AN CHÚIRT UACHTARACH

THE SUPREME COURT

[S:AP:IE:2018:000107]

Clarke C.J.
O'Donnell J.
McKechnie J.
Dunne J.
O'Malley J.

Between/

Merck Sharp & Dohme Corporation

Plaintiff/Appellant

AND

Clonmel Healthcare Limited

Defendant/Respondent

Judgment of O'Donnell J. delivered the 31st day of July, 2019.

Introduction

1 The appellant, Merck Sharp & Dohme Corporation ("Merck"), appeals against the decision of the Court of Appeal (Peart and Whelan JJ., Hogan J. dissenting) upholding the judgment of the High Court (Haughton J.) refusing an interlocutory injunction restraining the infringement by the respondent, Clonmel Healthcare Limited ("Clonmel"), of a Supplementary Protection Certificate ("S.P.C."), which itself had expired before the hearing of this appeal. As such, it might appear to be a matter of, at best, academic interest, and then only to the specialist. However, this appeal raises important questions as to the proper approach to the application for an interlocutory injunction, which is an important remedy in many different disputes.

Facts

2 Merck (or its corporate parent), was the holder of a number of patents and S.P.C.s which are relevant to these proceedings. The earliest relevant patent was European Patent No. 0 033 538 ("the 538 patent") relating to simvastatin, a statin for the treatment of cholesterol. The patent was filed in 1981 and an S.P.C. obtained, which expired in turn in May 2003. Merck (or its corporate parent) is also the proprietor of European Patent No. 0 720 599 ("the 599 patent") which, it is agreed, covered the active ingredient ezetimibe. The 599 patent expired on 14 September 2014. S.P.C. No. 2003/014 was granted in 2003 ("the 014 S.P.C.") in respect of ezetimibe, which itself expired on 16 April 2018.

3 Merck marketed both simvastatin and ezetimibe as monotherapies, but these proceedings concern a product marketed under the name *Inegy*, which was a combination of the two, and which it is accepted had greater therapeutic effect in the reduction of cholesterol. Merck maintained, and still maintains, that the combination was covered by the 599 patent, and, accordingly, obtained a separate S.P.C. No. 2005/2001 ("the 001 S.P.C."). The 001 S.P.C. was due to expire, in turn, on 1 April 2019. This case concerns the window period between the expiry of the 014 S.P.C. on 16 April 2018 and the expiry of the contested 001 S.P.C. on 1 April 2019. Clonmel does not dispute that *Inegy* was protected by the 599 patent and by the 014 S.P.C., since it contained the active ingredient ezetimibe, but argues that the 001 S.P.C. is invalid. Accordingly, it argues that it was entitled to launch a generic competitor to Inegy, which it did on 17 April 2018, the day after the expiry of the 014 S.P.C. There had been some correspondence between the parties' lawyers in Ireland culminating with Clonmel's solicitors notifying Merck's lawyers of the launch of its generic competitor and maintaining that "the balance of convenience clearly lies with our client and damages will fully compensate your client should an infringement be found to have occurred (which infringement is denied)".

4 The High Court (McGovern J.) granted an interim injunction on the *ex parte* application by Merck, but Haughton J. refused the application for an interlocutory injunction. The Court of Appeal, by a majority, upheld that decision (see [2018] IECA 177). There was, however, a significant difference in approach between the different judgments. Haughton J. had considered that damages were an adequate remedy for Merck in the event that it succeeded in establishing the validity of the 001 S.P.C., and consequently an infringement, and, therefore, it was not necessary to go further and consider any question of the balance of convenience (including whether damages would have been an adequate remedy for Clonmel). In the Court of Appeal, Peart J. considered that damages would be an adequate remedy for Merck but would not adequately compensate Clonmel on the assumption that it was restrained by an injunction pending trial, but nevertheless succeeded at the trial. He considered that Clonmel would lose its first mover advantage and an opportunity to become the "incumbent generic" on the expiry of the monopoly. Whelan J., for her part, considered that the case should be approached on the basis that the grant of the injunction at the interlocutory stage would dispose of the case as a whole. Relying on the decision of this court in *Curust Financial Services Ltd. v. Loewe-Lack-Werk* [1994] 1 I.R. 450, she held that that the damages Merck might suffer in the event that an injunction was refused and the challenge to the validity of the 001 S.P.C. was rejected were nevertheless pre-eminently a commercial loss, since the 001 S.P.C. was so close to expiration. On the other hand, she considered that Clonmel, in the event that it was restrained by injunction but nevertheless succeeded at trial, would lose the benefit of the first mover advantage and its standing as the market leader in the critical post-monopoly stage, which was something that

could not be adequately compensated for by damages. Hogan J. (dissenting), for his part, laid emphasis on the nature of the property right at issue, and considered that damages were not an adequate remedy for a breach of that right in the event that it was determined that the 001 S.P.C. was valid. In the circumstances, he considered that some modification of the test in *Campus Oil v. The Minister for Industry (No. 2)* [1983] I.R. 88 was required, and that weight should be given in such circumstances to the existence of the 001 S.P.C. and to the at least tentative view which he had formed as to the likely merits of the claim on invalidity. He considered that Clonmel's claim of invalidity was not likely to succeed, and that accordingly an injunction should be granted.

5 This case has proceeded with commendable speed through the system of the courts. Indeed, the Court of Appeal heard the appeal before the full written judgment in the High Court was available. Nevertheless, it became clear in the course of case management of this appeal that it was unlikely that it would be possible to have a hearing and a decision in this case much before the expiry of the 001 S.P.C. However, Merck in particular, maintained that the appeal raised important points of principle in relation to the grant of injunctions in respect of S.P.C.s which were due to expire. While Merck itself held a number of such S.P.C.s, this was a matter of general interest in the pharmaceutical sector. Accordingly, it pressed for a hearing of the appeal. It was agreed at case management, however, that the appeal should proceed on the basis that Merck would not argue that, if it was successful on the appeal, any injunction ought to be dissolved. This effectively conceded to Clonmel the benefit of having no threat of an injunction prior to April 2019, when it would have been free, on any view, to market its product, and meant that it was not essential that the matter be determined before the expiry of the S.P.C. It was also agreed, therefore, that the court could approach the case on the basis of the matters as they stood at the date of the initial application for an interlocutory injunction. Accordingly, it would not be necessary to have a further round of evidence as to developments since the launch of Clonmel's product in April 2018, and furthermore, the analysis could be approached free of any constraints which might be contended to apply when an appellate court is invited to review the decision of a trial court on an interlocutory application. The net, albeit difficult, issue to which this appeal was confined was whether or not an interlocutory injunction should have been granted to Merck as the position then stood when this application came before the High Court in April 2018.

The Supplementary Protection Certificate

6 It is well known that the underlying objective justifying the grant of a patent is to provide a monopoly for a limited period in order to encourage invention and the dissemination of knowledge, which is beneficial to the wider community. However, the grant of a valid patent does not in itself lead inevitably to a commercially viable product. Because of the necessity to seek a patent at the earliest viable stage, claims are made at a point where it may not be clear how the invention may ultimately be marketed, if at all. Particularly in the medicinal and pharmaceutical field, the process of obtaining authorisation for the marketing of a product is lengthy and demanding. Accordingly, it may be some time before a commercial product can be launched to exploit the monopoly granted by the patent. Even then, there is no guarantee that the product will be successful, since other competing products may have been launched in the intervening time. Furthermore, even if a product is successfully launched, the length of time in obtaining marketing authorisation has the effect of significantly reducing the period during which patent protection is of benefit. This difficulty was recognised by the European Union, which made provision for the grant of Supplementary Protection Certificates by Regulation 469/2009 concerning the supplementary protection certificate for medicinal products ("the Regulation").

Regulation 469/2009

7 Recitals 3 and 4 of the Regulation set out the essential justification for the establishment of a regime permitting the grant of S.P.C.s:-

> "(3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.
>
> (4) At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research."

8 There was a risk of research centres moving between Member States or outside the Union. It was proposed that an S.P.C. should be granted under the same conditions by each Member State at the request of the holder of a national or European patent relating to a medicinal product in respect of which market authorisation had been granted. The duration of the protection should be such that a holder of a patent and S.P.C. should be able to enjoy an overall maximum period of 15 years of exclusivity from the time the product first obtained authorisation to be placed on the market in a Member State. However, a certificate could not be granted for a period exceeding five years. Furthermore, the protection granted should be "strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product".

