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The interlocutory injunction dilemma in patent infringement and invalidity disputes

Dr Charles Lawson *

Interlocutory injunctions pose a dilemma for patent law and practice as they require a court to assess the parties' submissions and make decisions before all the issues are thoroughly argued. While the relevant legal principles are settled, there remains some uncertainty for intellectual property owners (or licensees or assignees) maintaining their statutory privileges and protecting their broader commercial interests in exploiting their privileges (such as market share, brand, good will, reputation etc). This article examines interlocutory injunctions where there is both an alleged infringement of a Patents Act 1990 (Cth) "standard patent" and a challenge to patent invalidity, to explore the potential of interlocutory injunctions as a tool to promote, encourage and coerce patent owners to provide access to, and disseminate, their patent protected products, method and processes while respecting core exclusive rights.

I. Introduction

The place of interlocutory injunctions in Australian intellectual property law is essentially one of means (and instruments) rather than ends.¹ That is, interlocutory injunctions are concerned with the procedural law by which the ends of the substantive patent laws articulated by the Parliament are to be achieved.² These court awarded interlocutory injunctions³ are primarily intended to restrain or forbid conduct that allegedly infringes the statutory "exclusive rights" (a negative injunction),⁴ although they may also require the alleged infringer to perform certain acts or do certain things (a positive injunction).⁵ Their stated principal purpose is to maintain the status quo between the parties until their rights can be finally adjudicated and determined.⁶ However, they are uncertain and expensive, albeit that they are essential to intellectual property owners (or licensees or assignees) maintaining their statutory privileges and protecting their broader commercial interests in exploiting their privileges (such as market share, brand, good will, reputation etc). Perhaps surprisingly earlier courts almost presumed that interlocutory injunctions were not to be granted in patent disputes,⁷ although more recently there appears to be a presumption that an interlocutory injunction should be awarded.⁸

The purpose of this article is to examine some of the complexity in seeking and obtaining an interlocutory injunction⁹ for an alleged infringement of a *Patents Act 1990* (Cth) "standard patent",¹⁰ where patent invalidity is asserted, and to explore the potential of interlocutory injunctions as a tool to promote, encourage and coerce patent owners to provide access to, and disseminate, their patent protected products, methods and processes. The issue is of particular importance as interlocutory injunctions have the potential to significantly limit competition in a market, whether temporary or permanent, to the detriment of consumers, by either allowing the patent holder to act without competition, or diminishing the incentive of future inventors to invent by undermining their short term (statute-based) exclusivity. Importantly, this article does not address interlocutory injunctions sought in circumstances where the same purposes might be addressed and characterised under the *Trade Practices Act 1974* (Cth) or some other grounds.¹¹

The article is structured as follows: the next part sets out the jurisdictional matters allowing a court to award interlocutory injunctions in patent disputes; the following parts address the evolution of interlocutory injunction law to the current consensus principles and its application to patent disputes where there is both a claim of infringement and invalidity (including a survey of recent cases); and the final part sets out a discussion of the current approach and suggests an initial conceptual framework that might be considered in applying the court's discretion in interlocutory injunction matters.

Essentially, the conceptual framework addresses competition in the market for the patent protected product, method or process and suggests damages are a suitable remedy where the parties' businesses are in different markets.

II. Interlocutory injunctions under the Patents Act

The *Patents Act* provides for injunctions as a remedy for infringement.¹² Before this determination is made, however, the Federal Court may grant interlocutory relief, in the exercise of its original jurisdiction in dealing with matters arising under the *Patents Act*¹³ "to make orders of such kinds, including interlocutory orders ... as the Court thinks appropriate".¹⁴ The Federal Court is also bound to consider the justice of the matter:

The Court shall, in every matter before the Court, grant, either absolutely or on such terms and conditions as the Court thinks *just*, all remedies to which any of the parties appears to be entitled in respect of a legal or equitable claim properly brought forward by him or her in the matter, so that, as far as possible, all matters in controversy between the parties may be completely and finally determined and all multiplicity of proceedings concerning any of those matters avoided [emphasis added].¹⁵

The *Federal Court Rules* further provide:

- (1) In an urgent case, the Court or a Judge may, on the application of a person who intends to commence a proceeding:
 - (a) grant an injunction;...
to the same extent, as if the applicant had commenced the proceeding and the application were made in the proceeding and whether or not the party against whom relief is sought has been given notice of the application.
- (2) An applicant under subrule (1) must give an undertaking to the Court to commence proceedings in relation to the subject matter of the application within 14 days of the determination of the application.¹⁶

