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A Court of Justice reference breathes life into Sigma's parallel importation appeal

The Court of Appeal has recently handed down a decision indicating its intention to refer questions relating to the Specific Mechanism to the Court of Justice (Europe's highest court; the CJEU) on an appeal from the Patents County Court.

Legal background

One of the foundations of the European Union is the limitation of barriers to trade between member states, so as to allow free circulation of goods throughout the single market. Under the relevant rules, the owner of an intellectual property right in a first member state cannot use its rights to prevent the importation of goods from a second member state, if the goods were entered into circulation in the single market by or with the consent of the rights holder.

Importation from one member state into another is known as parallel importing. It is typically undertaken to exploit price differences between member states, for example where a pharmaceutical product is protected by a patent or supplementary protection certificate (SPC) in one state but is not in another (where prices may be lower due to generic competition).

However, where the exporting member state is one of the more recent joiners to the EU, a derogation from the principle of free movement is permitted for pharmaceutical products in certain circumstances. This is due to the Specific Mechanism which was written into the accession treaty of these states:

SPECIFIC MECHANISM

"With regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia or Slovakia, the holder, or his beneficiary, of a patent or supplementary protection certificate for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the abovementioned new Member States for that product, may rely on the rights granted by that patent or supplementary protection certificate in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent.

Any person intending to import or market a pharmaceutical product covered by the above paragraph in a Member State where the product enjoys patent or supplementary protection shall demonstrate to the competent authorities in the application regarding that import that one month's prior notification has been given to the holder or beneficiary of such protection."

Similar provisions also exist for some other states, e.g., Bulgaria and Romania.

Thus, if equivalent patent or SPC protection could not have been obtained in the new member state at the time the patent or SPC was filed in the importing member state, the rights holder can prevent the import of pharmaceutical products from the new member state even if they were put onto the market in the new member state by or with the rights holder's consent.

For a pharmaceutical product, parallel importation also needs to be approved by the competent regulatory authority, which is concerned with the product's safety and efficacy. The authority grants a parallel import licence which allows the importer to take advantage of an existing market authorisation (i.e. an approval that the pharmaceutical product is safe and effective), and thus allows marketing of the imported product on that basis. However, as set out in the second paragraph of the above quotation, where parallel importation might be prevented under the Specific Mechanism, the party intending to import the pharmaceutical product is additionally required to demonstrate to the regulatory authority that it has given one month's notification to the rights holder in the country of import.

Factual Background

Merck Canada Inc. started an action for infringement of a UK patent and a UK SPC (covering the active ingredient in the asthma treatment Singulair®) by Sigma Pharmaceuticals PLC, which was importing Singulair® from Poland into the UK. Sigma said that it had notified Merck of its intention to import in June 2009. On the basis that it received no response, Sigma began to import Singulair®. In December 2010, Merck notified Sigma that it objected. Sigma immediately ceased its activities. Merck in any case sued for the acts conducted by Sigma prior to ceasing its activities.

At first instance, the judge decided in Merck's favour. He granted an injunction and ordered Sigma to deliver up its unsold stocks of Singulair®. Before the Court of Appeal, Sigma argued that it was not liable for infringement prior to Merck's objection because Merck should have responded within the month set by the letter of June 2009. Sigma also argued that the lack of response prevented Merck from exerting its rights by estoppel under English law.

Merck argued that the Specific Mechanism did not require that it must exercise its rights on notice from the prospective importer and that, in any case, Sigma had failed to fulfil its obligations under the Specific Mechanism because the correct legal entity in the Merck group of companies had not been notified by the correct legal entity in the Sigma group of companies. Merck also argued that its silence did not satisfy the requirements for estoppel under English law.

The Judgment

The Court of Appeal agreed with the first instance judge that there was no estoppel resulting from Merck's failure to respond to Sigma's notification letter. It also affirmed that the judge was entitled to make the order for delivery up, if his finding of infringement was correct.

It appeared more sympathetic, however, to Sigma's arguments on the workings of the Specific Mechanism than the judge had been, noting that the "*free movement rule is one of the core principles of the European single market and any derogation from it must be interpreted strictly*". Even though the court appeared to favour Sigma's arguments, it opined that the issues were far from *acte clair*. In this situation it deemed that, before it could decide the appeal, a reference to the CJEU was appropriate in order to clarify the workings of the Specific Mechanism on the following issues:

1. *The conditions which must be satisfied before a patent holder may bring infringement proceedings under the Specific Mechanism and, in particular, whether the derogation confers upon the patent holder an option of preventing imports falling in its scope; and whether the derogation is inapplicable unless and until the patent holder demonstrates his intention to exercise that option.*

2. *The identity of the person who must give the notice under the Specific Mechanism and, in particular, whether a notification is compliant if it is given by an applicant for regulatory approval in the Member State into which the products are to be imported rather than the importer; and whether it makes any difference if notification and importation are performed by different legal entities within a group of companies.*

3. *The identity of the person to whom notice must be given, and whether when a group of companies form a single economic unit comprising a number of legal entities, it is sufficient if the notification is addressed to a legal entity which is the operating subsidiary and marketing authorisation holder in the Member State of importation rather than the entity within the group which has legal ownership of or an exclusive licence under the intellectual property right. This issue also raised the subsidiary question as to whether a notification which is otherwise compliant is rendered non compliant if it is addressed to the "the Manager, Regulatory Affairs".*

Although the exact form of the questions has yet to be decided upon, the Court of Appeal has instructed the parties to draft questions and a reference to the CJEU. The court considered the issues in the case to be worthy of a reference to the CJEU because the Specific Mechanism will continue to apply until 2019.

Further clarification of the issues raised in this case will be of interest to both originator pharmaceutical companies and parallel importers alike.

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Need advice

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