9 A careful balance is sought to be achieved by the Regulation. It did not simply extend the life of the patent granted by a specific period. Rather, the S.P.C. was to be confined to a product which itself would obtain authorisation and had been placed on the market. Subject to that significant limitation, the S.P.C. conferred the same rights as were conferred by the basic patent. The area of monopoly was cut down and limited to the product which had market authorisation, but in respect of that product, the monopoly rights continued. The legal requirements for the grant of a certificate were set out at Article 3, as follows:-

> "Conditions for obtaining a certificate.
>
> A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:
>
> (a) the product is protected by a basic patent in force;
>
> (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;
>
> (c) the product has not already been the subject of a certificate;
>
> (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product."

10 The conditions relating to product authorisation at subparagraphs (b) and (d) are capable of ready proof, and subparagraph (c) should not pose many difficulties. The main argument in a case in which the validity of an S.P.C. is challenged relates to the question of whether it can be said the product in this case, *Inegy*, being a combination of simvastatin and ezetimibe, was protected by the 599 patent. The difficulty here relates to the difference between a patent relating to claims and inventions and a product which can benefit from an S.P.C.. While there appears to be some difference between the characterisation of the issue in the judgments in the Court of Appeal, as I understand it, the essential claim made by Clonmel is that the *Inegy* product was not protected by the 599 patent. As is common in cases of this type, this issue has been raised and litigated in other jurisdictions. It is accepted for the purposes of this case that there is a serious issue to be tried in relation to the validity of the S.P.C.

The dispute in these proceedings

11 *Inegy* is a widely prescribed pharmaceutical medicine in Ireland. It is number six in the Merck portfolio of products in Ireland and approximately 15,000 patients take it each month. This is a very stable figure, and Inegy sales in Ireland have remained at about €8 million worth of the product in recent years. The simvastatin ingredient of the product is produced at the Merck plant at Ballydine in County Tipperary. Simvastatin represents the majority of the output of that plant. In addition, eight people, including a marketing manager, are employed by Merck for the marketing and selling of the *Inegy* product alone in Ireland. Prior to the launch of the Clonmel product, Inegy's price to pharmacists was approximately €41 to €44. Merck did not reveal its precise profits from the sales of Inegy for the purposes of these proceedings, but the High Court assumed, prudently in my view, that the product was profitable.

12 *Inegy* is on the list of interchangeable medicines established pursuant to the Health (Pricing and Supply of Medical Goods) Act 2013 ("the 2013 Act"), which means that it can be substituted by generic alternatives by pharmacists on their own decision once, of course, such generic alternatives are lawfully available. In addition to Clonmel, four other generic manufacturers had obtained marketing authorisations for a combined simvastatin-ezetimibe product, which could be substituted for *Inegy* pursuant to the regime established under the 2013 Act. There were, accordingly, perhaps five generic manufacturers poised to enter the market, or at least in a position to do so, once any valid intellectual property protection for Inegy expired. The law in Ireland, as in many other countries, seeks in this regard to reconcile two competing public interests. Patent law and patent extension by S.P.C. provide a monopoly as a reward and incentive for innovation and for the disclosure of the teaching involved, leading in this case to the development of beneficial products. However, once a monopoly comes to an end, whether by natural expiration, or by determination of invalidity, there is a strong competing public interest in encouraging entry to the market by generic alternatives, particularly since in Ireland, as in many European countries, the bulk of the cost of the drugs is met from the public purse. When a pharmacist substitutes a generic alternative for a branded product, the cost to the health budget is correspondently reduced.

13 Clonmel launched its product at a price of €16 to €18, which is already a significant discount compared to the price point for *Inegy*, but in addition offered the product to pharmacists at a further steep discount of 80 per cent of its retail price so that the price to pharmacists was in the region of €3 to €3.50. Pharmacists therefore had a considerable incentive to offer the Clonmel product as a substitute for Inegy. It seems clear that in setting the price at this level, Clonmel was not pricing against the incumbent in this case, Merck, but rather against the other prospective generic entrants. The object appears to have been for Clonmel to establish itself as what Peart J. in the Court of Appeal called the "incumbent generic".

14 The legal argument from each side in this case is clear. Clonmel argued that the market for *Inegy* was very stable. Therefore, the S.P.C., even if valid, gave Merck what could properly be described as an income stream, *i.e.* the right to obtain profits from the sale of a product in a stable market up to the date of expiry of the S.P.C. It was said that if an injunction was refused, but it should transpire that the S.P.C. was held valid at the trial of the action (or on appeal), damages were readily quantifiable and would be an adequate remedy, as it would be possible to quantify the loss of profits in the lost sales to Merck from the date of Clonmel's entry into the market until the date of expiry of the S.P.C. Clonmel placed considerable reliance in this regard on the decision in *Curust Financial Services Ltd. v. Loewe-Lack-Werk* [1994] 1 I.R. 450 and, in particular, the oft-quoted phrase that the damage to Merck was therefore "clearly and exclusively a commercial loss … in a stable and well established market". Accordingly, it was said that an injunction should not be granted since damages could readily be assessed considering that, as set out in *Curust*:–

> "Difficulty, as distinct from complete impossibility, in the assessment of such damages should not … be a ground for characterising the award of damages as an inadequate remedy".

15 Clonmel also placed reliance on the application of the *Curust* approach in the field of intellectual property (and in particular patents) by Kelly J. in *SmithKline Beecham plc v. Genthon B.V.*, (Unreported, High Court, Kelly J., 28 February 2003), and by Barniville J. in *Teva Pharmaceutical Industries Ltd. v. Mylan Teo*. [2018] IEHC 324, (Unreported, High Court, Barniville J., 5 June 2018). It followed, Clonmel said, that damages were an adequate remedy for Merck should it succeed at the trial of the action, and accordingly an injunction ought to be refused.

16 The strongest version of the argument for Clonmel, and that which succeeded in the High Court, was that once it was determined that damages would be an adequate remedy for Merck, that resolved the matter and an injunction could not be granted. Even if, however, it was necessary to go further, it was contended that Clonmel, by contrast, would suffer a damage which could not be compensated adequately by the award of damages pursuant to any undertaking for damages that Merck would be required to offer, should an injunction be granted and Clonmel succeed at the trial of the action. That was because Clonmel, it was said, would lose its first mover advantage. It would no longer be able to enter the market as it hoped to in April 2018, but would rather be required to enter the market with the other generic competitors. It would be difficult, if not impossible, to assess how the market would have developed had Clonmel been able to enter the market in April 2018.

17 Merck, for its part, relies heavily, in this court at least, on authorities from the United Kingdom courts dealing with claims for injunctions by S.P.C. holders seeking to restrain entry by generic competitors. This current of authority favours the grant of an injunction restraining generic entry and has become so well established that it could be summarised in the recent edition of *Terrell on the Law of Patents* (18th ed., Sweet & Maxwell, 2016) at paras. 19-88 and 19-89 as follows:-

> "Adequacy of damages
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> Many patent cases are not appropriate ones for the grant of an interim injunction because damages would be an adequate remedy for the patentee. Where the infringement causes the patentee to lose sales, provided the defendant keeps proper records of the sales they have made, the court can award damages based upon its assessment of the proportion of the defendant's sales that the patentee would have made and the patentee's unusual profit margin.
>
> However, there is a well-established line of patent cases in which interim injunctions are commonly granted. These all concern the launch of a generic pharmaceutical product. Although each case turns on its own facts, the court has shown itself to be ready to accept an argument that the launch of a generic pharmaceutical product will cause substantial and

> unquantifiable loss to the patentee because it will permanently depress the patentee's price. The argument goes that entry of the generic product(s) will result in a downwards spiral in the price of the product and that even if the patentee were to be successful at trial and remove the generic products from the market, they will not be able to put the price back to previous levels. Examples of cases where this argument has been accepted are listed in the footnote."

18 The footnote referred to in the text cites in particular the decision of the Court of Appeal of England and Wales in *SmithKline Beecham plc v. Apotex Europe Ltd.* [2003] EWCA Civ 137, [2003] F.S.R. 31, and *Novartis A.G. v. Hospira U.K. Ltd.* [2013] EWCA Civ 583, [2014] 1 W.L.R. 1264. An early case in this line of authority appears to be the decision of Jacob J. in *SmithKline Beecham plc v. Apotex Europe Ltd.* [2002] EWHC 2556 (Pat.) (Unreported, High Court of England and Wales, Jacob J., 28 November 2002). He considered that there would be formidable difficulties in the plaintiff's way if it tried to get back to his present position after a major collapse of prices. He was firmly convinced that "the damage caused by entry into the market on a substantial scale will be both very, very substantial and not adequately quantifiable". Jacob J. was also influenced by the fact that the defendant had not moved to determine either that their product did not infringe the patent or that the patent in question was invalid. In an earlier case. *SmithKline Beecham v. Generics U.K. Ltd* [2001] EWHC 563 (Pat.), he had said it was "purely commercial common sense. If there may be an obstacle in your way, clear it out. To my mind this is a case where the retention of the status quo was a rational thing to do. It was something that could have been avoided by the defendants; they chose not to do it". The defendant had been, as he put it, eyeing the U.K. market for a long time. There was bound to be litigation unless the case was hopeless: both sides were aware of it, and he considered that if the defendant intended to introduce its product, it could avoid all the problems of an interlocutory injunction if it cleared the way first where litigation was bound to ensue. That was what the procedures for revocation and declaration for non-infringement were for. Accordingly, he granted the injunction.