A Federal Court Practice Note provides, in part:

The "usual undertaking as to damages" if given to the Court in relation to any interlocutory order made by it or any interlocutory undertaking given to it, is an undertaking:

- a. to submit to such order (if any) as the Court may consider to be just for the payment of compensation, to be assessed by the Court or as it may direct, to any person, whether or not a party, adversely affected by the operation of the interlocutory order or undertaking or any continuation (with or without variation) thereof; and
- b. to pay the compensation referred to in (a) to the person there referred to.¹⁷

The exercise of the court's discretion to grant an interlocutory injunction traces its origins to equity, and as a consequence, equity considerations apply in determining whether, and in what circumstances, an interlocutory injunction may be granted.¹⁸

III. Evolution of interlocutory injunction law

In *Beecham Group Ltd v Bristol Laboratories Pty Ltd* (1968) [118 CLR 618](#)^[PDF], the Australian High Court (Kitto, Taylor, Menzies and Owen JJ) considered an application for an interlocutory injunction in a patent infringement dispute. The patented invention concerned therapeutically active antibiotic ampicillin and the alleged infringement (advertising, offering for sale, selling and supplying) of that patent by the temporary and transient production of ampicillin in the process of obtaining hetacillin, and the breakdown of hetacillin upon ingestion into ampicillin.

The High Court accepted that there were substantive questions of fact and law to be determined by the court, and considered the basis upon which it might exercise its discretion in patent and other cases. The relevant conditions were considered to be (at 622-623):

The first is whether the plaintiff has made out a prima facie case, in the sense that if the evidence remains as it is there is a probability that at the trial of the action the plaintiff will be held entitled to relief ... How strong the probability needs to be depends, no doubt, upon the nature of the rights he asserts and the practical consequences likely to flow from the order he seeks. Thus, if merely pecuniary interests are involved, "some" probability of success is enough ... and in general it is right to say, as Roper CJ in *Equity* said in *Linfield Linen Pty Ltd v Nejoin* ...

There are disputes of fact as to a number of matters ... but this being an application for an interlocutory injunction I look at the facts simply to ascertain whether the plaintiff has established a fair prima facie case and a fair probability of being able to succeed in that case at the hearing.

...

... The second inquiry ... is whether the inconvenience or injury which the plaintiff would be likely to suffer if an injunction were refused outweighs or is outweighed by the injury which the defendant would suffer if an injunction were granted. It is of course to be remembered that if an injunction be granted it will be upon terms of the plaintiff submitting, in the event of his ultimately failing, to such order as to damages as the Court may make in order to compensate the defendant for any injury caused by the injunction; and likewise it is to be remembered that if the injunction be refused the defendant may be required to keep an account of the profits ... so that, if he loses the case and the plaintiff elects ... to recover the amount of those profits rather than damages, the quantum will be readily ascertainable [footnotes omitted].

In assessing the first consideration the High Court cited authority for the proposition that in patent cases the prima facie case should be a "strong one" (at 623).¹⁹ Further, the discretion should *not* be exercised (that is, the injunction should be refused) "unless either the patent has already been judicially held to be valid or it has stood unchallenged for a long period [being at least six years]" (at 624),²⁰ and "that the defendant shows by evidence 'some ground' for supposing that he has a chance of successfully disputing the validity of the patent at the trial" (at 624):²¹

This should be read, however, with Sir George Jessel's statement in *Dudgeon v Thomson* which divides into three classes the cases in which an injunction may be granted before the hearing in such a case. They are: (1) cases where the patent is an old one and the patentee has been in long and undisturbed enjoyment of it; (2) cases where its validity has been established elsewhere and the court sees no reason to doubt the propriety of the result; and (3) cases where the conduct of the defendant is such as to enable the court to say that, as against the defendant himself, there is no reason to doubt the validity of the patent [footnotes omitted].

