News and Views

The Court of Justice clarifies certain provisions governing parallel importation

Summary

On 12 February 2015, the Court of Justice (CJEU) handed down its judgement in *Merck Canada, Merck Sharp & Dohme v Sigma Pharmaceuticals* (C-539/13). The judgement effectively confirms the earlier opinion of Advocate-General Jääskinen and provides guidance on the interpretation of the provisions of the so-called Specific Mechanism, which governs parallel importation of certain medicinal products from the "newer" Member States of the EU (i.e. states acceding to the EU since 2003).

The CJEU's judgement effectively means that, where the Specific Mechanism applies, the following principles govern the proposed parallel importation.

1. The entity intending to import the medicinal product must provide notification of the proposed importation to the holder of patent or SPC rights in that product (or the "beneficiary" of those rights, such as a licensee).

2. Said notification must be given by the proposed importer, or must at least clearly identify that entity.

3. Regulatory authorisation for importation of the medicinal product can be sought (and, subsequently, importation and marketing of the product can commence) if, within 1 month of the notification, the rights holder does not object to the proposed importation.

4. However, the rights holder can subsequently seek to use his rights to prevent the importation and marketing of the medicinal product – but may not obtain compensation for the loss suffered as a result of the parallel imports which he failed to oppose in good time.

Although providing some concessions to parallel importers, these answers (especially points 1 and 4 above) are generally good news for rights holders. This is because they seek to ensure that:

- the rights holder is provided with effective notice of the proposed importation and a short (but perhaps not unreasonably so) period within which objections to the proposed importation can be raised; and
- there is a useful fall-back position for proprietors that do not raise objections in due time.

For those involved in parallel importation, however, there are a number of practical lessons to be learned from the CJEU's judgement. Foremost of these is that a party who has identified an opportunity to parallel import a medicinal product from one territory to another will need to conduct careful due diligence on the status and ownership of the patent and SPC protection in force for the medicinal product in both territories.

This is because such due diligence will be required to establish:

- whether the Specific Mechanism could apply to the proposed importation of that medicinal product; and, if so
- to which entity (rights holder) notification of the proposed parallel importation must be given.

For various reasons, the Specific Mechanism is perhaps more likely to be triggered by SPC protection than it is by patent protection. Consideration of SPCs should therefore play an important part in any due diligence exercise connected with proposed parallel importation.

Background: the Specific Mechanism

The principle of free of movement of goods within Europe usually means that the owner of a patent or a Supplementary Protection Certificate (SPC) that protects a medicinal product cannot use those rights to prevent the (parallel) importation into one EU Member State of medicinal product that he himself has marketed in another EU Member State.

However, such parallel importation may be prevented in certain, limited circumstances. These include where a rights holder invokes the Specific Mechanism, which is a provision that applies when:

(a) the importation is from one of the "newer" EU Member States (Bulgaria, Croatia, Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Romania, Slovenia and Slovakia); and

(b) the importation is into a Member State where patent or SPC protection for the medicinal product concerned was filed at a time where such protection could not be obtained in the Member State mentioned in (a).

Prior to their accession to the EU, not all of the "newer" EU member states, provided *per se* patent protection for pharmaceutical products. Similarly, SPC protection was not always available. Indeed, in the case of both Bulgaria and Hungary, SPC protection was (in contrast to at least some forms of patent protection) completely unavailable prior to EU accession.

Bearing the above in mind, as well as the fact that SPCs expire up to 5½ years later than the patents upon which they are based, the Specific Mechanism is perhaps more likely to be triggered by SPC protection than it is by patent protection.

Background: the case before the CJEU

Beginning in June 2010, Sigma Pharmaceuticals plc imported into the UK (as well as repackaged and sold in the UK) a pharmaceutical product originally sold in Poland by MSD BV (a company in the Merck group) under the name Singulair®. Importation and sales of the (repackaged) product from Poland ceased when Merck subsequently objected in December 2010.

The active ingredient of the medicinal product is montelukast sodium. At the time of importation, that substance was protected by a patent in the UK that was held by Merck Canada Inc. The same entity was also the holder of an SPC for montelukast sodium that came into force when the patent expired in October 2011.

Merck Canada's patent for montelukast sodium was filed at a time when it was not possible to obtain *per se* protection for that compound in Poland. Thus, it was accepted by all parties that, in principle, Merck Canada's patent and SPC protection in the UK could be invoked under the Specific Mechanism to oppose the importation of Singulair® purchased in Poland.

