

Merck's silence irrelevant as Sigma left gasping

Merck Canada Inc. holds a UK patent and a UK SPC covering the active ingredient in the asthma treatment Singulair. It started an action for infringement of these rights by Sigma Pharmaceuticals PLC, which was importing Singulair from Poland into the UK.

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 product is protected by a patent/SPC in one state but is not in another (where prices may be lower due to generic competition).

A derogation from the principle of free movement is permitted in certain circumstances, such as where the state of export is one of the more recent additions to the EU. 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 protection equivalent to the patent/SPC in the state of import could not be obtained in the new member state, the rights holder can prevent the import of goods from the new member state even if they were put onto the market in the new member state by or with the 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. As set out in the second paragraph of the above quotation, however, where parallel importation might be prevented under the specific mechanism, the party intending to import the pharmaceutical product is additionally required to inform the regulatory authority that it has given one month's notification to the rights holder in the country of import.

Case background

Sigma said that it notified Merck of its intention to import Polish Singulair into the UK, as required by the specific mechanism, in June 2009. On the basis that it received no response, Sigma began to import Polish Singulair. In December 2010, Merck notified Sigma that it objected. Sigma immediately ceased its activities.

There was no dispute that the imported product fell within the scope of protection provided by the patent and the SPC, and there was no attack on the validity of either.

The parties' arguments

Sigma argued that it was not liable for damages in relation to its activities prior to Merck's objection because Merck should have responded, under the specific mechanism, within the month set by the letter of June 2009. Sigma also argued that because Merck did not respond, it was prevented from exerting its rights by estoppel under English national law.

Merck argued that the specific mechanism did not work as Sigma contended because there is no requirement that the patent/SPC holder must exercise its rights on notice from the prospective importer. Further, it contended that the correct Merck company had not been notified by the correct Sigma company in the June 2009 letter. Merck also argued that its silence did not satisfy the requirements for estoppel.

The decision

The judge noted that there is no reference to notice **by** the rights holder in the specific mechanism. The only reference is to notice by the importer **to** the rights holder, through the indirect route that the importer must tell the regulatory authority that notice has been given. Accordingly, the fact that Merck did not take action between June 2009 and December 2010 does not mean that it cannot assert its rights under the specific mechanism. Once this had been decided, the argument on the exact identities of the companies who had written and received the June 2009 letter was deemed not pertinent.

The judge also rejected a point made by Sigma that the judge's interpretation of the specific mechanism created a burden on parallel importers to work out what the patent position might be for a given drug. He noted that parallel importers are sophisticated operators in their field and should be able to check the publically available registers, or at least instruct patent attorneys to do this on their behalf, to determine the position.

On the estoppel point, the judge considered that Merck's silence had merely permitted an already existing misunderstanding to continue, rather than causing it. Accordingly, there was no estoppel.

Conclusion

There is no burden on the patentee/SPC holder to reply to a potential importer's notification under the specific mechanism. In the present case, Merck's silence did not imply consent, and Sigma had no basis to assume that Merck did not object. Sigma had infringed Merck's rights and Merck was entitled to damages.

Sigma has been given permission to appeal on the specific mechanism point.

Authors: [Hugh Goodfellow](#) & [Stephen Duffield](#)

Need advice?

For more information, please contact: email@carpmaels.com.

Carpmaels & Ransford is a leading European intellectual property firm based in London. For more information about our firm and our practice, please visit our website at www.carpmaels.com.

This information provides a summary of the subject matter only. It should not be acted on without first seeking professional advice.

Carpmaels & Ransford is regulated by the Intellectual Property Regulation Board (IPREG).

This briefing note was first published in the IAM IP Newsletter.