On the evidence, the High Court ordered an interlocutory injunction as other courts in other jurisdictions assessing the same dispute had made such orders, the patents had been granted at least six years before the application to the court, and the dispute concerned only infringement without a challenge to validity, and so the plaintiff was very likely to establish the patent's validity at trial. A further relevant factor appears to have been that the plaintiff had an existing market for ampicillin that the defendant sought to overturn with hetacillin, despite warnings from the plaintiff of infringement proceedings to protect its statutory exclusivity (at 626):

It was in the face of this warning that the defendant commenced the acts now complained of, and the action was thereafter instituted without delay. Any goodwill the defendant may since have built up for hetacillin would of course be destroyed or damaged by granting an injunction, but that was a risk the defendant took *with its eyes open*. If it be not restrained, it will presumably take advantage of the time before the hearing to subject the goodwill of the plaintiff's established trade in ampicillin to the prejudice of competition from a product which the defendant maintains has some points of superiority.

In no meaningful sense could matters be said to be kept in statu quo if in these circumstances the defendant were left free to pursue its course, merely keeping an account of the profits it makes [emphasis added].

Following this decision, the House of Lords in *American Cyanamid Co v Ethicon Ltd [1975] 1 All ER 504* considered an application for an interlocutory injunction in a patent infringement dispute. The patent was for artificial absorbable surgical sutures and an allegedly infringing (through supplying to the market) competing suture. The Court of Appeal had rejected the application based on its consideration (at 508):

that there was a rule of practice so well established as to constitute a rule of law that precluded them from granting any interim injunction unless upon the evidence adduced by both the parties on the hearing of the application the applicant had satisfied the court that on the balance of probabilities the acts of the other party sought to be enjoined would, if committed, violate the applicant's legal rights.

Lord Diplock (with whom Viscount Dilhorne, Lords Cross of Chelsea, Salmon and Edmund-Davies agreed) considered the modern requirements for the grant of a patent meant that there was a prima facie reason for supposing a patent was valid,²² and that patent cases were governed by the same principles as other actions. The policy objective in granting interlocutory injunctions was, in Lord Diplock's view (at 509):

when an application for an interlocutory injunction to restrain a defendant from doing acts alleged to be in violation of the plaintiff's legal right is made upon contested facts, the decision whether or not to grant an interlocutory injunction has to be taken at a time when ex hypothesi the existence of the right or the violation of it, or both, is uncertain and will remain uncertain until final judgment is given in the action. It was to mitigate the risk of injustice to the plaintiff during the period before that uncertainty could be resolved that the practice arose of granting him relief by way of interlocutory injunction; but since the middle of the 19th century this has been made subject to his undertaking to pay damages to the defendant for any loss sustained by reason of the injunction if it should be held at the trial that the plaintiff had not been entitled to restrain the defendant from doing what he was threatening to do. The object of the interlocutory injunction is to protect the plaintiff

against injury by violation of his right for which he could not be adequately compensated in damages recoverable in the action if the uncertainty were resolved in his favour at the trial; but the plaintiff's need for such protection must be weighed against the corresponding need of the defendant to be protected against injury resulting from his having been prevented from exercising his own legal rights for which he could not be adequately compensated under the plaintiff's undertaking in damages if the uncertainty were resolved in the defendant's favour at the trial. The court must weigh one need against another and determine where "the balance of convenience" lies.

Lord Diplock doubted the usefulness of expressions such as "a probability", "prima facie case" or "a strong prima facie case" in the context of exercising the discretionary power, although clarified that the "court no doubt must be satisfied that the claim is not frivolous or vexatious; in other words, that there is a serious question to be tried" (at 510). He also considered that the exercise of the discretion *only* arose where damages were not an adequate remedy for either party. It was only then that the "the question of balance of convenience arises" (at 511) and these were to be determined, and their relative weight assessed, according to the particular circumstances of each case.

On the facts in this case, Lord Diplock accepted that there was a serious case to be tried, that the defendant's grounds of objection to the patent were on the affidavit evidence unlikely to succeed, the allegedly infringing sutures were not yet on the market so there was no business to be lost, the existing plaintiff's business would lose an opportunity to build its market against other substitutable products already on the market, and introducing and then later depriving the market of the infringing suture might adversely affect the defendant's other products on the market. On this basis Lord Diplock considered that an interlocutory injunction should be granted (at 511-512).

