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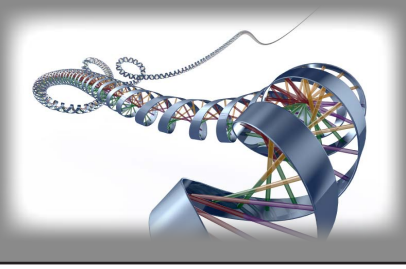

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Infringement of U.S. Method Patents Abroad

In a recent Federal Circuit en banc decision, the court held one does not infringe a U.S. method patent of another by supplying components that perform the patented method from the U.S. to foreign countries. Cardiac Pacemakers, Inc. et al. v. St. Jude Medical, Inc. et al., 2009 WL 2516346 (Fed. Cir. 2009). The ruling may allow one U.S. entity to directly compete abroad with another entity holding a U.S. method patent. The existence of related foreign patents can reduce direct competition abroad. For this case to apply, the components cannot actually perform the patented method within the U.S., but the components are intended to perform the patented method outside of the U.S. The court held the term "patented invention" in 35 U.S.C. § 271(f) does not include method or process claims in a U.S. patent.

The holding in Cardiac v. St. Jude relates only to U.S. method or process patents, and not to U.S. patents protecting a machine, an article of manufacture, or a composition of matter. It is illegal to supply unassembled components from the U.S. to another country, where the components are intended to be assembled abroad into a machine, an article of manufacture, or a composition of matter that would infringe a U.S. patent. 35 U.S.C. § 271(f).

The U.S. has enacted laws to prevent one from skirting patent infringement by conducting certain activities outside the U.S. and certain related activities within the U.S. For example, if an article was manufactured abroad by a method protected by a U.S. method patent, it is illegal to import the article into the U.S., or offer for sale, sell, or use the article in the U.S. 35 U.S.C. § 271(g).

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CASE DETAILS

This case involved a lengthy history between the plaintiffs and the defendants. Many issues in the case were decided before a Federal Circuit panel of three judges, but the portion of the case regarding 35 USC § 271(f) was heard before the Federal Circuit en banc.

The case involved implantable cardioverter defibrillators ("ICDs"). ICDs can be implanted in a patient and detect and correct potentially fatal abnormal heart rhythms. The ICD administers a calibrated electrical shock to the heart to restore normal function. Cardiac owns U.S. Patent 4,407,288 ("the '288 patent"), which relates to cardiac defibrillators. Claim 4 of the '288 patent was the only claim at issue on appeal. Claim 4 was for "a method of heart stimulation using an implantable heart stimulator …comprising: determining a heart condition…; selecting at least one mode of operation of the implantable heart stimulator … corresponding to said determined condition; (and) executing said… mode of operation … to treat said … heart condition," where the mode of operations includes cardioversion. U.S. Patent 4,407,288, Claims 1 and 4.

Through a complicated trial history, claim 4 of the '288 patent was found to be valid. The court held damages could be limited to the ICD's that actually performed the steps of the method claimed in the'288 patent, as opposed to the sale of devices capable of performing the steps of the method. The court reasoned "a method claim is directly infringed only by one practicing the patented method." Joy Tech. v. Flakt, Inc., 6 F.3d 770, 775 (Fed. Cir. 1993). "The law is unequivocal that the sale of equipment to perform a process is not a sale of the process." Id. at 773.

HISTORY OF 35 U.S.C. § 271(f)

The court reviewed the history of 35 USC § 271(f). In Deepsouth Packing Co., Inc. v. Laitram Corp., 406 U.S. 518 (1972), the U.S. Supreme Court held it was not patent infringement for a manufacturer to ship unassembled parts of a patented machine abroad. The court reasoned "it is not an

infringement to make or use a patented product outside of the United States." Id. at 527.

Congress enacted Section 271(f) in response to Deepsouth. See, e.g., Patent Law Amendments of 1984, S. Rep. No. 98-663, pp 2-3 (1984)(describing Section 271(f) as a response to the "Deepsouth decision which interpreted the patent law not to make it infringement where the final assembly and sale is abroad").Section 271(f) made shipment from the U.S. of unassembled parts of a U.S. patented invention infringement where the final assembly and sale is abroad.