19 The same analysis has been applied in a series of subsequent cases such as *Warner-Lambert Company L.L.C. v. Teva U.K. Ltd.* [2011] EWHC 1691 (Patent), (Unreported, High Court of England and Wales, Floyd J., 27 June 2011). That case involved the launch of a generic, Atorvastatin, ahead of the anticipated expiry date of the S.P.C. held by the plaintiffs. In *Novartis A.G. v. Hospira U.K. Ltd.* [2013] EWCA Civ 583, [2014] 1 W.L.R. 1264, the Court of Appeal of England and Wales (Lewison, Kitchin, and Floyd L.JJ.) granted an injunction pending appeal in circumstances where the High Court had found the patent in question to be invalid. At paras. 52 to 54 of the judgment Floyd L.J. cited with approval the *SmithKline Beecham* approach:-

> "52. This proposition rings particularly true in the pharmaceutical industry. In [*SmithKline Beecham plc v. Generics U.K. Ltd*. [[2001] EWHC 563 (Pat.)], Jacob J. articulated the need in the pharmaceutical industry for a generic manufacturer who makes plans to launch a generic medicine, to take steps to clear the obstacles facing its manufacture out of the way before it is launched. He said:
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> 'You would have to be very naïve in the pharmaceutical industry to think that the patentee, with a product as important as this, would not, if it had anything other than a frivolous chance of success, take action.'"

20 At para. 53 of his judgment Floyd L.J. quoted the portion from the judgment in *SmithKline Beecham* already set out above and continued at para. 54:-

> "54. The way to market for a generic manufacturer is not clear until all arguable objections from the patentee have been eliminated. If the generic manufacturer allows the trial of the action at first instance to coincide with the intended launch date he runs the risk that a successful appeal could get in the way, even if judgment at first instance is given in his favour."

21 In *Teva Pharmaceutical Industries Ltd. v. Actavis U.K. Ltd.* [2015] EWHC 2604 (Pat.), (Unreported, High Court of England and Wales, Arnold J., 9 September 2015), Arnold J. dealt with a number of the arguments raised in this case. He acknowledged that the defendant was the first generic entrant into the market and therefore had the advantage of being the "incumbent generic supplier", a position which allowed the first entrants to establish relationships with customers for the generic product in question and thereby obtain a market advantage as compared to the later entrants. He considered accordingly that he was faced with a familiar dilemma that "on both of the contrasting hypotheses, one side is going to suffer harm which will be difficult to quantify, and therefore the risk of irreparable harm. In those circumstances, the court's task is to adopt the course which appears least likely to cause the risk of ultimate injustice". In doing so, he considered it was a counsel of prudence to preserve the *status quo*:-

> "In that connection, it seems to me that an important factor to take into account is Actavis' [sic] failure to undertake what is a familiarly known as 'clearing the path'".

22 In *Warner-Lambert Company L.L.C. v. Sandoz GmbH* [2015] EWHC 3153 (Pat.), (Unreported, High Court of England and Wales, Arnold J., 4 November 2015), Arnold J. granted an injunction restraining the defendants from infringing a European patent by dealing a generic pregabalin product. At para. 103 of the judgment he concluded:

> "In my judgment, granting the relief sought by Warner-Lambert would create a lesser risk of irremediable harm than refusing it. This is for two main reasons. First, I consider that there is a greater risk of Warner-Lambert suffering unquantifiable and irremediable loss if an injunction is refused than there is of Sandoz suffering unquantifiable and irremediable loss if an injunction is granted. Secondly, I consider that there is a strong case for preservation of the status quo pending trial … If no injunction is granted, the arrival of full label generic pregabalin on the market will make it significantly more difficult for the Court to ensure appropriate compensation for those parties which it is finally determined merit compensation."

23 A similar approach was taken in the Scottish case of *AstraZeneca A.B. v. Teva U.K. Ltd.* [2017] CSOH 150, 2018 S.L.T. 52, where Lord Bannatyne observed that if the case fell into the classic category of generic pharmaceutical litigation there was "a clear line of authority that interim relief should be granted." It is therefore apparent that the proposition in Terrell (op. cit.) now applies with, if anything, greater force in the courts of the United Kingdom.

24 I infer from the absence of reference to these U.K. cases in the judgments of the Court of Appeal and the High Court that they were not relied on, or relied on as forcefully, in those courts. However, the existence of these decisions creates a striking dichotomy between the arguments on either side. To some extent, the arguments are ships that pass in the night without engaging with each other. Merck rely heavily on the U.K. authorities and downplay the Irish cases, in particular the decision in *Curust Financial Services Ltd. v. Loewe-Lack-Werk* [1994] 1 I.R. 450, which is treated as a case on a contractual issue alone and of little relevance in the field of patents. On the other hand, Clonmel rely heavily on the trend in the Irish authorities and place particular emphasis on the Curust approach and tend to downplay the U.K. authorities. Indeed, they are sceptical of the factual basis of the arguments relating to a downward price spiral and the failure to clear the way. In addition, it was argued that Merck's claim here sought to superficially cut

and paste the arguments which had succeeded in the U.K., without regard to the facts of the case, and that there was in this case little if any evidence to support the arguments beyond mere assertion.

25 The stark difference between the approaches is illustrated by the fact that if either argument is accepted it would establish a very strong presumption indeed, if not an absolute rule, either in favour of or against the grant of an injunction in cases where an injunction is sought to restrain infringement of an S.P.C. prior to its expiry. If an S.P.C. is considered as merely protecting an income stream in a stable market, then it will normally almost always follow that an injunction should be refused since on this view damages would be an adequate remedy. On the other hand, if the entry by a generic competitor would lead inevitably to a downward price spiral that cannot be recovered from, and there has, by definition, been a failure to clear the way, then, as the U.K. cases show, an injunction will, invariably, be granted. What is indeed even more striking is, however, that these diametrically opposed results are both said to follow from the same legal source: that is the observations of the then House of Lords on the principles to be applied on the grant of interim or interlocutory injunctions in *American Cyanamid Co. v. Ethicon Ltd.* [1975] A.C. 396, adopted with approval in this jurisdiction in *Campus Oil v. The Minister for Industry (No. 2)* [1983] I.R. 88 (referred to hereinafter, for convenience, as "*Campus Oil"* and "*American Cyanamid*"). *American Cyanamid*, it might be noted for good measure, is itself a patent case in which a patent holder obtained an interlocutory injunction restraining the entry on to the market of a competing product.

26 Before addressing the legal issues, it may be useful to observe that there are some distinct features which will nearly always arise when a competitor seeks to enter a market with the product contending that an S.P.C. granted in respect of the incumbent product is invalid. As already observed, when a patent is granted, there is no guarantee that it will be capable of commercially viable exploitation. However, an S.P.C. can only be granted for a product in respect of which a marketing authorisation has been granted. Normally, it follows that the producer of the product is benefitting from the monopoly granted by the original patent and by the S.P.C. As has also been observed, the later period of the patent and S.P.C. protection is normally the most profitable for the holder of the rights since the product has been launched, and has acquired a market share and can exclude competitors. It follows from this also, however, that the market will attract generics who will seek to enter it when the S.P.C. expires, or if the S.P.C. is determined to be invalid. Since generic competitors have to seek and obtain market authorisation, their intentions are likely to be known in advance of expiry. Where it is sought to contend that the S.P.C. does not prevent entry by the generic competitor, the range of legal arguments is smaller than those which will apply in a classic patent case. There can, by definition, be no question of a dispute as to the fact of infringement (other than perhaps in relation to an intention to enter the market). The whole object of a generic manufacturer is to produce a copycat product which can accordingly benefit from the market authorisation, and which can be entered in the register of substitutable products. Accordingly, it seems that in most cases the only argument that could be made will relate to the validity of the S.P.C., which normally would involve a consideration of whether Article 3 of the Regulation had been satisfied. While that can be a difficult task, it does not have the range of complexity that is involved in disputes where it is contended that there has been no infringement, or where there has been a challenge to the validity, and perhaps where there are claims for amendment of the patent. More importantly, for present purposes, the features of (1) a successful product enjoying a monopoly, (2) that success attracting generic competitors, (3) the knowledge that such competitors will likely enter the market on the expiration of the S.P.C., and (4) the fact that entry before the date of expiry can only be achieved if it can be successfully contended that the S.P.C. is invalid , are all features which arise in any such case. To that extent, a presumptive approach is perhaps unavoidable.