In the Australian High Court in [Australian Coarse Grain Pool Pty Ltd v Barley Marketing Board](#) (1982) 46 ALR 398, Gibbs CJ appeared to favour the House of Lords decision in *American Cyanamid*, although patent cases are arguably likely to also take into account the High Court's unanimous views in *Beecham*. Gibbs CJ said (at 398):

It seems to me, notwithstanding what was said in *Beecham Group Ltd v Bristol Laboratories Pty Ltd*, that the proper approach, in considering whether an interlocutory injunction should be granted, is first to inquire whether there is a serious question to be tried, and then to determine the matter on the balance of convenience. In other words, I incline to the view taken by the House of Lords in *American Cyanamid Co v Ethicon Ltd*, rather than to some of those expressed *obiter* in [*Beecham*]; the latter case was one in which a substantial issue arose as to the validity of a patent,²³ and the remarks in the judgment may be restricted to such cases.

However, subsequent decisions of the Australian High Court were not so clear.

In [Murphy v Lush](#) (1986) 65 ALR 651 at 653 the High Court (Gibbs CJ, Mason, Wilson, Brennan, Deane and Dawson JJ) merely accepted "that there are, in the sense used in the well-known authorities, serious questions to be determined".

In [Castlemaine Tooheys Ltd v South Australia](#) (1986) 161 CLR 148^[PDF] at 153-154 Mason ACJ addressed the relevant principles:

The principles governing the grant or refusal of interlocutory injunctions in private law litigation have been applied in public law cases, including constitutional cases, notwithstanding that different factors arise for consideration. In order to secure such an injunction the plaintiff must show (1) that there is a serious question to be tried or that the plaintiff has made out a prima facie case, in the sense that if the evidence remains as it is there is a probability that at the trial of the action the plaintiff will be held entitled to relief; (2) that he will suffer irreparable injury for which damages will not be an adequate compensation unless an injunction is granted; and (3) that the balance of convenience favours the granting of an injunction.

Recently two members of this Court have held that the plaintiff must establish that there is "a serious question to be tried", to use the expression favoured in *American Cyanamid v Ethicon Ltd*, in preference to the "prima facie case" test which was adopted in *Beecham* ... In my opinion that is the correct test to be applied at least in the majority of cases ... However, it may be that in some cases where the public interest would be adversely affected by the grant of an injunction the plaintiff may need to show a probability, even a distinct probability of success, in order to obtain an interlocutory injunction.

Then in [Patrick Stevedores Operations No 2 Pty Ltd v Maritime Union of Australia \[No 3\]](#) (1998) 195 CLR 1^[PDF] at 24, the High Court joint judgment of Brennan CJ and McHugh, Gummow, Kirby and Hayne JJ accepted the requirement that there must be a "serious question to be tried", citing *Castlemaine Tooheys* and *American Cyanamid* as authority for the proposition. Gaudron J and Callinan J, similarly accepted that there was a requirement to establish a "serious questions to be

tried". These judgments did not specifically articulate the required principle, they merely responded to the contentions in argument from the lower court reasoning.²⁴

In the lower court, North J had stated the proposition that "[t]he principles which govern the determination of an application for interim injunctions are well established. The Court must determine whether there is a serious question to be tried and whether the balance of convenience favours the grant of relief",²⁵ and this appears to have been accepted by the Full Federal Court²⁶ and High Court (Brennan CJ, McHugh, Gummow, Kirby and Hayne JJ at 21; Gaudron J at 60; Callinan J at 76²⁷).

The various conflicts were then addressed in detail²⁸ by the High Court in [Australian Broadcasting Corporation v O'Neill](#) (2006) 227 CLR 57^[PDF]. This case concerned a defamation action in which an interlocutory injunction was sought to stop a television broadcast of a potentially damaging documentary pending the hearing of the action. The significance of the decision was that a majority of the High Court (Gleeson CJ and Crennan, Gummow, and Hayne JJ), provided a clear statement about the relevance principles to be applied in *all* interlocutory injunction applications.

Gleeson CJ and Crennan J identified the relevant principles (at 68):

As Doyle CJ said in [Jakudo Pty Ltd v SA Telecasters Ltd \[No 2\]](#) (1997) 69 SASR 440^[PDF] at 442-443], in all applications for an interlocutory injunction, a court will ask whether the plaintiff has shown that there is a serious question to be tried as to the plaintiff's entitlement to relief, has shown that the plaintiff is likely to suffer injury for which damages will not be an adequate remedy, and has shown that the balance of convenience favours the granting of an injunction. These are the *organising principles*, to be applied having regard to the nature and circumstances of the case, under which issues of justice and convenience are addressed. We agree with the explanation of these *organising principles* in the reasons of Gummow and Hayne JJ (see [65]-[72]), and their reiteration that the doctrine of the Court established in *Beecham* ... should be followed [emphasis added].²⁹

