Preliminary injunctions in Ireland

THE CASES:
Gilead Sciences Inc v Teva Pharmaceuticals (and related case Gilead Sciences Inc v Mylan)
Teva Pharmaceuticals v Generics t/a Mylan
Merck Sharp & Dohme Corporation v Clonmel Healthcare Ltd
Irish High Court
2017 & 2018

Gerard Kelly and **Eimear O'Brien** analyse three recent Irish patent cases to see if the judicial thinking has changed relating to blocking orders

Preliminary injunctions in patent cases have historically received relatively little judicial attention in Ireland. Since 2003, the main Irish authority on the subject has been the High Court decision in *SmithKline Beecham plc v Genthon*.[1] In short, the Irish High Court refused to grant a preliminary injunction in that case on the basis that any commercial loss suffered by the plaintiff would be compensatable in damages. For 14 years, no further decision had been handed down. Recently three patent injunction proceedings were heard by the Irish courts in the space of six months, including a dissenting judgment in the Court of Appeal.[2] The requirements for obtaining a preliminary injunction in the Irish courts are the same as those in the UK, as set out in *American Cyanamid Co v Ethicon Ltd*.[3] Therefore, once the court is satisfied that there is a serious issue to be tried (a relatively low threshold), the next question is whether damages would be an adequate remedy for the plaintiff or the defendant. If damages would not adequately compensate either party, the court must consider where the balance of convenience lies and whether to preserve the *status quo*.

The question of whether damages are an adequate remedy remains the key consideration for the Irish courts when deciding patent injunction cases. This has been confirmed by the recent decisions.

Gilead Sciences Inc v Teva Pharmaceuticals (and related case Gilead Sciences Inc v Mylan)

In the first decision, dated 7 November 2017,[4] the Irish Commercial Court refused Gilead's application for interlocutory relief against the launch by Teva and Mylan of a generic alternative to its anti-retroviral drug, Truvada. The underlying proceedings, which remain ongoing, relate to the alleged infringement of a supplementary protection certificate (SPC) and a counterclaim for invalidity.

The transparency in relation to the calculation of pharma sales and market share data (through service providers such as Quintiles IMS) was a key factor in the court's consideration. In addition, Truvada was not widely dispensed and was available solely through several specialised clinics involved with the treatment of HIV in the state. As such, the product was not dispensed in retail pharmacies.

Gilead asserted that they would suffer irreversible price reductions should competition enter the market. However, the possibility of irreversible price erosion appears to be somewhat less likely in Ireland than in other jurisdictions. In practice, the Irish Health Service is not prone to enforcing price reductions immediately following the launch of a generic particularly when a product is the subject of patent litigation. In any event, the court was of the view that any such damages were capable of being assessed.

Another contention was that the SPC is a property right, protected by the EU SPC Regulation[5] and the Irish Constitution. Judge McGovern held that a property right is not determinative of whether or not an injunction should be granted before trial and is no more than a factor to be considered in the balance of convenience (which did not need to be decided).

In corresponding UK proceedings for the SPC in that jurisdiction, a preliminary reference was sent to the Court of Justice of the European Union concerning the criteria for deciding whether a SPC is protected by a basic patent. Irish courts do not generally review the merits of the infringement or invalidity case in deciding preliminary injunctions. Therefore, even though there had been a number of judicial decisions indicating that the particular SPC was invalid, this did not have a bearing on the decision to grant or refuse an injunction. The focus of the judgment was that damages could be calculated in view of the nature of the market. It was also relevant that a trial on infringement/invalidity was possible within months.

Teva Pharmaceuticals v Generics t/a Mylan

Another set of patent proceedings issued in November 2017 concerned the manufacture of a drug, the generic version of Copaxone used in the treatment of multiple sclerosis (MS) by Mylan in Ireland for export to the US market. The product itself did not have a marketing authorisation and was not sold in Ireland. Teva's claim of infringement related solely to the issue of manufacturing and export within the state.

In an application for a preliminary injunction,[6] Mylan argued that Teva's application was tainted by delay and should be dismissed on this ground before considering the usual principles on whether to grant an injunction. The court disagreed with this argument and held that delay (and the contention that Mylan failed to clear the way) should be assessed in the context of the balance of convenience, if required, and not

before. Adequacy of damages remained the focus.

On the question of whether damages would be an adequate remedy, Teva sought to distinguish the earlier *Gilead* case on the basis that the market in the earlier case was a stable one with data and evidence readily available in relation to sales. In contrast, Teva argued that the market for MS therapies in the US is dynamic and highly competitive. The court did not accept this position and held that damages would adequately compensate Teva. The preliminary injunction was refused on this basis.