The decision in American Cyanamid

27 The grant of an injunction is an equitable remedy. While statutory authority for the grant of an injunction when a court considers it just and convenient to do so can be traced to the provision of the Judicature Acts, the injunction nevertheless retains its origins in the law of equity administered in the Courts of Chancery. It has always been a flexible remedy and is one of the most important ways in which equity tempered the rigidity of the common law. But, law develops incrementally and rarely proceeds in a straight line. Instead, there is an almost endless process of refinement, qualification, correction, and (sometimes) overcorrection. There is also a discernible tendency to reduce the approach taken in cases to rules which sometimes become calcified so it becomes necessary periodically to reassert the essential flexibility of the remedy. This process is visible in the decision in *American Cyanamid* itself, where Lord Diplock observed that there had been a rule of practice that where a patent was not well established, an injunction would not be granted if it was stated that the defendant intended to challenge the validity of the patent. This reflected the common law's traditional hostility to monopoly and it was some time before the appreciation of the administrative procedure leading to the grant of a patent led to a change in this approach.

28 The decision in *American Cyanamid* was principally concerned with another rule of thumb that had become an almost fixed and immutable rule: namely, that before an interlocutory injunction could be granted in any case, it was necessary to establish a prima facie case: that is, that on the balance of probabilities it was more likely than not that the plaintiff would succeed at the trial of the action. That rule was reflected in this jurisdiction and was discernible in the decisions in *Educational Company of Ireland Ltd. v. Fitzpatrick* [1961] I.R. 323 and *Esso Petroleum Co. (Ireland) Ltd. v. Fogarty* [1965] I.R. 531.

29 Lord Diplock's speech comprehensively dismantled the basis for any such supposed rule. The logic of an interlocutory application is that it is heard and determined in advance of the trial. It would make little sense for valuable and expensive court time to be used in an attempt to predict, on the balance of probabilities, the outcome of a case which is yet to be heard, where the evidence had not been ascertained and, more relevantly, had only been adduced on affidavit, and where the arguments were not fully developed. Accordingly, Lord Diplock concluded that there was no rule that a *prima facie* case should be established before an injunction could be granted. Instead, the court should consider whether a fair issue was to be tried, which means no more than the case not being frivolous or vexatious. If so, the court should then proceed to consider how the matters should best be regulated pending the trial which involved a consideration of the balance of convenience.

30 Lawyers, whether judges, practitioners, teachers, or students, tend to favour propositions which can be reduced to some simple formulae that can be readily understood, remembered, and applied. The lucidity of the admirably short judgment in *American Cyanamid* has lent itself to the reduction to some apparently simple and logical steps. Once it is established that there is a serious issue to be tried, then it was normally no part of a court's function when considering an application for an interlocutory injunction to attempt to anticipate the outcome of the case. Instead, the court should proceed to assess the balance of convenience. As to that the governing principle related to the adequacy of damages, this involved considering two hypotheses and balancing the outcome. If the plaintiff was refused an injunction but succeeded at the trial would he or she be adequately compensated by the award of damages at the trial? On the other hand, if the defendant was restrained by injunction, but nevertheless succeeded at the trial, would he or she be adequately compensated by the award of damages pursuant to the undertaking for damages which the plaintiff would have been required to give at the time of the grant of the injunction? In either case, it was also relevant to consider if the party was capable of meeting any award of damages if made.

31 This has been the basic approach which resolves many applications for interlocutory injunctions, and remains a valuable guide to analysis of any application. There is a clear logic to it. As long as the outcome of the case is unknown, a court must take steps to avoid any possible injustice being created by the length of time it will be necessary to take before a decision can be rendered. A claimant may have what appears to be a strong case, but if damages will be a complete remedy and there is the possibility of some irreparable harm to the defendant if he or she is restrained pending the hearing, then justice will be served by refusing an injunction and making the plaintiff wait until the trial of the action for his or her remedy. Similarly, a case may appear weak, but if it is demonstrable that irreparable harm would be caused if an injunction is not granted, then justice may require the grant of an injunction, and in the event that the plaintiff now fails at the trial of the action, that the court be in a position to take steps to adjust the position of the parties in a way which insures that the defendant has not been harmed irreparably by the grant of the injunction.

32 If there is doubt as to the outcome of the analysis of the respective decision to the parties, then other factors may come into play. For example, where other matters appeared balanced, it was a counsel of prudence to take such measures as were calculated to preserve the *status quo*. If the defendant was restrained from doing something which he or she had previously not done, the only effect of the interlocutory injunction would be to postpone the date on which he or she was able to embark on that course. Other than in "the simplest cases", there would be some disadvantages to either party which would not be compensated fully by an award of damages. If the uncompensatable damage to each party did not differ widely, it might not be improper to take into account in tipping the balance the relative strength of each party's case as revealed by the affidavit evidence. This was only appropriate, however, if there was no credible dispute that the strength of one party's case was disproportionate to that of the other.

33 While the decision in *American Cyanamid,* adopted in *Campus Oil*, has been distilled over subsequent years and reduced to some simple, readily understood, and helpful rules of thumb, it is important, in my view, to note that the essence of the decision was negative: it rejected the *prima facie* case test. Second, the underlying theme of the decision was to reassert the flexibility of the remedy and the essential function of an interlocutory injunction in finding a just solution pending the hearing of the action. Even though the judgment is lucidly and succinctly expressed, it should not, in my view, be approached as though it were the laying down of strict mechanical rules for the control of future cases. It is apparent, for example, that there is some ambiguity in the judgment about a matter which arises in this case, which is whether the question of adequacy of damages is part of or antecedent to the balances.

Adequacy of damages and the balance of convenience

34 Clarke J. (as he then was) observed in *Metro International S.A. v. Independent News & Media plc* [2005] IEHC 309, [2006] 1 I.L.R.M. 414 that this is largely a semantic issue, and I agree that in most cases either approach would lead to the same conclusion. It is apparent, however, that Clonmel, for example, lay some stress on the argument that if damages are an adequate remedy for the plaintiff, then an injunction should be refused without any further inquiry as to the balance of convenience or indeed other factors. While I consider it as an error to treat the observations in *American Cyanamid* and *Campus Oil* as akin to statutory rules, it is nevertheless necessary to consider if the judgment supports this approach. At para. 408B of the report of the judgment in *American Cyanamid*, the judgment stated that unless the material available to the court at the hearing of the application for an interlocutory injunction fails to disclose that the plaintiff has any real prospect of succeeding in his claim for a permanent injunction at the trial, "the court should go on to consider … the balance of convenience". As to that, the "governing principle" is the adequacy of damages. This implies that the adequacy of damages is part of the balance of convenience. However, at para. 408F Lord Diplock states:- "It is where there is doubt as to the adequacy of the respective remedies in damages … that the question of [the] balance of convenience arises". This suggests that adequacy of damages comes before the balance of convenience, which on this approach would involve a consideration of a number of unusual factors. The ambiguity in this regard is an indicator that the decision was not intended to lay down strict guidelines: instead, it was intended to remove the existing guideline of a requirement of a *prima facie* case which had become entrenched, and reassert the flexible nature of the remedy.

35 In my view, the preferable approach is to consider adequacy of damages as part of the balance of convenience, or the balance of justice, as it is sometimes called. That approach tends to reinforce the essential flexibility of the remedy. It is not simply a question of asking whether damages are an adequate remedy. As observed by Lord Diplock, in other than the simplest cases, it may always be the case that there is some element of unquantifiable damage. It is not an absolute matter: it is relative. There may be cases where both parties can be said to be likely to suffer some irreparable harm, but in one case it may be much more significant than the other. On the other hand, it is conceivable that while it can be said that one party may suffer some irreparable harm if an injunction is granted or refused, as the case may be, there are nevertheless a number of other factors to apply that may tip the balance in favour of the opposing party. This, in my view, reflects the reality of the approach taken by most judges when weighing up all the factors involved.