Gummow and Hayne JJ identified (at 82) the relevant principles as those set out by Kitto, Taylor, Menzies and Owen JJ in *Beecham* :

The first is whether the plaintiff has made out a prima facie case, in the sense that if the evidence remains as it is there is a probability that at the trial of the action the plaintiff will be held entitled to relief ... The second inquiry is ... whether the inconvenience or injury which the plaintiff would be likely to suffer if an injunction were refused outweighs or is outweighed by the injury which the defendant would suffer if an injunction were granted.³⁰

In dealing with this first limb, Gummow and Hayne JJ said (at 82):

By using the phrase "prima facie case", their Honours did not mean that the plaintiff must show that it is more probable than not that at trial the plaintiff will succeed; it is sufficient that the plaintiff show a sufficient likelihood of success to justify in the circumstances the preservation of the status quo pending the trial.

This was then qualified by again referring (at 82) to the decision of Kitto, Taylor, Menzies and Owen JJ in *Beecham* : "How strong the probability needs to be depends, no doubt, upon the nature of the rights [the plaintiff] asserts and the practical consequences likely to flow from the order he seeks".³¹

Gummow and Hayne JJ then referred to *Castlemaine Tooheys* and *American Cyanamid* as appeals against decisions that "had placed too high the bar for the obtaining of interlocutory injunctive relief", and that their decision in *ABC v O'Neill* was, in effect, re-setting the bar at an appropriate level (at 82, 83):

When *Beecham* and *American Cyanamid* are read with an understanding of the issues for determination and an appreciation of the similarity in outcome, much of the assumed disparity in principle between them loses its force. There is then no objection to the use of the phrase "serious question" if it is understood as conveying the notion that the seriousness of the question, like the strength of the probability referred to in *Beecham* , depends upon the considerations emphasised in *Beecham* .

Gummow and Hayne JJ (at 83-84) *also* clarify the differences between the *Beecham* standard and Lord Diplock's juxtaposition in *American Cyanamid* of the phrase "that the claim is not frivolous or vexatious" with the phrase "that there is a serious question to be tried" and the subsequent statement in *American Cyanamid* apparently reversing the onus of proof. Their Honours confirmed that the relevant standard was established by *Beecham* and that the "governing consideration" was "that the requisite strength of the probability of ultimate success depends upon the nature of the rights asserted and the practical consequences likely to flow from the interlocutory order sought" (at 84).³² And further, the "practical consequences" are "illustrated by the particular considerations which arise

where the grant or refusal of an interlocutory injunction in effect would dispose of the action finally in favour of whichever party succeeded on that application" (at 84).

Gleeson CJ and Crennan J (at 68-74), and Gummow and Hayne JJ (84-89) then went on to consider the particular circumstances dealing with defamation and interlocutory injunctions in *ABC v O'Neill*. The significance of the decision was that Gleeson CJ and Crennan, Gummow and Hayne JJ established a three-limbed principle for considering interlocutory injunction applications that might be stated as:

- (a) Whether the plaintiff has made out an adequate case, in the sense that if the evidence remains as it is the plaintiff shows a sufficient likelihood of success to justify in the circumstances the preservation of the status quo pending the trial: "a serious question to be tried" (Gleeson CJ and Crennan J at 68; Gummow and Hayne JJ at 81-84).
- (b) Whether the inconvenience or injury which the plaintiff would be likely to suffer if an injunction were refused outweighs the injury which the defendant would suffer if an injunction were granted: "balance of convenience" (Gleeson CJ and Crennan J at 68; Gummow and Hayne JJ at 81-84).
- (c) Whether the plaintiff is likely to suffer injury for which damages will not be an adequate remedy having regard to the nature and circumstances of the case where issues of justice and convenience are also addressed (Gleeson CJ and Crennan J at 68).