It was also accepted that, prior to Sigma Pharmaceuticals commencing any importation, notification was given to Merck of the proposed activities. Nevertheless, a dispute between the parties arose, which centred upon the facts that said notification was:

- from Pharma XL, a company in the same group as Sigma Pharmaceuticals but not the company who would import Singulair®; and
- directed to "the Manager, Regulatory Affairs" of Merck Sharp & Dohme, and not to the "holder or beneficiary" of the relevant rights at the time (i.e. Merck Canada).

When the case came before the UK High Court, judgment was given in favour of Merck on the grounds that, in the judge's view:

- the Specific Mechanism does not require the patent holder to demonstrate his intention to oppose importation before that activity is rendered an infringement; and
- Merck was therefore not estopped from relying on its patent rights.

Sigma appealed against that judgement and argued that:

- on its proper interpretation, the Specific Mechanism confers upon the patent holder an option to invoke its protection and that in order to do so, he must demonstrate his intention to exercise that option; and
- the letter sent by Pharma XL to Merck Sharp & Dohme provided adequate notification under the Specific Mechanism (meaning that Merck was estopped from asserting its causes of action for patent or SPC infringement against

the acts which Sigma carried out prior to notification by Merck of its objections).

After hearing arguments on these points, as well as upon parallels that could allegedly be drawn between the Specific Mechanism and the so-called Iberian derogation (a similar provision that applies to rights obtained at a time when neither Spain nor Portugal granted patents to pharmaceutical compounds *per se*), the UK Court of Appeal decided to refer various questions to the CJEU.

The questions referred may be found at this link. In general, the questions relate to the issues of:
(A) who must provide notification (and to whom); and
(B) the precise circumstances under which the rights holder can prevent (or claim compensation for) parallel importation by invoking the Specific Mechanism.

The CJEU's judgement

With regard to the issues under point (A) above, the CJEU held that the Specific Mechanism is to be interpreted as:

"*not requiring the person intending to import or market the pharmaceutical product in question to give notification himself,* ***provided that it is possible from the notification to identify that person clearly***" (emphasis added); and

"*meaning that the* ***notification must be given to the holder, or beneficiary, of the patent or the supplementary protection certificate****, the latter term designating any person enjoying the rights conferred by law on the holder of the patent or the supplementary protection certificate*" (emphasis added).

Commentary in the judgement indicates that the term "beneficiary" must be understood as "*designating any person who enjoys rights conferred by law on the holder of the patent, inter alia by virtue of a licence agreement*".

Further, in connection with the issues under point (B) above, the CJEU held that the Specific Mechanism is to be interpreted as "*not requiring the holder, or beneficiary, of a patent or supplementary protection certificate to give notification of his intention to oppose a proposed importation before invoking his rights under the first paragraph of that mechanism*". However, the CJEU added that:

"***if such a holder or beneficiary does not indicate such an intention during the one-month waiting period*** *laid down in the second paragraph of the mechanism,* ***the person proposing to import the pharmaceutical product in question may legitimately apply to the competent authorities for authorisation to import the product and, where appropriate, import and market it****. The Specific Mechanism thus denies that holder or his beneficiary the possibility of relying on his rights under the first paragraph of the mechanism with regard to any importation and marketing of the pharmaceutical product carried out before such an intention was indicated*" (emphasis added).

Commentary and Action Points

For a case having a connection with SPCs, the judgement in C-539/13 is fairly unusual in that the responses provided by the CJEU answer more questions than they pose.

Indeed, as discussed in the Summary above, it is even possible for parallel importers to glean some practical tips from the CJEU's answers – the most important of which being the necessity to conduct careful due diligence on the status and ownership of the patent and SPC protection in force for the medicinal product(s) to be imported.

Moreover, rights owners who may have inadvertently failed to invoke the Specific Mechanism within 1 month of receiving notification of proposed parallel importation can now be confident of their right to prevent future importation and sales. It may even be possible to recover losses due to past importation and sales, but only if there are convincing grounds to assert that the notification provided by the parallel importer was inadequate (i.e. if it did not meet the standards set out by the CJEU).

Please contact Mike Snodin (at mike.snodin@parkgrove-ip.com) if you would like our advice on this or any other matter.