36 A further noteworthy feature of the judgment for present purposes, is Lord Diplock's acknowledgement that, save in the simplest cases, both parties will be able to show that they would suffer some damage that cannot be adequately compensated for in damages. Even if a very structured and sequential approach is taken, therefore, it is important to keep in mind that, while the end point of most civil cases is the award of damages, the interests that the law exists to protect often extend beyond the purely financial. In the aftermath of the decision in *American Cyanamid* it was, however, recognised (though more slowly in Ireland) that the judgment could not be treated as single test for the grant of interlocutory injunctions applicable in all circumstances, and instead required sometimes substantial qualifications and exceptions. The so-called rule in *Doherty v. Allman* (1878) 3 App. Cas. 709 or *Dublin Port and Docks Board v. Britannia Dredging Co. Ltd.* [1968] I.R. 136 may, in truth, be seen as a corollary to the *American Cyanamid* test rather than an exception to it. If there is no dispute, then a court will normally grant an injunction (if that is the appropriate remedy) without regard to any question of the consideration of the balance of convenience. It has also been recognised that the traditional rule against prior restraint is unaffected by the *American Cyanamid* and *Campus Oil* approach: if a publisher indicates that they intend to plead justification, or indeed any recognised defence, and have ground for doing so, then an injunction will be refused without any assessment of the balance of convenience. A number of other exceptions and qualifications are set out in Bean, Parry, & Burns, *Injunctions* (13th edn., Sweet & Maxwell, 2018) at pages 38 to 41, such as injunctions to restrain trade disputes (now covered by statute), claims in relation to covenants in restraint of trade, and claims to restrain the exercise of public functions. The observation of this court in *Okunade v. Minister for Justice* [2012] IESC 49, [2012] 3 I.R. 152 that a court should, in an appropriate case, give weight to the public interest in the orderly implementation of measures which were *prima facie* valid is an example in this jurisdiction of a similar approach. Although these cases could be described as exceptions to the basic approach, they do not indicate any weakness in the internal logic of the decision, but simply illustrate the boundary of its field of application. In particular, the underlying assumption on which the decision proceeds is that the interlocutory injunction is to be considered pending trial, which it is assumed will take place and finally resolve the merits of the action. If, however, it is unlikely that a trial will take place (for example, if the injunction sought is the entire remedy, such as an injunction restraining a strike or other industrial action, or restraining some form of public protest), then the grant of the injunction will almost always determine the case and the parties will have little practical

incentive to proceed to trial and incur the time and expense necessary to do so. In *N.W.L. Ltd. v. Woods* [1979] 1 W.L.R. 1294, only four years after the decision in *American Cyanamid*, the House of Lords itself decided that the principles did not apply to the grant or withholding of an interlocutory injunction in a trade dispute case where it was unlikely that there would ever be a trial on the merits. Accordingly, the court could not simply take the approach of considering whether there was a fair issue to be tried, but rather was required to make its best estimate of the strength of the respective parties' case. This decision is entirely consistent with the logic of the *American Cyanamid* case. If the *American Cyanamid* principles were applied in such circumstances, then there would be a real risk of injustice, since a party with perhaps a flimsy case might obtain an injunction that was effectively permanent against the other party, and perhaps, for good measure, on the basis that that defendant had insufficient assets to pay any damages, the plaintiff might recover (where on this hypothesis any damages would be highly unlikely). The decision in *N.W.L. Ltd. v. Woods* was approved by Clarke J. in his judgment in *Allied Irish Banks plc v. Diamond* [2011] IEHC 505, [2012] 3 I.R. 549. It is noteworthy that authors of *Bean (op. cit.)* observe at para. 3.34 that these special cases comprise a high proportion of cases in which interlocutory injunctions are sought.

37 While it is not perhaps in the same stark category it is nevertheless important to recognise that the *American Cyanamid* and *Campus Oil* approach is predicated on the basis that a trial will occur. It should be recognised, however, that even outside the trade dispute type cases, trials do not occur in all cases where interlocutory injunctions are sought. This is not simply because of the issue such as occurred in *N.W.L. Ltd. v. Woods* [1979] 1 W.L.R. 1294, but also because commercial and practical reality means it may be sensible to compromise the claim. Parties who have been restrained by an injunction are often understandably unwilling to devote time and resources to a further hearing at some time in the future simply to establish that the plaintiff was wrong and that an injunction ought not to have been granted. The existence of an interlocutory injunction in such circumstances may therefore have a significant impact upon the party's position in such negotiations. Courts should be aware of this possibility on an application for interlocutory injunction which is a further reason why the test must be, and normally is, applied with a degree of flexibility and sensitivity.

38 If approach in *American Cyanamid* and *Campus Oil* is not applied with some degree of flexibility, it can have a distorting effect on the application itself. A party seeking an interlocutory injunction will normally be concerned with its contention that the defendant is acting wrongfully and unlawfully, and, furthermore, the substantial damage that will be done and might be avoided by an injunction. However, affidavits drafted with one eye on the *American Cyanamid* criteria will tend to downplay these aspects of the case and emphasise sometimes peripheral features with a view to establishing the much sought after irreparable harm which may trigger the grant of the interlocutory injunction. Furthermore, an interlocutory injunction can be such a powerful weapon in commercial and other disputes that the possibility of a decisive first strike can be irresistible. There are, as Lord Diplock recognised, some cases which are so simple and clear cut that it is apparent that damages will be a wholly adequate remedy. There may also be other cases where it may be more convenient (in the broadest sense of the word) and where there may be less risk of injustice if events simply proceed, and the court can adjudicate on the merits when the facts are known and established and award remedies based on established facts, rather than the speculation involved in any injunction application. *Curust Financial Services Ltd. v. Loewe-Lack-Werk* [1994] 1 I.R. 450 can be seen in this light, and as a corrective against the temptation to dress up standard commercial disputes about money into more high octane disputes about interlocutory injunctions.

The decision in Curust

39 While the facts in *Curust Financial Services Ltd. v. Loewe-Lack-Werk* [1994] 1 I.R. 450 were in dispute, and the legal consequences of the disputed facts were hotly debated, the underlying contention was not complex. *Curust* argued that it had an exclusive distribution agreement for the defendant's product and was, therefore, entitled to restrain the defendant whether by itself or the second named defendant from selling or supplying the product until the agreement was lawfully terminated. The market was by definition stable. The products were identical. There was no question of damage to either reputation by the existence of the other product on the market. The measure of damages was simple. The plaintiff would be able to measure the impact of the defendant's sales either by showing the diminution of its own sales, or by calculating the profit it would have made on the sales achieved by the second named defendant who had agreed to keep an account. There were no longer term implications. There was a fundamental and basic dispute as to whether the agreement had been terminated, and subsidiary disputes as to the entitlement of the plaintiff to have a product manufactured by a third party without the consent of the defendant. However, the arguments about an interlocutory injunction risked erecting an elaborate structure when it was more sensible to seek to resolve the single underlying issue. O'Flaherty J. considered that the case was finely balanced, but that the crucial matter was that Curust would not be deprived of access to the market but simply obliged to share it in competition with the second named defendant. It was preferable to allow this position to obtain pending the trial of the action, rather than exclude the second named defendant from the market. Viewed in this way, the decision was a robust and pragmatic approach to the regulation of the period between the commencement of the proceedings and the trial of the action.

40 In my view, the oft-quoted passage from the judgment of Finlay C.J. at pp. 468 and 469 should be understood in this context and should not be understood as establishing a rule of general application that if damages may be awarded an injunction must be refused. However, significant reliance is placed upon the last sentence of the paragraph:–

> "Difficulty, as distinct from complete impossibility, in the assessment of such damages should not … be a ground for characterising the award of damages as an inadequate remedy".

It is accordingly necessary to consider the question in greater detail.

41 There may be circumstances where it can be said that the calculation of damages involves a complicated formula with a number of component parts but that there is no dispute about the correct formula or the figure it would produce in a particular case. In that sense, I would agree that the difficulty of the calculation does not itself mean that damages are not an adequate remedy. However, the sentence has also been relied on as suggesting that it must be completely impossible to assess damages before such damages can be said to be an inadequate remedy for a plaintiff, so that an injunction could be granted. I doubt that this was what was intended, or indeed that it is regularly applied in this way, but if it is so capable of being so understood, then, and with respect, I consider it requires some qualification.

