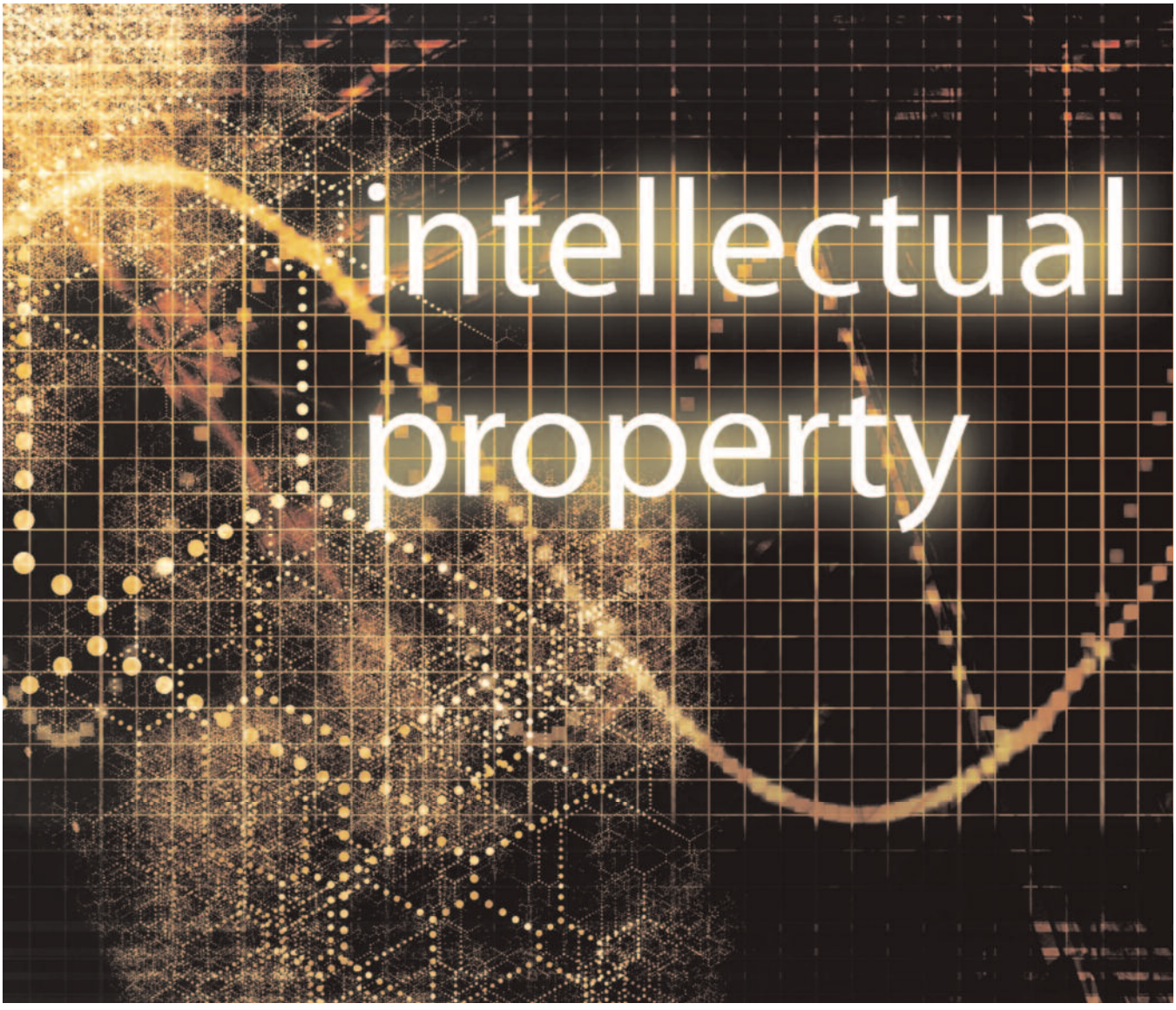


Safeguarding Your IP, Part II

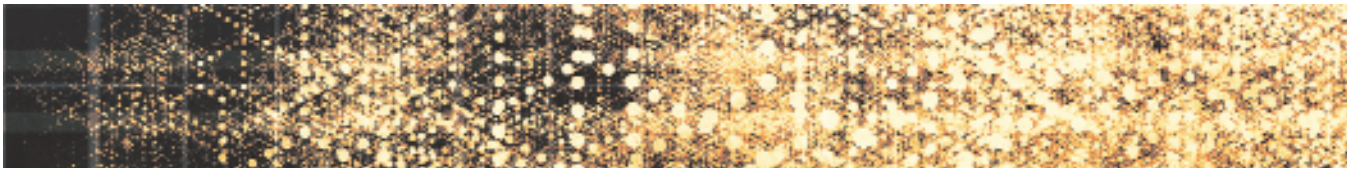
The use of the International Trade Commission's "Section 337" can be a powerful tool to protect medical device firms' intellectual property.

