Medical devices: recent developments in the UK and the US

As it becomes harder for rightsholders to control the flow of infringing medical products, Baker Botts' **Neil Coulson** and **Mark Whitaker** review developing case law on both sides of the Atlantic

Whether a company develops physical tools for medical purposes or has pre-existing pharmaceuticals that can be commercialised in new ways via innovative devices, the ability to seek patent protection for as long as possible is a key issue for any medical technology company. A 2013 study by PricewaterhouseCoopers[1] showed that the litigation success rate for medical device patent holders was 42%, 10% higher than the success rate for all patent owners combined. The same study showed that the median damage award in the US in respect of medical device patent cases was $16m, compared with an 'all-industries' median of $6m. The international nature of the industry has allowed competitors to import and export their products to new markets, making it difficult for rightsholders to control the flow of infringing products. Here we look at a recent decision in the UK relating to the applicability of supplementary protection certificates (SPCs), and the developing jurisdiction of the US International Trade Commission (US ITC), specifically as it relates to medical devices.

UK: SPCs

A recent decision[2] of the UK Intellectual Property Office (UK IPO) highlights some of the difficulties faced by the holders of medical device patents which are nearing the expiry of their protection period. The applicant requested SPCs[3] for two medical devices based upon the granted patent, EP0707476.

SPCs are granted by the UK IPO under the EU Regulation (EC) No 469/2009 (the SPC Regulation) that states that all products are eligible provided that:

a) They undergo "an administrative authorisation procedure as laid down in Directive 2001/83/EC or Directive 2001/82/EC." (Article 2); and
b) "A valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate" (Article 3(b)).

The Directives referred to above (the Product Directives) relate to medicinal products for human and veterinary use. Each requires thorough investigations on safety, quality and usefulness prior to receiving a marketing authorisation for any new product.

Medical devices

Medical devices are governed by EU Directive 93/42/EC (the Device Directive). In the present case, the medical devices contain a physical device combined with a medicinal product. Article 1.3 of the Device Directive states that where a device is combined with a medicinal product to form a single integral product, which may only be used in that given combination, the combined product shall be governed by the Product Directives and are eligible for an SPC.

Article 1.4 of the Device Directive states that where a device incorporates a product with an action that is ancillary to that of the device, the combined product shall be governed by the Device Directive. Therefore, rather than the "*administrative authorisation procedure*" required by the Product Directives, the combined product undergoes a related but more straightforward procedure called the "conformity assessment procedure" under Article 11 of the Device Directive.

Decision of the UK IPO

The Hearing Officer stated that a literal interpretation of the SPC Regulation leads to a simple conclusion. Medical devices are not subject to the approval procedures contained in the Product Directives, but rather the Device Directive, and therefore are not eligible for the grant of an SPC.

However, the Hearing Officer went on to say that, "It is a well-established principle of EU law that it is necessary to take account of the purpose and objectives behind the EU legislation in question."[4]

This approach led the Hearing Officer to a question: Is the conformity assessment procedure equivalent to the administrative authorisation procedure as laid down in the Product Directives? If so, the Hearing Officer suggested that Articles 2 and 3(b) of the SPC Regulation may be satisfied and SPCs available.

Basis of the decision

The Hearing Officer stated that, "I do not consider that the requirements to carry out the assessment 'by analogy with appropriate methods specified under Directive 2001/83/EC' is the same as carrying out the assessment of a medicinal product in accordance with Directive 2001/83/EC."[5]

Therefore, in short, it was held that the conformity assessment procedure was not as comprehensive a process and medical devices falling under Article 1.4 of the Device Directive were not eligible for SPCs.

However, a major issue remains. Based on the decision, the Device Directive and Product Directives necessitate different treatment for the same substance where it is used (a) with a device due to its desired use necessitating a device, and (b) with a device for a different use that is simply ancillary to a device. The strict testing required in the first instance under the Products Directive would not suffice for the granting of an SPC in the second instance, even though SPCs are granted over active substances rather than for particular uses. Will the appearance of contradictory EU case law influence the future decisions of the UK IPO in this area? In 2010, the German Federal Patent Court granted an SPC for a combined product/device using the reasoning that the medicinal product had been subject to the same level of regulatory scrutiny as stand-alone medicinal products.

The Hearing Officer held that the German case was unpersuasive and not binding upon his decision. However, it is likely that this issue remains to be finalised, most likely at the Court of Justice of the European Union (CJEU).