In 2006, a panel of the Federal Circuit held that Section 271(f) applied to method claims. Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co., 426 F.3d 1366 (Fed. Cir. 2005). The Court in Union Carbide held Section 271(f) applied to the exportation of a catalyst which was necessary to perform a patented method abroad. Id. The Union Carbide case is overruled to the extent that this case and Union Carbide conflict.

ANALYSIS BY THE COURT

Much of the court's analysis was focused on the language in 35 U.S.C. § 271(f), which reads:

(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer. 35 U.S.C. § 271(f)

The following is a summary of the court's analysis. A component of an apparatus is a tangible article, but a component of a method is a step in the method. The components of a method are not the physical articles used to perform the method, but instead are the intangible steps performed in the method.

The language of 35 U.S.C. § 271 indicates different treatment for tangible article inventions and method inventions. 35 USC § 271(c) contrasts "a component of a patented machine, manufacture, combination, or composition" with a "material or apparatus for use in practicing a patented process." 35 U.S.C. § 271(c).

Section 271(f) requires components be supplied to infringe. It is physically impossible to "supply" an intangible step. Section 271(f) forbids supplying the actual components of a patented invention, not supplying the results of the steps of a patented method. Because it is impossible to supply the steps of a method, one cannot infringe a method or process patent under Section 271(f).

The court reviewed the legislative history of Section 271(f), and determined this holding consistent with that history. This holding was also found to be consistent with the presumption against extraterritorial imposition of US laws.

If St. Jude does not supply the components (steps) of Cardiac's patented method within the United States, St. Jude does not infringe Cardiac's patented method within the United States. The shipment of a device capable of performing the patented method from the United States to another country does not fall within the scope of Section 271(f). This summary of the court's analysis does not include many supporting details provided in the opinion.

DISSENT

Judge Newman was the sole dissenter, and Judge Newman only dissented to the court's holding regarding the applicability of Section 271(f) to U.S. method or process patents. The following is a summary of Judge Newman's dissent. Title 35 defines "inventions patentable" to include all patent-eligible subject matter, including methods and processes. Many sections of Title 35 use the term "patented invention" when referring to all types of patents, and it is explicitly stated when a specific type of patent is intended. Section 271(f) does not include any stated limitation on the types of patents included.

Congress intended Section 271(f) to include process patents, as evidenced by the legislative history. Early drafts of Section 271(f) included "a patented machine, manufacture, or composition of matter," but this language was changed to "patented invention" in subsequent bills. The legislative history does indicate an understanding that Section 271(f) would cover process patents. The USPTO issued a report, published in the Hearing Review, observing that the Deepsouth holding had been applied to process patents, and there was no reason to treat process patents differently.

Interpreting Section 271(f) to include method or process patents does not impact sovereign foreign rights, because liability is based on activities within the United States. Judge Newman provided many facts and details to support his dissent which are not presented in this summary. The holding of the court is the law, not the dissent of Judge Newman.

CONCLUSION

The Cardiac v. St. Jude decision allows competitors of U.S. method patent holders, especially when the method is implemented by an apparatus, to skirt U.S. infringement

litigation under certain circumstances when competing in foreign countries.

There's More to U. S. Export Laws and Regulations Than Meets the Eye

Technology does not always take the form of consumer goods, commodities, parts, or supplies, and it is easy to overlook the fact that technology and technical information, data and services, as well as biological materials and chemical substances, are subject to various United States export laws and regulations.

The emphasis here is on "various" because there is no one set of statutes, rules or regulations under which exports are implemented and enforced. While the Department of Commerce's jurisdiction extends to the export and re-export of a number of commercial items, the Department of State oversees military or defense articles and applications, technical information, data, and services, and the Department of the Treasury oversees controls relating to exports to certain embargoed destinations.

In addition, biological materials and chemical substances are subject to various special packaging, labeling, and shipping rules and must comply with other U.S. regulations (such as, those imposed under the Toxic Substance Control Act and by the U.S. Department of Transportation and under the United Nations guidelines for shipping "hazardous materials" in domestic and international transport) in specific cases.

A general understanding of U.S. commercial export regulations and related packaging, labeling, and shipping rules is an essential step in determining how, where, and to whom biological materials, chemical substances, technology, and technical information, data, and services may be exported. In short, there is little or no substitute to actually plowing through the commercial export rules and the packaging, labeling, and shipping requirements, but they are lengthy. Here are a few basic concepts, a few reminders, and a few traps for the unwary:

I. An "export" includes any item or service that moves across a U.S. border to a foreign destination. The manner or method by which an item (including biological materials and chemical substances), technology, or technical information, data, service moves across our national border does not matter -- whether in cargo containers, carried by hand, sent digitally, delivered e-mail, up-loaded or down-loaded from the Internet, or transmitted by facsimile -- the way in which it crosses our border generally is irrelevant. Similarly, there is no need for an export transaction to include a sale.