Gary M. Hnath • *Mayer Brown LLP*

Section 337 proceedings, administered by the U.S. International Trade Commission (ITC) in Washington, D.C., provide a fast and effective means for excluding infringing products from the United States and preventing other unfair acts in the importation of articles into the United States.

The first part of this two-part series (published in the September 2010 issue of *Medical Product Outsourcing*) provided basic information on Section 337 proceedings, what kinds of cases can be brought under the statute, how the process works, and the remedies available at the ITC. The article also discussed why Section 337 proceedings may be particularly attractive to medical device companies attempting to exclude infringing products from the United States.

Major corporations increasingly are turning to the ITC to



Section 337 proceedings may be particularly attractive to medical device companies attempting to exclude infringing products from the United States.

resolve their intellectual property disputes. The ITC provides several key advantages compared to the federal courts, including a highly accelerated procedure for investigating complaints and powerful remedies in the form of exclusion orders that are not available in federal courts.

This second installment in the series will discuss how Section 337 has been used in a specific case involving medical devices, *Certain Vein Harvesting Surgical Systems, Investigation No. 337-TA-645*. The case involved alleged infringement of two patents relating to an innovative technology for minimally invasive harvesting of healthy blood vessels for uses such as heart bypass surgery.

The case was brought by Maquet Cardiovascular against Terumo Corporation in Japan and its U.S. affiliate, Terumo Cardiovascular Systems Corporation. Maquet's complaint, filed on April 1, 2008, alleged infringement of two different patents. One of the patents covered a method for harvesting the vein from a patient's body. The other patent covered the actual device used to harvest the vein.

Applying the Law

In the medical device arena, some patents cover the devices themselves while other patents cover methods for using the devices, for example, in a patient's body. That was precisely the case in the Vein Harvesting investigation. The allegations as to the device patent clearly came within the ITC's jurisdiction because Terumo was manufacturing the devices outside the United States and importing the devices into the United States. As to the method patent, that too came within the ITC's jurisdiction, even though the actual method was practiced in the United States, because the vein harvesting was performed with the use of the imported devices.

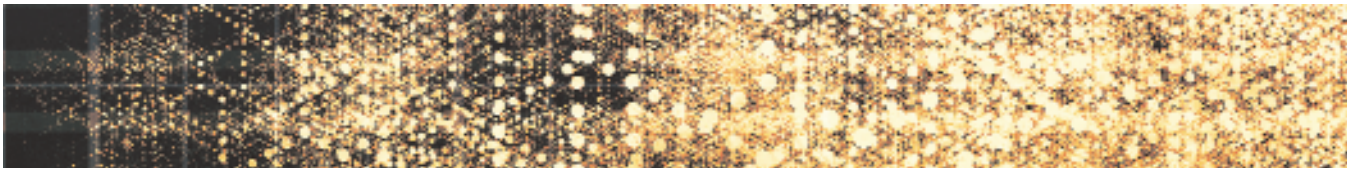
On May 5, 2008, just one month after Maquet's complaint was filed, the ITC instituted the investigation. The case was promptly assigned to an Administrative Law Judge (ALJ), who set a 15-month target date for completion of the investigation. A schedule was set for the case to go to trial on Feb. 18, 2009, with the ALJ's decision due in May 2009 and the final Commission decision due by the target date of Aug. 5, 2009.

More than 90% ...
The percentage of cases at the ITC that involve patent infringement.

Once the investigation had been instituted it moved rapidly, as do all Section 337 investigations. Both sides immediately served requests for information in the form of written questions (interrogatories) and requests for production of documents. Responses to these requests were due within 10 days. Terumo was required to respond to the complaint within 20 days after service by the ITC. When Terumo delayed in producing discovery and refused to provide dates for depositions of its witnesses, Maquet filed motions to compel (a move that asks the court to order either the opposing party or a third party to take some action) with the ITC. Agreement to provide the information was reached promptly after the filing of the motions.

