Merck Sharp & Dohme Corp vs Clonmel Healthcare Ltd (2018)
The Court of Appeal, Ireland, No. 2018/166[1]

Prepared by UNCTAD's Intellectual Property Unit

Summary

In June 2018, the Appeal Court of Ireland refused to grant a preliminary injunction restraining Clonmel Healthcare Limited ("Clonmel"), a generic manufacturer, from infringing a Supplementary Protection Certificate ("SPC") for a cholesterol lowering drug held by Merck Sharp & Dohme Corp. ("MSD"). The Appeal Court considered *inter alia* that preliminary injunctions may not be granted when damages are an adequate remedy for the plaintiff and when the defendant is likely to suffer the greater irreparable damage if the preliminary injunction is granted.

The facts

MSD is the holder of the European patent number 0 720 599 ("the 599 patent"). The 599 patent covers the active ingredient ezetimibe and expired on September 14th, 2014. MSD received an SPC 2003/014 ("the 014 SPC") extending the patent term until April 16th, 2018 in accordance with the applicable EU law, which is designed to compensate for delays in the regulatory approval of a drug by extending the period of exclusivity of patents for active ingredients. Relying on patent 599, MSD obtained an additional SPC 2005/2001 ("the 001 SPC") for a product containing ezetimibe in combination with simvastatin and valid until April 1st, 2019. The said combination therapy used to reduce cholesterol levels is marketed under the brand *Inegy*.

On April 17th, 2018, i.e. after the expiry date of the 014 SPC but prior to that of the 001 SPC, a generic manufacturer, Clonmel, launched on the Irish market an alternative to MSD's product *Inegy* at a discount of approximately 92%. After being sued by MSD for infringement, Clonmel claimed the 001 SPC was invalid. In April 2018, the High Court of Ireland granted an interim injunction on the *ex parte* application by MSD, preventing Clonmel from selling its generic version of *Inegy*. The Court was convinced that there was a significant dispute between the parties about the validity of the 001 SPC pertaining to the said drug combination. However, one week later and after hearing the arguments of both parties, the same Court refused to continue the injunction previously granted to MSD. The Court argued that granting damages would be an adequate remedy for MSD if infringement of the 001 SPC is established. At the time of the High Court's decision, 15,000 patients in Ireland were using *Inegy* prescriptions on a monthly basis and the number had been substantially stable for over three years. MSD appealed the decision.

[1] In 2019, however, the Irish Supreme Court overturned the decision of the Court of Appeal (see below under the section titled "Update").

The legal issues

The Appeal Court of Ireland had to decide whether the High Court erred in refusing to restrain Clonmel from selling its generic version of *Inegy* on the basis that damages would be an adequate remedy for MSD.

According to the Appeal Court, the "existence of a monopolistic right to exclude does not per se dictate in equity the remedy for a violation of that right." Moreover, "there is no basis for adopting expansive principles suggesting that injunctive relief could or could not issue in the context of alleged patent infringement upon criteria other than those that normally apply under the rules of equity where an interlocutory injunction is sought".

Turning into the rationale for interlocutory injunction, the Appeal Court cited the decision of the Supreme Court in *Campus Oil v. Minister for Industry & Energy (No. 2)* [1983] I.R. 88:

> "Interlocutory relief is granted to an applicant where what he complains of is continuing and is causing him harm or injury which may be irreparable in the sense that it may not be possible to compensate him fairly or properly by an award of damages. Such relief is given because a period must necessarily elapse before the action can come for trial and for the purpose of keeping matters in status quo until the hearing … The application for an interlocutory injunction is often treated by the parties as the trial of the action. When that happens, the rights of the parties are finally determined on the interlocutory motion. In cases where rights are disputed and challenged and where a significant period must elapse before the trial, the court must exercise its discretion (to grant interlocutory relief) with due regard to certain well established principles."