US International Trade Commission

Given that trading of medical technology has expanded into a worldwide network of importation and exportation, the sources of possible infringement have multiplied. The US ITC is an independent, quasi-judicial federal government agency that provides trade advice to both the legislative and executive branches of government. It evaluates the impact of imports on US industries and adjudicates actions against unfair trade practices, including patent infringement.

Section 337 of the Tariff Act of 1930 declares unlawful unfair methods of competition and unfair acts (and provides relief against patent infringement) in relation to imports into the US.

Why use the US ITC?

The US ITC has a number of benefits to offer medical device patent holders:

- The US ITC can prohibit the importation of infringing goods by virtue of its ability to order an exclusion order for the US Customs and Border Protection Agency to bar particular products. This powerful remedy is particularly useful if the medical device has a short life cycle and commercial losses from counterfeits would be substantial. This is similar to seeking injunctive relief against an infringer in the federal courts, but importantly, does not require a demonstration of irreparable harm or injury to the patent holder.
- US ITC proceedings are fast. Generally, it only takes 15-19 months from filing to final decision, as opposed to an average of 26-35 months to adjudicate a patent case before a federal district court.
- The US ITC's Administrative Law Judges (ALJs) are experienced IP judges who are also acutely familiar with foreign discovery rules and problems. In addition to this, the Office of Unfair Import Investigations is normally a party to Section 337 investigations.
- The US ITC has jurisdiction over all products and components of complete products (ie, articles) imported into the US, irrespective of the domicile of the importer.
- While affirmative defences may be asserted, respondents are precluded from filing counterclaims.

EU-based importers

There are several defences available for EU or non-US-based importers to limit the risk of an US ITC action being triggered upon import into the US. If, when it is imported, a medical device does not include a component of an apparatus claim, or a component required to practice a step of a method claim, the device cannot *directly* infringe that claim 'as imported', pursuant to Section 337. The medical device may, however, *indirectly* infringe either type of claim. But the proof requirements for indirect infringement provide various defences that may be used to avoid such a finding. Under the theory of contributory infringement, for example, the patent owner must establish that the medical device has 'no substantial non-infringing uses'.[6] The 'substantial non-infringing uses' requirement for contributory infringement, therefore, allows an importer to avoid infringing apparatus claims by developing a medical device that may be combined with other components to form non-infringing articles, even if it sometimes is combined with other components to form infringing articles. Additionally, even where a patent owner is able to establish infringement, the public welfare exception to an exclusion order may apply. Although there have been only three instances in which the US ITC has not provided an exclusion order based on public welfare concerns, one of those instances involved a medical device patent. In that investigation, the Commission denied the patent owner's request for an exclusion order because "the resulting shortage of the product along with the increase in price would pose a significant and dangerous shortage for domestic healthcare."[7]

US ITC procedure

To successfully work through a 337 investigation, proprietors of a US medical device patent must allege: (a) that the product that infringes a US patent was imported, sold or offered for sale after importation into the US; and (b) that they have a 'domestic industry', ie, a complainant must establish a certain level of economic activity within the US that has a nexus with the asserted patent and products covered by the relevant IP right. An initial determination by the ALJ can be expected within approximately 12 months of starting the investigations. If the US ITC decides to accept the initial determination, it becomes a final decision. The US ITC often decides to undertake a review. Post-determination, a finding of infringement may be disapproved by the US Trade Representative (although this is rare) and a finding of infringement or non-infringement may be appealed to the US Court of Appeals for the Federal Circuit. Exclusion orders may be general (a widespread pattern of infringement) or limited (restricted to a named respondent). Cease-and-desist orders are available against individuals/entities selling infringing goods post-importation.

Footnotes

1. http://pwc.to/1rMmST6
2. Decision of the UK IPO Hearing Officer, BL O/141/14.
3. Application No SPC/GB/07/043 and SPC/GB/07/044.
4. Id footnote 2. Para 61 of the decision.
5. Id para 93 of the decision.
6. See, *Certain Endoscopic Probes For Use In Argon Plasma Coagulation Systems*, Inv 337-TA-569, US ITC Pub No 4111, initial determination, 2009 WL 4473543 at *35 (Nov 2009).
7. See *Certain Fluidized Supporting Apparatus and Components Thereof*, Inv No 337-TA-182/188, initial determination, 1984 WL 273788 at *69 (1 Oct 1984).

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