Research, as well as non-research, transactions are subject to the export rules. Research which is conducted with non-U.S. collaborators outside the U.S. may require an export license for items, technical information, data, or services, or technology that is being transferred to conduct research, testing, or development activities or merely to develop research proposals.

Export transactions that involve a "temporary stay" apply to items (such as, biological materials, encryption software, or data or other information stored on a computer) that leave the U.S. for some use in a foreign country and then return to the U.S. Exports also include items that arrive in the U.S. for a temporary stay (such as, trade show or conference materials) and then are returned to their country of origin or are sent on to another foreign location. A temporary stay in the U.S. and "re-export" to a foreign destination also includes goods that are held in a Foreign Trade Zone for modification or the addition of an accessory or special part or some other type of special handling or treatment and then are forwarded to their ultimate foreign country destination. Transshipments through the U.S. on the way to another destination also are considered "temporary stays".

A "deemed export" includes the disclosure in the U.S. or a foreign country of technology or technical information, data or services (including, source code) which is otherwise subject to the U.S. commercial export rules to a person who is not a U.S. citizen or a resident alien under U.S. immigration laws. Assuming you have biological materials, chemical substances, technical information, data or services or technology in an export transaction or you are disclosing technical information, data or services, or technology (which can include biological materials or chemical substances) in the U.S. to a person who is foreign national, you should either obtain an export license or your activities should comply with an appropriate export license exception. "Deemed exports" can be overlooked in the management of research activities and laboratory work.

II. As the "exporter," it is your responsibility to determine whether an export license is needed (and if needed, to obtain it) or whether your export transaction qualifies for an export license exception. Although help desks at various federal offices will provide assistance, ultimately, it is the exporter who must decide. Be aware, however, that there are penalties for failing to obtain the correct export license (or an export license at all), including seizure and confiscation of the exported item (generally at the U.S. border), delays in shipment, monetary penalties, and in the worst cases, criminal charges and criminal fines against the individuals involved.

Having a solid grasp of (i) the identity and nature of what is being exported and any special packaging, shipping, and transport rules or requirements for the exported item, technology, or technical information, data, or services, (ii) the ultimate destination and any intermediate destinations, (iii) the identity and location of the recipient, and (iv) the intended use of the exported item or service is important. You also should know the sales price or "value" of the exported item or

service. Even though you may be exporting items or services which are not being sold to the recipient, you will need an invoice which contains the name and address of the exporter and recipient, the value and a description of the exported item or service, and the reason for export (that is, the intended use of the item, or service).

The commercial export rules contain classifications for specific types of items and services, and accurate classification of your technology, technical information, data, or services, biological material, chemical substance, or other exported item and is the basis for determining whether or not an export license is needed or an export license exception is available. The U.S. and international labeling and transport rules contain packing requirements for biological materials (including diagnostic specimens). Shipments which contain or could contain a pathogen or toxin are subject to additional packaging and shipping regulations under the U.S. Department of Transportation rules and the United Nations guidelines adopted and implemented in the International Air Transporters (IATA) regulations.

III. Although you may have determined that your biological materials, chemical substance, technology or technical information, data, or services require an export license or qualify for an export license exception, the ultimate destination country and any intermediate destination countries may have their own import rules and related restrictions. In short, not all biological materials, technology, technical information, data, or services, chemical substances, or other exports can be sent to or delivered in all foreign countries.

References to embargoed countries (including Cuba and North Korea) appear in the news from time to time. However, countries that are deemed to pose a threat of terrorist activities also are subject to export restrictions. The U. S. commercial export rules contain country lists and other information needed to determine whether or not technology, technical information, data, or services, biological materials, chemical substances, and other export items in specific classifications can be exported to specific countries.

Ultimately, whether or not you need an export license or use an export license exception depends upon the classification of the exported item or service and whether or not under the U.S. commercial export rules there is any need to control that exported item or service in light of the identity of the recipient and any intermediate foreign destinations, and the end use of the exported item or service.