It is, however, the application of the established principles that is practically important because the principles as stated are a discretion that depends for their effect on the particular circumstances of the matters in dispute. Recall that *ABC v O'Neill* concerned a defamation action in which an interlocutory injunction was sought, from broadcasting a documentary on television, pending the hearing of the action (Gleeson CJ and Crennan J at 63; Gummow and Hayne JJ at 75; Kirby J at 91-93). That interlocutory injunction grant was successful at trial,³³ and on appeal in the State Supreme Court.³⁴ Those proceedings were conducted on the basis that the documentary was capable of conveying that the respondent was a suspect in the disappearance of the identified children, that the respondent was a suspect in the murder of those children, and that the respondent was a multiple killer of children (Gleeson CJ and Crennan J at 63; Gummow and Hayne JJ at 75-76; Kirby J at 92). There was no question of prejudging a trial as the respondent was already in custody for other murders, although there was the prospect of "trial by media, with all the unfairness and injustice that entails" (Gleeson CJ and Crennan J at 63). Based on the then elements of a defence of "public interest" in the *Defamation Act 1957* (Tas), the trial judge had concluded:

My view is that, in general, it is not for the public benefit that the media should publicly allege that a person has committed crimes of which he or she has not been convicted, whether or not there are currently proceedings afoot with respect to the crimes. It is instead in the public interest that such allegations should usually be made to the public only as a result of charges and subsequent conviction. That the media on occasions makes such allegations is often referred to as "trial by media" ... However, so far as concerns the imputation that the accused is a multiple killer of children, a more appropriate description in this case would be "conviction by media". No suggestion of a trial, as we understand that word, will be involved here. Similarly, I can see no aspect of public benefit in the making public of allegations that the plaintiff was responsible for the disappearance and murder of ... children or that he is suspected of being responsible. The responsibility owed to the public with regard to the investigation of crime is entrusted by our society to the police and other public investigators and prosecutors. If there is evidence available that might assist the authorities to investigate the disappearance of the children in question, it should be made available to them. I have difficulty accepting that it is in the public interest that instead, such information be bandied about in public.³⁵

On appeal in the State Supreme Court, the majority upheld the trial judge's application of the relevant law, finding that the trial judge had correctly exercised his discretion in rejecting a finding that there was a public interest in free speech, and that free speech was not decisive in denying interlocutory injunctions specifically in defamation actions.³⁶ The dissent, however, distinguished between the "public interest" in a defamation defence and the "public interest" for an interlocutory injunction, saying that the "public interest" for an interlocutory injunction was governed by different legal principles.³⁷

On appeal to the High Court the concerns about the "public interest" were central to the various decisions,³⁸ and illustrated the normative nature of the relevant inquiry and the role of legal principle in what otherwise might be considered a matter of practice and procedure (Gummow and Hayne JJ at

78). Significantly (Gummow and Hayne JJ agreeing at 89), Gleeson CJ and Crennan J concluded (at 73-74):

The primary judge, and the majority in the Full Court, erred in principle in two respects in their approach to the exercise of the discretionary power to grant an interlocutory injunction in the special circumstances of a defamation case. They failed to take proper account of the significance of the value of free speech in considering the question of prior restraint of publication, and they failed to take proper account of the possibility that, if publication occurred and was found to involve actionable defamation, only nominal damages might be awarded. The appeal should be allowed.

In effect, this decision stands for the proposition that in considering interlocutory injunctions in defamation cases the value of free speech is a significant factor.³⁹ The question now is whether the various patent cases demonstrate the kinds of relevant factors and normative perspectives that might be significant in exercising the discretion. This is addressed next.

IV. Interlocutory injunctions and patents

In the context of patents, interlocutory injunctions generally arise where there is an allegation of infringement and a counterclaim of patent invalidity or vice versa.⁴⁰ In these circumstances the approach of the court determining an interlocutory injunction award is now well settled: the party alleging infringement and seeking the interlocutory injunction must establish that there is a serious case to be tried for *infringement* of the patent and the party asserting patent invalidity must establish that want of validity is a serious triable question of greater weight/significance than the party alleging infringement.⁴¹ It is then for the court to determine in its discretion whether the injury from *not* granting an interlocutory injunction will not be adequately addressed by damages ("adequacy of damages") *and* whether the balance the inconvenience or injury addressed by granting an injunction is outweighed by the injury which the defendant would suffer ("balance of convenience").⁴² While these are undoubtedly separate elements there is some overlap.⁴³

The complexity arises in patent matters because of the nature of a patent. A "standard patent"⁴⁴ is a statutory privilege of "exclusive rights"⁴⁵ that is essentially a monopoly to deal with the idea in the patent protected product, method or process, together with controlling how the patent protected product, method or process is used. An interlocutory injunction then challenges both the intellectual property owner (or licensees or assignees) maintaining their statutory privileges *and* protecting their broader commercial interests in exploiting their privileges (such as market share, brand, good will, reputation etc). This poses interesting challenges for assessing the "balance of convenience" and adequacy of damages considerations. A survey of recent cases perhaps shows that the courts may also be moving to a much more lenient approach in granting interlocutory injunctions in patent cases and that the balance of convenience and other discretionary factors may be being cast in favour of the patent holder. The following cases illustrate the courts' approaches.