By August of 2008, each side had produced several hundred thousand pages of documents to the other side in response to the discovery requests. Discovery proceeded at a rapid pace, with both sides taking depositions of witnesses knowledgeable about the facts of the case including the inventors of the patents, attorneys involved in prosecuting the patents, and Terumo witnesses with knowledge of the development and marketing of its vein harvesting products. Both companies followed up with motions to compel discovery to the extent they believed it to be important for their cases. The ITC's rules require responses to motions within 10 days. The ITC's Administrative Law Judge ruled on these motions, ordering the production of documents where appropriate, to the extent the parties were still unable to reach agreement.

Another unique aspect of ITC proceedings is the role of the Office of Unfair Import Investigations, or OUII. An attorney assigned from this office participates in the investigation as a neutral third party representing the public interest. The OUII attorney has the right to take discovery, respond to motions, and question witnesses and present evidence at trial.



The ITC provides several key advantages compared to the federal courts, including a highly accelerated procedure for investigating complaints and powerful remedies in the form of exclusion orders that are not available in federal courts.

Ultimately, just before trial, the OUII attorney will take positions on each issue in the case. Here, the OUII attorney often was helpful in facilitating disputes, either before or after a motion was filed.

In addition to depositions of Terumo's U.S. subsidiary, discovery also was taken of Terumo in Japan. Because of international law requirements, depositions of Terumo only could be taken at an embassy or consulate in Japan, which required orders from the ITC and the U.S. District Court authorizing the taking of Terumo depositions in Tokyo. Those depositions took place in September of 2008.

Another interesting aspect of the case was the fact that because one of the patents related to a method for harvesting the vein from patients, Maquet was required to obtain discovery and evidence about how the Terumo device was actually being used by doctors, clinicians and hospitals. The ITC has nationwide subpoena power, which meant that Maquet could obtain from the ITC subpoenas for hospitals, doctors and medical assistants throughout the United States to provide documents and testimony to assist Maquet in putting together its case. Once again, the ITC's fast pace and streamlined procedures makes this a relatively quick and effective process, enabling Maquet to obtain this information in a relatively short period of time. Maquet also was able to obtain marketing and training materials which demonstrated visually how the accused devices were actually being used by doctors and clinicians.

As fact discovery drew to a close, expert discovery proceeded rapidly. Each side named experts with expertise in medical device technology and doctors who were experts in how the devices actually were used, as well as experts who would testify concerning patent office practice and procedure. Expert reports were submitted in November, followed by depositions of the experts in November and December 2008.

With trial quickly approaching in the coming year and with the benefit of the extensive information that had been obtained during the course of the investigation, the case ultimately was resolved through settlement, the details of which are confidential. A motion to terminate based on the settlement was filed on Dec. 28, 2008, and the investigation was officially terminated on Feb. 9, 2009.

A Good Example

While the Vein Harvesting investigation never went to trial, the case nevertheless provides a vivid example of how the speed of the ITC can be used to a patent holder's advantage in order to bring a dispute to a quick conclusion. The same process in a U.S. District Court might have taken several years. In the example of the Vein Harvesting case, the case was settled after extensive discovery, which took place within eight months after institution of the investigation, including extensive fact discovery in the United States and Japan, and discovery of the experts. In U.S. District Court, it may have taken that long just to complete service of the complaint on Terumo in Japan.

The case also illustrates how Section 337 can provide effective relief even in the case of methods for using medical devices in the United States, provided that there is some use of an imported product in connection with that method.

Finally, the case provides an example of the powerful use of the ITC's discovery procedures to obtain extensive information not only from the opposing party, but third parties with important information as well.

In summary, the Vein Harvesting investigation provides a good primer of how Section 337 can be used by medical device companies to provide a fast and effective remedy for enforcing their patents against products imported into the United States, or to combat any other unfair act in the importation of articles into the United States. ❖

Gary Hnath is a partner in Mayer Brown's Washington D.C. office. His practice focuses on intellectual property litigation and counseling, including disputes involving patent, trademark and copyright infringement and trade secrets. He is a leading authority in the area of Section 337 litigation and former president of the ITC Trial Lawyers Association. Gary can be reached at ghnath@mayerbrown.com.