42 There is a conundrum in any case in which an interlocutory injunction is sought. The parties at the interlocutory hearing vie with each other in arguing that they will suffer a loss or damages which cannot be compensated for by the award of monetary damages if they succeed at trial. Nevertheless, if the trial of the action proceeds then the plaintiff will put forward a claim for damages, and the defendant would be in a position to make a claim for damages under the plaintiff's undertaking, if the defendant succeeded in defeating the plaintiff's claim. In either case, a court will award damages and it cannot be suggested that the outcome is not to do justice to both parties. It is rarely, if ever, asserted by a successful plaintiff that it is simply impossible to award damages to compensate it for its loss, and rarer for any plaintiff to maintain that position at trial. On the other hand, the fact that it is possible to award damages does not preclude the grant of a permanent injunction, and should not be understood as an absolute bar to the grant of an interlocutory order. To take an extreme example, the assessment of damages for certain personal injuries is well developed, and

there is considerable guidance now available in respect of the damages which can be assessed for certain routine injuries. It could not, however, be suggested that this would be a valid ground to refuse an interlocutory injunction restraining conduct which it was alleged was wrongful and could give rise to such injuries. The position is more nuanced.

43 There are some cases, of which the personal injuries example may be one, where the interest protected by the law can be said to extend further than the obligation to pay compensation to the injured party when a wrong is carried out. Traditionally that is why permanent injunctions are granted in certain classes of action. But even in the field of a purely commercial transaction, a court, if it establishes a breach of contract, may grant damages for prior breach and, if appropriate, an injunction restraining a continuing or future breach.

44 To take an example closer to this case, if the alleged infringement had occurred early in the life of the S.P.C. and a very speedy trial was held so that there was a significant period of the S.P.C. still to run, then if the court at trial concluded that the S.P.C. was indeed valid, it would be likely to award damages for prior breach, but could certainly grant an injunction restraining future breach. However, inadequacy of damages is a ground upon which a permanent injunction may be refused. It must follow, therefore, that damages are not a perfect remedy, and cannot be a complete answer to an application for an injunction whether permanent or interlocutory. It should be recalled that the basic role for the intervention of equity in any case, is that the common law remedy is inadequate. I consider that the correct test is that set out at p. 58 of Spry, *Equitable Remedies* (4th edn., Sweet & Maxwell, 1990):-

> "The precise question that has been asked is whether the relegation of the plaintiff to such remedies as he has in damages or other legal remedies would leave him in as favourable position in all relevant respects as would exist if the obligation in question was performed in specie."

45 There is still substances in the test advanced by Lord Redesdale in *Harnett v Yielding* (1805) 2 Sch. & Lef. 549 at 553:-

> "Unquestionably the original foundation of these decrees was simply this: that damages at law would not give the party the compensation to which he was entitled, that is, would not put him in a situation as beneficial to him as if the agreement were specifically performed. On this ground, the court in a variety of cases, has refused to interfere where, from the nature of the case, the damages must necessarily be commensurate to the injuries sustained."

46 This does not mean that an equitable remedy, whether specific performance or injunction, must be granted, but simply that since in the exercise of the court's discretion, it may decide to award damages rather than relief in specie, and other discretionary considerations may mean that it is just to leave a party to his or remedy in damages. The sole question at this stage, however, is whether the remedy in damages can be said to be necessarily commensurate with any possible injury so as to preclude the possibility of the grant of an injunction. In that regard, it is noteworthy that in *American Cyanamid* itself, at p. 408H of the report, Lord Diplock observed that "save in the simplest cases, the decision to grant or refuse an interlocutory injunction will cause to whichever party is unsuccessful in the application some disadvantages which is ultimate success at a trial may show he ought to have been spared and the disadvantage may be such that the recovery of damages to which he would then be entitled either in the action or under the plaintiff's undertaking would not be sufficient to compensate him fully for any of them".

47 Difficulty of calculation of damages may be relevant at the interlocutory stage because the more complex the calculation and the greater the number of variables involved, the more likely it is that a court at trial would be forced to make an estimate or indeed to compound one hypothesis with another to arrive at its best assessment of damages to do justice in the case. But that necessarily increases the risk that the award of damages, although the best the court can do, may be something less than the doing of justice to either the plaintiff or indeed the defendant. In such a case, it may be more convenient not to leave one or other party to the possibility of an assessment of damages which is theoretically possible, but highly imprecise, speculative and therefore inconvenient. The fact that it is in theory possible to gather every feather does not mean that it is not more convenient to stop the pillow being punctured in the first place. Thus, if the action of the defendant which the plaintiff seeks to restrain would involve contact with many other businesses or members of the public, which it would be necessary to restrain if the plaintiff succeeded at the trial of the action, then, if no other factors are present, it may be more convenient, and therefore more conducive, to the capacity to do full justice in the case to simply restrain the defendant from doing so pending trial. The fact that it is not completely impossible to assess damages should not preclude the grant of an injunction to the plaintiff in an appropriate case. Accordingly, I cannot agree that it is possible to resolve this case merely by determining that it is not completely impossible to assess the damages which the plaintiff might obtain, and therefore that it is not necessary to consider further any other aspects of the case. An injunction should not be granted merely because an applicant can tick the relevant boxes of arguable case, inadequacy of damages, and ability to provide an undertaking as to damages, and by the same token should not be refused merely because damages may be awarded at trial. This approach is consistent with, and in my view accurately describes, the practice of the courts.

48 It is necessary however to address the defendant's arguments, that the decision in *Curust Financial Services Ltd. v. Loewe-Lack-Werk* [1994] 1 I.R. 450 has been applied in a series of cases in the area of intellectual property, and establishes a general principle that damages are an adequate remedy for a claim of breach of infringement of a patent or S.P.C. *SmithKline Beecham plc v. Genthon B.V.* (Unreported, High Court, Kelly J., 28 February 2003) is often cited for this proposition. In that case, the plaintiff was refused an injunction and undoubtedly reliance was placed on the decision in *Curust*. However, the admirable ex tempore judgment delivered by Kelly J. on that application deserves closer analysis. In particular, at p. 13, he specifically rejected a contention by the defendant "to the effect that a claim for patent infringement is almost always remedial by an award of damages" and adopted with approval the observations of Laddie J. in the English case of *Unilever plc v Frisa N.V.* [2000] F.S.R. 708. He stated specifically that "there is no hostility, inherent or otherwise, to the grant of interlocutory injunctions in patent infringement proceedings". In that case in question, the defendant had challenged the validity of the plaintiff's patent both before the European Patent Court (where the claim had failed but been appealed), and perhaps significantly, in the High Court of England and Wales, where, applying a very similar regime to that which would apply in Ireland, Jacobs J. had found the patent invalid. Furthermore, the defendant had commenced proceedings some months prior to the launch of its product, seeking a revocation of the plaintiff's patent. Perhaps most significantly, both parties agreed that possibly in light of the extensive litigation of the issue in other jurisdictions, the case was capable of being tried in a matter of months. The judgment of the interlocutory application was delivered at the end of February, and it was accepted that the case could be tried in July. In all the circumstances of the case, Kelly J. refused an injunction pending the trial.

49 The matter was subject to comprehensive review more recently in a detailed judgment in the High Court by Barniville J. in *Teva Pharmaceutical Industries Ltd. v. Mylan Teo.* [2018] IEHC 324, (Unreported, High Court, Barniville J., 5 June 2018). Again, that was a somewhat usual case. Teva, part of an international pharmaceutical company, was the holder of an Irish patent which covered a product for the treatment of multiple sclerosis ("M.S."). Mylan is an international generic producer which had the facilities in Ireland where it manufactured a generic drug to complete with the plaintiff's Copaxone 40mg which was launched by Mylan in the United States on 4 October 2017. Significantly, while Mylan's 40mg product is manufactured in Ireland, it does not have authorisation to be sold in Ireland. It is exported to the United States where it is supplied and prescribed to M.S. patients.