Merck Sharp & Dohme (MSD) Corp v Clonmel Healthcare Ltd

On 17 April 2018, Irish generic manufacturer Clonmel Healthcare ("Clonmel") launched an alternative to MSD's product, Inegy, at a discount of approximately 92%. MSD sought an *ex parte* interim injunction three days later on 20 April 2018. An interim injunction was granted by the Commercial Court pending the outcome of the application seeking interlocutory relief on notice.

One week later the Commercial Court heard and refused MSD's application for interlocutory relief on the basis that damages would be an adequate remedy for MSD. In coming to this conclusion, Judge Haughton noted that the market for Inegy is stable and well-established and there was a relatively short period of time to run before the SPC expires, namely 11 months. Further, any argument that the refusal of an injunction may reduce funds available for the development of medicines was not considered persuasive in light of the size, global strength and strong history in R&D of MSD.

This decision was appealed. Haughton J's detailed reasons for his conclusion that damages would be an adequate remedy for MSD were not available to the Court of Appeal at the time of the hearing and, due to the urgency of the appeal, it was agreed that the Court of Appeal would decide the matter afresh with reference to the evidence before the High Court.

MSD suggested the Court of Appeal should reach a firm conclusion on the validity of the SPC in the context of its decision as the injunction application was likely to be determinative of the proceedings generally. At the date of the judgment, the maximum life of the SPC was just nine months and a High Court judgment on the merits of the substantive dispute was unlikely to be delivered within that timeframe. In the Court of Appeal, Mr Justice Peart rejected this approach stating that, should the injunction be refused, the plaintiff would seek to recoup its losses from the defendant on foot of the latter's undertaking as to damages and the question of the validity of the SPC will need to be decided in any event. MSD claimed that damages would not be an adequate remedy as the introduction of the Clonmel product would leave MSD with no alternative but to reduce the price of its product (even on a voluntary basis) and it was highly unlikely that such a price reduction could be reversed. In addition, it was argued that parallel importers could purchase the product in Ireland for resale in other EU countries. The majority judgment of the Court of Appeal rejected this argument and held that any losses arising to MSD were easily quantifiable.

Conversely, the court held that any losses arising to Clonmel would not be quantifiable, in particular, given the uncertain nature of damages which could result from the loss of "first mover advantage". Ultimately, the Court of Appeal (by majority 2:1) upheld the decision of the Commercial Court and refused to grant an injunction in the circumstances.[7]

"The question of whether damages are an adequate remedy remains the key consideration for the Irish courts when deciding patent injunction cases."

There are two points worth noting in the dissenting decision delivered by Mr Justice Hogan. First, the learned Judge disagreed with the contention that the fact that the patent infringer is prepared to pay damages and is also a mark for such damages is a ground for not granting an interlocutory injunction in the first place. Mr Justice Hogan considered this inconsistent with Article 40.3.2 of the Irish Constitution and Article 47(1) of the Charter which oblige the courts to secure litigants an effective remedy to vindicate their constitutional rights to persons and property.

Secondly, Mr Justice Hogan held that, as the issue of validity of the SPC could not be meaningfully litigated to a conclusion, the ordinary principles could not be applied without some modification and, in the circumstances, the court was required to form a view – however tentative and provisional – on the substantive issue. On the evidence available, Hogan J was not persuaded that the SPC in question was invalid and considered that the least injustice would be caused by allowing the appeal. His dissenting judgment is of limited persuasive value but may be relevant if this decision is further appealed to the Supreme Court.

Relevant principles

The main points to be taken into consideration following the recent judgments are as follows:

- An order for an interlocutory injunction is unlikely to be considered 'mandatory' in nature solely by virtue of the fact that the defendant has launched in advance and an injunction would require the launch to be dismantled.
- There is no rule presuming that damages are an inadequate remedy simply because a patent or SPC is a property right.
- Due to the transparency of the pharmaceutical industry when it comes to the recording of sales and market share, damages arising from loss of profit/sales are generally considered easy to calculate and therefore an adequate remedy.
- Arguments relating to delay and any alleged 'failure to clear the way' by the defendant are to be considered in the balance of convenience assessment with adequacy of damages being the main consideration in such matters.

Footnotes

1. [2003] IEHC 623.
2. Patent Injunctions and the legal basis for obtaining same in Ireland has been the topic of a previous article by Gerard Kelly in the February 2011 edition of *Intellectual Property Magazine*.
3. [1975] FSR 101.
4. [2017] IEHC 666.
5. Regulation (EC) No. 469/2009.
6. [2018] IEHC 324.
7. 2018 IECA 177.

Authors

Gerard Kelly is a partner in the IP group at Mason Hayes & Curran. Eimear O'Brien is an associate at the firm.