Cúirt Uachtarach na hÉireann
Supreme Court of Ireland

Merck Sharp & Dohme Corp v. Clonmel Healthcare Ltd

On appeal from: [2021] IECA 54/[2019] HC 814

Headline

The Supreme Court today referred the appeal of Merck Sharp & Dohme Corp to the Court of Justice of the European Union, finding that the legal position under Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products and its effect on supplementary protection of combination products is not currently capable of a definite interpretation; it is not a*cte clair*.

Composition of Court

O'Donnell CJ; MacMenamin, Dunne, Charleton & Woulfe JJ.

Background to the Appeal

The issues in this appeal centered on the validity of a Supplementary Protection Certificate (SPC) obtained by MSD. An SPC extends patent protection for up to five years post-patent expiry to compensate for the intermediary period between the granting of the patent and the obtaining of a marketing authorisation, following clinical trials. MSD was granted a patent in respect of the monotherapy ezetimibe, product title Ezetrol, in 1999, lasting 20 years from its filing date in September 1994. Ezetimibe lowers cholesterol by inhibiting its absorption into the bloodstream. The claims of the patent refer to the use of ezetimibe as a monotherapy and also in combination with a statin, specifically listing public domain medicine simvastatin, which lowers cholesterol levels by decreasing production in the liver. An SPC was granted in respect of Ezetrol in 2003, the monotherapy ezetimibe, extending patent protection until April 2018. A second SPC was subsequently granted in respect of ezetimibe and simvastatin in combination, product name Inegy, extending its patent protection until April 2019. Clonmel Ltd, after the expiration of the first SPC, and before the expiry of the second SPC, started producing ezetimibe and simvastatin in combination as a generic medicine. In response to infringement proceedings taken by MSD, Clonmel counterclaimed that the second SPC was invalid. This case centres around whether the second SPC for Inegy is invalid on the basis of Articles 3(a) and 3(c), which enables an SPC where "the product is protected by a basic patent in force" and "the product has not already" being granted an SPC.

McDonald J. in the High Court held that the SPC for Inegy was invalid on the basis of Article 3(a), interpreting the CJEU decision in Case C-121/17 *Teva UK and Others v Gilead Sciences Inc* [2018] as requiring that, for a product to be covered by a patent, it must come within the limits of the patent's invention to satisfy Article 3(a). In the Court of Appeal, Costello J. agreed; the combination product was not under the protection of the basic patent as it did not fall under the invention covered by the patent. While this invalidated the second SPC, both the High Court and Court of Appeal also considered that it followed that the SPC was also invalid on the basis of Article 3(c).

Judgment

The Supreme Court referred a series of questions relating to this appeal to the CJEU.

Reasons for the Judgment

Charleton J., writing on behalf of the Court, highlights the significant controversy concerning the interpretation of the two relevant Articles. Similar cases in other EU Member States have led to

diverging conclusions as to the combination SPC's validity. The correct application of Article 3 of the Regulation cannot be said to be *acte clair*. **[46]-[49] Judgment**

The difficulties arising in the interpretation of the Regulation are considered through an examination of CJEU case law. The Court analysed the decision in Case C-577/13 *Actavis Group Ptc EHV v Boehringer Ingelheim Pharma GmbH* [2015], noting that the judgment indicates that, on the one hand, a claim in a patent for an invention as a monotherapy may give rise to an SPC, so also may that medicine combined with other public domain medicines, meaning more than one SPC, and, on the other hand, that this may not occur. There is uncertainty involved in applying the tests outlined by the CJEU in *Teva*. There is confusion as to whether a mere mention of a product in the claims of a patent is sufficient to conclude that the patent covers that product for the purposes of Article 3(a), or whether a court must also look beyond the claims. The judgment highlights that there is no evidence of a requirement of having regard to the "core inventive advance" of the patent in this context, in the joined cases C-650/17 and C-114/18 *Royalty Pharma Collection Trust v GD Searle LLC, Sandoz Ltd v GD Searle LLC* [2020], either in the court's judgment, or the Opinion of Advocate General Hogan [2019]. **[23]-[26] Judgment**

A draft reference is appended to the Court's judgment, wherein the Court outlines the nature of the issue. If *Boehringer* is treated as a statement of general application, this lends strong support to Clonmel's argument that the court has to identify the "sole subject matter of the invention". MSD contends that subsequent case law has clarified that there is no separate test of inventiveness. It is unclear also whether this case applies generally, or is limited to its facts where the combination claim was made later in time as a result of an amendment. The Opinion of Advocate General Wathelet in *Teva* provides support for MSD's claim, stating that the issue under Article 3(a) is simply identification of the product in the patent. Clonmel argues that the Grand Chamber's decision did not endorse this view. Reading [37]-[38] of that judgment, the Court finds that it does appear to adopt the same approach as the Opinion. **[25]-[32] Reference**

Advocate General Hogan, in his Opinion in *Royalty Pharma*, said that the test in *Teva* is clear: both parts must be satisfied before a product is deemed to be covered by a patent. There was no reference in that judgment to the requirement of "core inventive advance". **[36] Reference**

The conflicting interpretations of the CJEU's *Teva* decision in the Court of Appeal in this case, and the Court of Appeal of England and Wales in *Teva UK Ltd v Gilead Sciences Inc* [2019] EWCA Civ 227, points to the need for clarity. **[39]-[41] Reference**. Clarity may also be required as to whether a first SPC for a monotherapy makes a second SPC for a combination product invalid on the basis of Article 3(c). **[43]-[44] Reference**

Note

This summary is provided to assist in understanding the Court's decision. It does not form part of the reasons for the decision. The full judgment of the Court is the only authoritative document.

Case history

8th and 9th December 2020	Oral submissions made before the Court
[2021] IESCDET 92	Supreme Court Determination granting leave
[2021] IECA 54	Judgment of the Court of Appeal, Costello J
[2019] IEHC 814	Judgment of the High Court, McDonald J