Some items (such as those in certain chemical and nuclear categories) are subject to worldwide restrictions. Seizure, confiscation, delays, and monetary penalties may be the fate of illegal, prohibited or restricted imports.

IV. Each export must have an ultimate recipient, and it is the exporter's obligation to know who that recipient is and where that recipient is located. In many instances, exports to recipients identified as a warehouse and similar facility will suffer delays or be seized by customs officials. With the heightened governmental concern regarding the export of biological materials, chemical substances, technology, technical information, data, and services, and other items to alleged or suspected terrorists, each exporter has a responsibility for assuring that the recipient is not listed on any U.S. Government list of entities or individuals engaging in (or deemed to be engaging in) activities relating to the proliferation of weapons of mass destruction or known to engage in narcotics trafficking or terrorism or on a list of individuals or firms that are identified as having violated the export laws or about inadequate information is deemed to be available.

Export transactions with any person or entity on a restricted list or that has been denied export privileges may cause a federal investigation and can result in loss of export privileges, fines, and criminal charges. Exporters who are solicited or contacted by any restricted person or entity regarding an export transaction or by any person or entity regarding export for delivery to a suspect foreign destination should report these requests or solicitation the Department of Commerce or another appropriate U.S. governmental agency. Typical suspect exports include a delivery location where use of the exported item or service highly unusual or unlikely or delivery to a recipient that is not the person or entity named in the export invoice.

V. Certain export license exceptions pertain to biological materials, chemical substances, technology, and technical information, data, and services, assuming all of the specific exception conditions are met. Like export licenses, however, some export license exceptions also are subject to restrictions or limitations based on the ultimate or intermediate foreign country destination, the use or purpose for which the export is being conducted, and the identity or type of recipient for the export.

Frequently used export license exceptions include those for technology, technical information, data, and services, and other exported items which are used temporarily in a foreign country for trade shows, conferences, sales events, for demonstrations, sales and personnel training, and for personal use while in a foreign country. Certain training, maintenance, repair, implementation, or instructional manuals and certain equipment, technology, technical information, data or services, or other exported items also may qualify for an export license exception. Intra-company transfers of technology, technical information, data, or information or other exported items for use in a foreign country, as well as such transfers to affiliates in a foreign country, generally are made under a special export license for such purpose. In 2008, the Department of Commerce considered creating an export license exception for the frequent technology transfer activities, but that exception has not been adopted.

VI. Exports which include biological materials or chemical substances not only must comply with U.S. export rules, but also U.S. and international packaging, labeling, and transport requirements.

The IATA rules address international shipments of "hazardous materials," including toxins, infectious substances, and genetically modified microorganisms. As a general rule, diagnostic specimens are not considered hazardous materials, unless the source patient or animal has or may have a serious communicable disease for which effective treatment is not usually available. In this arena, however, caution and concern for public health and safety should prevail, and treating diagnostic specimens as "hazardous materials" should be considered. Shipments which are refrigerated or frozen or which are shipped in liquid nitrogen or dry ice also must comply with specific packaging and transportation rules. Compliance with these special packaging, labeling, and shipping is enhanced by special training, accurate and complete communication with shipping vendors regarding their own rules and restrictions and with other third parties who may have custody or shipping management of these special materials. Particular note should be made that some shipping vendors do not accept infectious substance shipments.

Lastly, the exporter should be aware of which third party shippers do or do not accept certain types of shipments and recognize that hand carrying certain items (such as, toxins or infectious materials) may result in criminal penalties, including imprisonment and fines.

VII. The export area is replete with traps for the unwary. An array of regulations (including a requirement to self-report errors, whether or not accidental), substantial record-keeping requirements, various shipping and other transportation rules, and the possibility that the jurisdiction of another federal agency over the export transaction may result in delays and require the exporter to commence its export transaction again, all point to the need for an exporter to:

(i) become familiar with export basics and how they apply to your specific situation;

(ii) educate and train your group about your specific labeling, packaging, and shipping rules, as well as your recipients' requirements;

(iii) plan for the time and costs required to obtain a required export license or comply with conditions of an export license exception and to compete the required export activities; and

(iv) develop relationships with experienced outside service providers to provide information or training and to handle certain export activities for you.

The foregoing is for information purposes only and is not intended, and should not be used or relied upon, as a substitute for careful review and compliance with U.S. export requirements, U.S. and international packaging, labeling, and shipping rules, and all applicable laws.

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