The Appeal Court found that the aim of an interlocutory injunction is to protect the plaintiff against irreparable harm or injury ensuing from violation of his rights in the pre-trial period. However, this need has to be weighed against the defendant's need to be protected also against irreparable injury resulting from his having been prevented from exercising his own legal rights.

Serious question to be tried

Relying on jurisprudence, the Appeal Court first assessed whether MSD demonstrated a fair, *bona fide* or serious question to be tried. After assessing the claims and counterclaims of the parties, the Court was satisfied that both parties had identified serious issues to be determined at the trial of the action. The Court highlighted Clonmel's counterclaim that there was no basis in the 599 patent for the 001 SPC concerning the combination of ezetimibe with simvastatin. With respect to MSD's claim, the Court held that, as the holder of intellectual property rights, MSD enjoyed the ordinary incidents of title including the right to invoke equitable remedies to protect its monopoly from infringement.

Damages

At a second stage, the Appeal Court assessed whether the plaintiff can be adequately compensated by an award of damages for any loss suffered between the refusal of an interlocutory injunction and the trial of the action. It also considered whether damages would adequately compensate the

defendant, should the latter be successful at the trial of the action, in respect of any loss suffered due to the injunction being enforced pending the trial.

The main argument of MSD was that the trial judge erred in his determination that damages would be an adequate remedy for them. MSD argued *inter alia* that:

- MSD will have to engage in very large price reductions of its own. In the event MSD succeeds at trial, it is highly unlikely that such price reductions could be fully reversed. A reversal of prices back to current levels would damage MSD's relationship with pharmacists. Hence, there will be permanent damage to the 001 SPC.
- Parallel importers may acquire the generic product for resale in other EU states occasioning loss to MSD in those markets, as there will be an impact on the prices in the relevant markets.

Clonmel asserted that "the sands of time are running out on the disputed SPC itself". It pointed out that if the matter proceeded to full trial and a permanent injunction was refused, then its first-mover advantage would be rendered nugatory and other generic manufacturers would have had ample opportunity to advance their involvement in the Irish market ahead of April 1st, 2019.

The Appeal Court disagreed with MSD and concluded that MSD's market had been demonstrated to be a stable and well-established one and that, in the event that an injunction should have been granted, its loss would be pre-eminently a commercial loss. Moreover, the Appeal Court highlighted the specific circumstances of the case, namely that the disputed 001 SPC was so close to expiration. Furthermore, in the view of the Appeal Court, the evidence was that Clonmel would be in a position to discharge any damages likely to arise. On the other hand, the Appeal Court noted that four other companies had already obtained market authorization approval for a combination drug for ezetimibe and simvastatin. An injunction would thus present significant and almost insuperable difficulties to Clonmel in proving the extent of its loss, in particular the benefit of first-mover advantage and the possibility of entering into parallel arrangements with importers and other EU markets. It would be, in the Court's words, "virtually impossible" to reliably evaluate any loss in retrospect based on how Clonmel's generic market share would or might have evolved. The Appeal Court was therefore satisfied that damages would not be an adequate remedy for Clonmel (in the event that an interlocutory injunction is granted to MSD).

The balance of convenience

At a third stage, the Appeal Court assessed "where the least harm would be done by comparing the consequences for the plaintiff in the event that an interlocutory injunction is refused but the plaintiff succeeds at trial with the consequences for the defendant in the event that an interlocutory injunction is granted but the plaintiff fails at trial".

In assessing the balance of convenience, the Appeal Court held that it was clear that MSD's market was finite, certain, stable and demonstrably established in terms of income stream. By contrast, Clonmel's position was nascent, evolving, aimed at maximizing first-mover advantage through exploitation of public health purchasing arrangements, availing of freedom of movement of goods within EU markets and parallel imports mechanisms. Given the uncertainty of Clonmel's position

at this stage as to whether it will or could achieve its objective regarding market share, the Appeal Court concluded that if the injunction is granted, Clonmel would suffer irreparable injury since the remedies available at law, such as pecuniary damages, are inadequate to compensate for any injury.

