdoj.gov/04foia/other_age.htm. However, because FOIA requests take a long time to process, they should be submitted early in the litigation in order to ensure timely receipt of the information.

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