50 Mylan sought permission in the U.S. to market its generic drug by way of the A.N.D.A. procedure: that is, the Abbreviated New Drug Application with the Food and Drugs Administration ("F.D.A.") in that jurisdiction. Teva responded by bringing proceedings for alleging infringement of its patents in the U.S. The United States District Court for the District of Delaware found that the four patents relied on by Teva were invalid. That decision was appealed to the United States Court of Appeal, but the District Court refused to stay its order, and no application for an injunction or stay pending the determination of the appeal was made in the Court of Appeal. Indeed, in relation to a slightly different drug (the 20mg product) the United States Supreme Court itself refused a stay on the grounds of the adequacy of damages. Having carefully and comprehensively reviewed both the detailed facts of the case, the complications of the proceedings in other jurisdictions, and the relevant law, Barniville J. refused the interlocutory injunction sought by Teva. He did so for a number of different reasons, including reliance upon *Curust Financial Services Ltd. v. Loewe-Lack-Werk* [1994] 1 I.R. 450, in concluding that damages would be an adequate remedy for Teva, and also refusing to consider that the failure to clear the way (in Ireland) by bringing proceedings for the revocation of the Teva patent was fatal to Mylan's case. However, perhaps the most significant feature of the case lay in its international dimension. The claim being brought was an attempt to rely on the *American Cyanamid* rules to obtain an injunction which would have the effect of preventing Mylan from selling a product in a jurisdiction (the U.S.) where it was not only lawful to do so, but the corresponding patents had been declared invalid in proceedings directed to that object. Barniville J. quoted with approval the judgment of McCracken in *Griggs Group Ltd. v. Dunnes Stores Ireland Co.* (Unreported, High Court, McCracken J., 4 October 1996):-

> "What influences me more is that this is part of a world-wide campaign by the plaintiffs to establish a monopoly in a certain design of footwear. While the outcome of the action eventually depends only on the reputation of the plaintiffs in this jurisdiction, nevertheless I am entitled to take into account that this is a small battlefield in a world war, and that the attack in this battle is against what I might call a secondary target – namely a retailer – while no real attack is mounted against the primary target, namely, the manufacturers.
>
> The granting of an injunction is an equitable remedy and the concept of the balance of convenience is an equitable concept. It seems to me inherently inequitable in this case that the proceedings should be brought against the retailer which, on the evidence before me, bona fide purchased these goods from two manufacturers […] while no action is taken against the manufacturers."

51 Barniville J. saw a resonance with that case, in particular in the statement that the proceedings were a small battlefield in a world war, and that it would be inherently inequitable to grant the relief sought against Mylan in this jurisdiction in circumstances where the entirety of the losses and virtually all of the relevant evidence in relation to those losses were alleged to arise in and emanate from the U.S., and where there was no legal or regulatory restraint on the supply and prescription of the Mylan product on that market.

52 Both *SmithKline Beecham plc v. Genthon B.V.* (Unreported, High Court, Kelly J., 28 February 2003) and *Teva Pharmaceutical Industries Ltd. v. Mylan Teo*. [2018] IEHC 324, (Unreported, High Court, Barniville J., 5 June 2018) were, in my view, correctly decided and are, when analysed, examples of careful and nuanced applications of the test relating to the grant of interlocutory injunction. It is true that both cases are examples of a court refusing an application for an interlocutory injunction with the effect that a plaintiff was left to the remedy in damages in the event that they should succeed, and in that regard, it is understandable that reliance is placed upon *Curust Financial Services Ltd. v. Loewe-Lack-Werk* [1994] 1 I.R. 450. However, the decisions cannot be understood, in my view, as extending the application of that case, or still less establishing some general principle that interlocutory injunctions are inappropriate in the field of patents, S.P.C.s, or intellectual property more generally.

The balance of convenience in this case

53 The assessment of the balance of convenience is more difficult and finely balanced, in my view, than the judgments in the High Court and the majority judgment in the Court of Appeal would allow. There is something of an inconsistency, in my view, in considering that any damage to the Merck would be met by an award of monetary damages, whereas any damages Clonmel might suffer if wrongly restrained would not. Both parties are large commercial enterprises engaged in businesses with the ultimate objective of obtaining profit from the sale of their products. Furthermore, the rights and interests they both assert are intended to protect that business. In principle, therefore, monetary damages would go a considerable distance to compensate Merck if Clonmel was wrongly permitted to launch its product, or to compensate Clonmel if they were wrongly restrained from doing so.

54 Furthermore, it is perhaps not necessary to go to the lengths of placing a constitutional right in the balance to agree with Hogan J. in the Court of Appeal that the majority judgments do not give appropriate weight to the right involved from the S.P.C. holder's point of view. It is, in my view, incorrect both to depreciate the 001 S.P.C. as being no more than a right to an income stream, and at the same time elevate Clonmel's interest in becoming the incumbent generic to the key status of an interest which, if damaged, cannot be compensated by the award of monetary damages. The interests of the S.P.C. holder and the interests of the generic challenger are both interests in acquiring a position in the market. The difference between them is that the S.P.C. holder has a right conferred by a process of law which is presumptively valid: something which, if anything ought perhaps to favour Merck.

55 I recognise that the interest of Clonmel in exploiting a first mover advantage is something of value which is to be considered and given weight in the application for an interlocutory injunction, since it will necessarily be lost if an injunction is granted. If Clonmel is correct, therefore, in its belief that the S.P.C. is invalid, then it should be entitled to reap the commercial reward for its acumen in identifying the frailty in the S.P.C. and being willing to back its judgement by investing in the product to the point of making both the regulatory application for approval and the practical preparations to launch a product in April 2018 rather than await the expiry of the 001 S.P.C. a year later. That, however, is the high point of Clonmel's case. If it is wrong in its contention that the 001 S.P.C. is invalid, then its conduct constitutes an actionable wrong. However, I cannot see how that interest can be said to outweigh the right of Merck (if it in turn is correct) to exploit its monopoly, granted, on this hypothesis, in accordance with law. The interest of Clonmel in exploiting the possible frailty of the 001 S.P.C. depends, indeed, on two things – the existence of the S.P.C. (and a prior patent granting monopoly to Merck and therefore excluding all others from the field) and the observation of that monopoly by other market contenders. It is only if both these features are present that Clonmel can hope to exploit what it describes as its first mover advantage and achieve a position of practical (if not legal) monopoly as the only generic in the field, and at one and the same time capturing the bulk of the market previously held by Merck by a deep price discount, while deterring entry by generic competitors. In a way, therefore, Clonmel's interest is dependent on and derivative of the assumption of validity of the 001 S.P.C. I do not see, therefore, that the case can be resolved by preferring that interest (which may or may not be valid) to the legal right to monopoly of Merck (which itself may or may not be invalid). The fact, indeed, that Merck's right is one which arises pursuant to a lawful procedure for the grant of a patent and S.P.C. and which is valid until otherwise declared invalid by a court, is also relevant to the balance of convenience.

56 On the other hand, I would, with respect, doubt that the question can be resolved quite as simply as the text in *Terrell (op. cit.)*

might suggest. In any event, the difficulty of restoring a price after a successful trial cannot apply with the same force here, since it was always apparent that the S.P.C. was likely to expire before there could be any determination of the proceedings in the High Court, and long before the matter was finally settled. Similarly, while I consider that weight should be given to the "clearing the path" argument, it cannot be accepted without qualification as dispositive of the issue. Lawyers tend to value order and process, but if full weight is to be given to Clonmel's interest in capturing a first mover advantage, then it must be recognised that clearing the way poses some problems for Clonmel and any other generic, since, of necessity, any such proceedings would clear the way not just for Clonmel itself, but for any other generic who would be to that extent a free ride on Clonmel's action. I also doubt that it can be said that, in every case, the damage to an S.P.C. holder is necessarily more unquantifiable than the damage which may be suffered by a prospective generic entrant.

57 Finally, I should say that, while the majority of Court of Appeal considered that the case fell within the line of jurisprudence which can be traced to *N.W.L. Ltd. v. Woods* [1979] 1 W.L.R. 1294, and was a case where there was no likelihood of a trial of the substantive issue, I cannot agree. It is true that by the time of the trial of any action, and certainly by the time of any appeal process, the S.P.C. would have long expired and the court would not be able to grant an injunction, since any future presence in the market would not constitute an infringement of the non-expired S.P.C. But that does not mean that the trial would not take place (and indeed a trial has taken place), since the question of damages would remain a very live issue. This would require the court to determine the issue of the validity of the 001 S.P.C. In any event, the majority judgments did not go on to consider the strength of the parties' cases, which should occur where it is determined that a trial is unlikely. The reference to this question does not appear relevant, therefore.

Balance of convenience considered

58 Part of the difficulty in this case is that each party asserts an interest which, if valid, is something encouraged by the law. The resolution of the same issue – the validity of the 001 S.P.C. – will determine which interest is to prevail. If the 001 S.P.C. is valid, then it is a monopoly which the law accords for good reason to an inventor. If the 001 S.P.C. is invalid, then a generic entry into the market with consequent competition is to be positively encouraged. There is, therefore, a symmetry of interests which turns on the question of which interest is to prevail, and this case depends on the resolution of the same question. That, in itself, is a reason to approach this case by seeking the earliest possible trial of that single issue, rather than protracted debate that must necessarily depend on a number of hypotheses and which does not advance the determination of that fundamental issue.

