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ITC Trends Medical Device Companies Should Know About

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Over the past 20 years, the number of patent infringement disputes filed annually at the U.S. International Trade Commission has more than tripled. Although typically associated with smartphones and semiconductor chips, the ITC has also seen quite a few disputes involving medical devices. Medical device companies should stay on top of trends in this fast-moving and high-stakes litigation, to avoid being caught unprepared.

Section 337 of the Tariff Act of 1930 allows U.S. intellectual property owners to seek exclusion orders barring the importation into the United States of articles that infringe their patents or other IP rights.[1] Since 1996, complaints involving infringement of medical device patents represented 4 percent of new Section 337 investigations instituted by the ITC.[2] In the past few years, cases involving medical devices have been instituted at nearly twice that rate, with almost one case in every 10 featuring a medical device. This modest growth in medical device cases has occurred quietly, while observers were focused on the rapid rise in smartphone-related Section 337 litigation and its sudden fall-off after 2011. Given the diversity of technologies represented, medical device cases are unlikely to exhibit the volatile filing trends observed in other technological fields.

While Section 337 complaints can target infringement of all types of intellectual property as well as other forms of unfair competition, medical device cases have focused almost exclusively on patent infringement, with one case claiming both trademark and patent infringement. Nearly half the time, a medical device Section 337 complaint alleges infringement of a single patent, although a few patentees have asserted seven or eight patents in a single complaint.

Multipatent complaints are far more common in Section 337 litigation involving information and communications technology products. Because the remedy under Section 337 is prospective, many complainants file parallel district court litigation seeking damages for past infringement. Among medical device cases, complainants brought district court complaints against the same parties with respect to one or more of the same patents 65 percent of the time, which is consistent with the overall rate of parallel ITC/district court patent litigation.

Although a Section 337 complaint can be filed at any point before complainant's patent expires, many

medical device complaints get filed at one of two times. For products that require U.S. Food and Drug Administration marketing approval, it is common to see a complaint filed shortly after the FDA grants such approval to the first product to compete for U.S. market share with a U.S. patentee's own product. For products that don't require FDA marketing approval, a complaint may be triggered when a competitor to the U.S. patentee begins importing a rival to the patentee's product in commercial quantities, or even by imports for use at trade shows or in patient trials.

To state a claim for relief under Section 337, complainant must prove that the articles accused of infringing are imported into the United States. In Section 337 litigation overall, the most common nationalities of respondent companies and/or their accused products are China and Korea. For medical device products, in contrast, the vast majority of respondents are located and produce their accused products in Europe, Japan, Canada and Israel. Since 1996, only three investigations have involved medical device products made in China: birthing simulators, adjustable height beds, and CPAP machines.

The third element of a violation of Section 337, in addition to importation and infringement, is the existence of a domestic industry with respect to complainant's IP. Based on publicly available information (much domestic industry information is confidential), nonpracticing entities represent a much smaller share of complainants in investigations involving medical devices than in Section 337 investigations generally. The ITC estimates that about 20 percent of complaints since 2006 have been filed by NPEs, of which about half were filed by patent assertion entities.[3]

Among 20 medical device cases instituted since 1996, only one appears to involve a nonpracticing entity. In all the other cases, the complainant manufactured its product wholly or in part in the United States, by itself or through contractors, or relied upon domestic warranty and repair or other production-related activities recognized by the ITC. This means early evaluation procedures developed by the ITC to quickly dismiss complaints based on nonmeritorious domestic industry claims may be of limited use to medical device companies responding to Section 337 complaints.

Before the ITC can issue a remedy in a Section 337 investigation, it must consider whether exclusion of imported products found to be infringing would be consistent with the public interest. While the majority of Section 337 investigations do not present public interest issues, a few do. In recent years, the ITC has endeavored to identify early in the process the cases that are likely to present serious public interest issues, so that the administrative law judge can take evidence and assemble a record for consideration by the commissioners.

Since these early identification procedures were adopted, the assigned ALJ has been asked to take evidence on the public interest in about 20 percent of Section 337 investigations. For cases involving medical devices, however, the referral rate is 50 percent — not surprising when one of the public interest factors the commission must consider is whether exclusion of a product would be detrimental to the public health and welfare. Indeed, one of the only three cases since the enactment of Section 337 in which the ITC found a violation but denied a remedy based on public interest concerns involved medical devices — specialized beds for treating burn victims. Because the ITC decides whether to refer public interest issues to the ALJ within 30 days of a new complaint being filed, medical device companies named as respondents in ITC complaints need to act quickly to evaluate the potential benefits of seeking such referral.

Even though Section 337 investigations move quickly, with trials scheduled for eight to 10 months after institution, fewer than a third of medical device cases go to trial. The ITC reports that between 2006 and 2014, Section 337 investigations had an overall settlement rate of approximately 46 percent (including

investigations terminated based on a settlement agreement and those terminated based on a consent order).[4] Among the 18 medical device cases that have been completed since 1996 (two are still active), 50 percent have concluded based on a settlement or consent order. An additional 20 percent of cases ended with withdrawal of the complaint. Only three cases went to trial.

When it comes to outcomes, the ITC is an even playing field. Overall, Section 337 investigations involving medical devices ended with an outcome that can be characterized as favorable to complainant (finding of violation on the merits, default or consent order) about a third of the time; another third can be characterized as favorable to respondent (finding of no violation, withdrawal of complaint); and the final third ended in settlement. With no statistical advantage to either side, thorough preparation and careful attention to the unique features of ITC practice are the keys to success.

Section 337 presents both pitfalls and opportunities for medical device companies. Careful planning by complainants and expeditious but informed strategic decisions by respondents are the best ways to take advantage of the opportunities and avoid the pitfalls. Keeping up with the trends in medical device cases at the ITC is a key step in the right direction.

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[1] 19 U.S.C. § 1337.

[2] Except as otherwise noted, data are based on a survey of ITC investigations instituted since June 1996 for which records are available on the ITC's Electronic Document Information System (EDIS), including 20 investigations involving medical devices.

[3] U.S. International Trade Commission, "USITC Section 337 Investigations -- Facts and Trends Regarding Caseload and Parties" (June 10, 2014 update) at 4.

[4] Id. at 4-5.