Conclusion

The Appeal Court refused to interfere with the High Court's refusal to grant interlocutory injunction and dismissed the appeal.

Points of significance

- Article 44 of the TRIPS Agreement requires member states to grant judicial authorities the power to order injunctions. Such orders may be limited against defendants that do not have prior knowledge or reasonable ground to know that their dealings would entail the infringement of an intellectual property right. In other cases, where injunctions and other remedies are inconsistent with a member state's law, declaratory judgments and adequate compensation shall be available. Article 44 of the TRIPS Agreement does not make it mandatory for the judicial authorities to grant injunctions in all cases where an intellectual property infringement is alleged. As this decision demonstrates, there is no need to treat patent and other intellectual property issues different from other cases where an interlocutory injunction is sought.
- The aim of an injunction is to protect a plaintiff against irreparable harm or injury ensuing from violation of his rights in the pre-trial period. This requires to be weighed against the defendant's need to be protected also against irreparable injury resulting from his having been prevented from exercising his own legal rights.
- When damages are commercial and quantifiable and where the defendant demonstrates the ability to pay the damage, the plaintiff can be adequately compensated without the need of an injunction.
- In determining "irreparable damage", it is important to consider what the relative position of the parties would be if the preliminary injunction is not granted.
- The damage caused by an injunction against a new market entrant can be irreparable since it would lose its first market entry advantage and "an opportunity to become the "incumbent generic" on the expiry of the monopoly".[2] By contrast, the damage resulting from the refusal of an injunction to a company that supplies a market under exclusivity, with a demonstrably established income stream that is coming to an end due to the expiry of exclusivity, can be predictably assessed and remedied by an award of damages.

Update

In July 2019, i.e. after the expiry of the 001 SPC, the Irish Supreme Court held that the High Court of Ireland should have granted an interlocutory injunction restraining the generic competitor Clonmel from infringing MSD's 001 SPC. In the view of the Supreme Court, there was "something

[2] Decision of the Irish Supreme Court, *Merck Sharp & Dohme Corp v. Clonmel Healthcare Limited*, IESC 65, 31 July 2019, para. 4.

of an inconsistency […] in considering that any damage to the [MSD] would be met by an award of monetary damages, whereas any damages Clonmel might suffer if wrongly restrained would not".[3] The Supreme Court considered that the balance of potential irreparable harm did not favour either party decisively. In such cases, i.e. where each party asserted a valid interest encouraged by the law and where damages would not be an adequate remedy for anyone, the Supreme Court held that other factors than the adequacy of damages should be considered and weighed in the balance. In the case at hand, the Supreme Court decided to place greater weight on Merck's case as the holder of a valid and effective SPC (effective until declared invalid by a court).

Nevertheless, the Supreme Court pointed out that it may be appropriate to consider the strengths and merits of each party's case. In the Court's words, "[i]n intellectual property matters where the same issue may have been addressed in other European countries, or the same issues adjudicated on in other comparable jurisdictions, it may be appropriate to take into account the outcome of such litigation".[4]

In short, the Supreme Court considered that "the preferable approach is to consider adequacy of damages as part of the balance of convenience".[5] By doing so, the Supreme Court introduced some flexibility when dealing with preliminary injunctions:

> "While the adequacy of damages is the most important component of any assessment of the balance of convenience or balance of justice, a number of other factors may come into play and may properly be considered and weighed in the balance in considering how matters are to be held most fairly pending a trial, and recognising the possibility that there may be no trial".[6]

Keywords: preliminary injunction, irreparable damage, equity, adequate remedy, infringement, first-mover advantage, supplementary protection certificate validity.

Available at:

https://www.bailii.org/ie/cases/IESC/2019/S65.html

[3] *Ibidem*, para. 53.
[4] *Ibidem*, para. 62.
[5] *Ibidem*, para. 35.
[6] *Ibidem*, para. 64.