59 Given the essential symmetry of the parties interests, I consider it appropriate to conclude that in neither case will damages be a fully adequate remedy, and, furthermore, the likelihood of some irreparable harm being occasioned to the successful party is also equally balanced between the parties. Both seek to maintain rights in respect of a stable market with 15,000 patients using a combination therapy of simvastatin and ezetimibe. In the real world, is it possible to rerun events like a laboratory experiment and consider what would or should have transpired had an injunction not been granted (if Merck succeeds at trial) or if an injunction is granted but it transpires that the 001 S.P.C. was invalid. It is true that if Clonmel were restrained pending the trial and the 001 S.P.C. is nevertheless determined to be invalid, Clonmel will never be able to gain the position of a first mover generic manufacturer which it sought to achieve by its launch in April 2018, and it will therefore be necessary to attempt a difficult estimation of both its likely profit if it had done so, and its position in the market, which would necessarily extend beyond the April 2019 expiry date. On the other hand, a similarly difficult calculation may have to be made if Merck succeed at the trial, but did not obtain an interlocutory injunction. Merck's right was not simply to recover income and profit pending the expiry of the 001 S.P.C. The rights of a valid S.P.C. holder are to exclude all competitors with products covered by the S.P.C. until the last day of the S.P.C. It follows that the S.P.C. holder will know the precise date on which its rights will expire, and one of those rights, therefore, is to be able to plan for that eventuality so that it may maximise its position in the market both until that period and the period immediately after expiry. If Clonmel is held to have wrongfully launched its product and yet was not restrained by injunction, then Merck would lose that significant benefit. The expiry of the S.P.C., as a matter of fact, if not law, would be determined by the fact of entry by Clonmel: a circumstance for which Merck would not be able to plan or take defensive steps in advance. In the event that no injunction was granted, but the validity of the S.P.C. was upheld, it would be necessary, therefore, to carry out essentially the same speculative calculation in reverse, and attempt to assess how Merck might have exploited its monopoly position pending expiry and defended its position in the market post-expiry, if it had not been deprived of the ability to control the date of expiry of the 001 S.P.C. In other words, it would be necessary to take the information in relation to the development of the market between April 2018 and 2019 and thereafter, and then hypothesise as to what would have occurred had Clonmel been restricted from entering until April 2019 when other generics might also have entered the market. Both parties must accept that this is not a case, as *Curust Financial Services Ltd. v. Loewe-Lack-Werk* [1994] 1 I.R. 450 was, where a market for a single product was shared between two parties. Instead the calculation is complicated further by the possibility of entry by up to four other generic producers.

60 I consider that this is a case where damages, while available, cannot be considered to be said to be a full or adequate remedy for Merck so as to exclude the necessity to seek an injunction. I also consider that damages will not be an adequate or full remedy for Clonmel if an interlocutory injunction is granted and it is then determined that the S.P.C. was invalid. Furthermore, it is plain that both parties have sufficient resources to pay any damages awarded. I do not consider, therefore, that the balance of potential irreparable harm favours either party decisively. While the question of the adequacy of damages to either party and the capacity of the parties to pay them is often the largest single element in the balance of convenience, and will often be decisive in most cases, there are other factors which are relevant and which, in a closely balanced case, may tip the balance.

61 One feature of this case, to which, in my view, weight should be given, can be viewed in three different, though related, ways. That is the fact that Merck is the holder of an S.P.C. granted pursuant to an authorisation process provided for by law and which involves the consideration both of the application for the 599 patent by the Controller of Patents, and the subsequent application for the S.P.C. As a matter of law, the S.P.C. is valid and effective until declared invalid by a court of competent jurisdiction. Just as in *Okunade v. Minister for Justice* [2012] IESC 49, [2012] 3 I.R. 152 it was recognised that it was appropriate to take into account the fact that an order had been made in accordance with law, by a body established and authorised by law to do so , and which must be treated as valid unless and until determined otherwise by a court or body, it is, in my view, not unreasonable to give this greater weight in the balance than the interests of Clonmel which only arise after it is determined that the S.P.C. is invalid. Another way of valuing this factor is that it represents the status quo ante. In this case, there was no unreasonable delay in the commencement of the proceedings, and the *status quo* must therefore be taken to be the position which existed prior to Clonmel's launch. Finally, the same factor comes into play if consideration is given to the question of clearing the way. For the reasons discussed above, this cannot be treated as a single dispositive argument and, for example, in cases where the defendant might plausibly contend that his product did not infringe a patent, it might be of lesser weight. Here, however, the only issue is validity and, moreover, that issue itself is to be determined within the limited confines of Article 3 of the regulation. Since, by definition, any generic challenger will have to have taken preparatory steps both of a practical and regulatory nature it is, in my view, a legitimate factor to which weight should be

given to consider that no steps have been taken to clarify the essential matters upon which Clonmel's right to launch the product depends: those concerning the question of the validity of the S.P.C.

62 In cases where the balance of convenience may be finely balanced, it may be appropriate to have regard, even on a preliminary basis, to the strength of the rival arguments as they may appear to the court. Certainly, if it was apparent that Clonmel's case for invalidity was strong, and/or if there had been successive determinations in Clonmel's favour of a similar challenge in other jurisdictions, then that might weigh against the grant of an injunction. In 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. It is recognised in the decision in *American Cyanimid* that if the question of adequacy of damages is evenly balance, it may not be inappropriate to consider the relative strengths and merits of each party's case as it may appear at the interlocutory stage. Courts are correctly reluctant to express views on cases which are to come to trial. However, it would be absurd if this rule of abstention were to result in a court conducting an agonised and necessarily imperfect assessment of a number of variable factors in a field with which it has little familiarity and where the evidence is indirect, written, and untested, all the while averting its attention from the area (perhaps of pure law) in which it can justifiably claim expertise. For this reason, I consider that Hogan J, taking the view he did of the balance of convenience, was quite correct to form some tentative view of the merits. However, it is, in this case, sufficient to say that Clonmel's case has not been shown to have that degree of strength which would outweigh the factors in favour of the grant of injunction. Accordingly, I consider that if the case was considered as of April 2018, then an interlocutory injunction ought to have been granted, subject to the Merck's undertaking in respect of damages, and a direction for a speedy trial on the issue of validity.

63 I am conscious that, although expressed in perhaps a nuanced way emphasising the flexibility of the remedy, this decision is nevertheless capable of being read as suggesting that in every case in which an S.P.C. holder seeks an injunction against a threatened challenge by a generic competitor, then an interlocutory injunction ought to normally be granted. Given the fact that a number of the features are common to any such claim, this is inevitable. I would, however, emphasise that the balance is a fine one, and is capable of being affected by the circumstances of particular cases and by a range of factors, such as the outcome of similar litigation in other jurisdictions, which may lead to a different outcome.

64 Finally, at the risk of perhaps creating a further rule that will require subsequent qualification and correction, it may be useful to outline the steps which might be followed in a case such this:-

> (1) First, the court should consider whether, if the plaintiff succeeded at the trial, a permanent injunction might be granted. If not, then it is extremely unlikely that an interlocutory injunction seeking the same relief upon ending the trial could be granted;
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> (2) The court should then consider if it has been established that there is a fair question to be tried, which may also involve a consideration of whether the case will probably go to trial. In many cases, the straightforward application of the *American Cyanimid* and *Campus Oil* approach will yield the correct outcome. However, the qualification of that approach should be kept in mind. Even then, if the claim is of a nature that could be tried, the court, in considering the balance of convenience or balance of justice, should do so with an awareness that cases may not go to trial, and that the presence or absence of an injunction may be a significant tactical benefit;
>
> (3) If there is a fair issue to be tried (and it probably will be tried), the court should consider how best the matter should be arranged pending the trial, which involves a consideration of the balance of convenience and the balance of justice;
>
> (4) The most important element in that balance is, in most cases, the question of adequacy of damages;
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> (5) In commercial cases where breach of contract is claimed, courts should be robustly sceptical of a claim that damages are not an adequate remedy;
>
> (6) Nevertheless, difficulty in assessing damages may be a factor which can be taken account of and lead to the grant of an interlocutory injunction, particularly where the difficulty in calculation and assessment makes it more likely that any damages awarded will not be a precise and perfect remedy. In such cases, it *may* be just and convenient to grant an interlocutory injunction, even though damages are an available remedy at trial.
>
> (7) 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;
>
> (8) While a structured approach facilitates analysis and, if necessary, review, any application should be approached with a recognition of the essential flexibility of the remedy and the fundamental objective in seeking to minimise injustice, in circumstances where the legal rights of the parties have yet to be determined.

65 If the matter was still live, I would, for the reasons set out above, allow the appeal against the orders of the High Court and the Court of Appeal and grant an interlocutory injunction pending the hearing. In the circumstances of this appeal, as outlined at the outset of this judgment, however, it is sufficient simply to allow the appeal.