Abbott GmbH & Co KG v Apotex Pty Ltd

In [Abbott GmbH & Co KG v Apotex Pty Ltd](#) (2009) 83 IPR 373 at 375-376, Apotex's solicitor advised Abbott that Apotex intended to market the chemical, sibutramine hydrochloride monohydrate, upon the expiration of an Abbott patent and that this would not infringe another similar Abbott patent with a later expiry date. Abbott then sought an interlocutory injunction to prevent Apotex marketing their chemical and infringing Abbott's remaining patent.

After an analysis of the patent claims and expert evidence about the chemical compositions, Jessop J concluded that there were both serious questions to be tried on infringement and validity (at 377 (infringement), 378 (novelty), 379 (manner of manufacture), 379-381 (anticipation), 381 (priority dates), 381-382 (fair basing)).

Interestingly, Apotex also pointed to Abbott's apparent reliance on the same active ingredient in a registered drug being used to support the extension (*Patents Act, s 70*) of *two different* patent grants and that this had been adversely commented on by a Deputy Commissioner of Patents. In essence, Apotex was pointing out that Abbott appeared to have two patents covering the same invention where

the earlier one had expired and hence the later patent was anticipated (and so invalid). Jessop J was not persuaded (at [28] 381):

I consider that the question whether the common reliance by both patents upon a single [drug registration] for the purposes of [a patent extension] necessarily means that the later patent was anticipated by the earlier is an open one, and cannot be resolved unfavourably to the applicants on an interlocutory hearing.

Jessop J then turned to the "balance of convenience" and other discretionary factors for and against granting an interlocutory injunction (at 382-386). Apotex submitted that the market for the chemical was "discrete" so that any lost sales for Abbott's product could be accurately calculated. Meanwhile Abbott contended that damages would not be adequate pointing to the following market features:

- (a) Abbott's promotional activities were primarily directed to medical practitioners to persuade those practitioners to choose their drug (a branded drug) for the treatment of their patients. Branded drugs generally attract a higher price, especially where they are patented and hold a monopoly in that market (at 382).
- (b) Apotex's promotional activities would have been primarily directed to pharmacies to provide an alternative generic substitute for a branded drug. Generic drugs generally attract a lower price than branded drugs, there being competition in the market for the drug lowering the prices (at 382).
- (c) Abbott considered that if a generic substitute (such as Apotex's drug) was available as a competitor, then medical practitioners might be inclined to prefer the lower priced generic substitute (at 382).
- (d) Abbott considered that their branded drug had two years of its patent protected life remaining and entry of a generic competitor would render Abbott's promotional activities of little worth; Abbott "ask rhetorically: if the only result of our sales efforts at the point of contact with medical practitioners is to increase the rate at which prescriptions for [their branded medicine] are written in circumstances where a generic substitute is permitted, why would we bother to continue with those sales efforts?" (at [35]). The consequence was that Abbott would make its sales representatives redundant (at 382-383).

In response Apotex contended that Apotex should not be confounded in bringing a generic drug to market by "no more than a prima facie case", the delay allowing other generic manufacturers to also bring their products to the market with Apotex's product (that is, losing the first mover advantage). Further, Abbott also appeared to have a generic drug ready to enter the market when the patent expired that would compete directly with Apotex's product (at 383). Balancing these factors Jessop J stated (at [36] 383):

Regrettably, perhaps, this case is an example of those in which the disadvantages that might be suffered by the parties if an injunction were, or were not, to be made on an interlocutory basis seem to depend upon how the parties – and how other interests not before the court – would react in the circumstances ... I consider that the arguments on the motion are finely balanced. The balance of convenience is not, as is sometimes said, "all one way". I am reluctant to place too much emphasis on the parties' predictions and estimations about how they and others would act in certain scenarios (unreliable as such a course would inevitably be), but I cannot ignore the effect which the grant or refusal of an injunction would be likely to have on the market in which [Abbott's drug] is presently sold.

Another important factor for Jessop J, although not determinative, was that Apotex knew of Abbott's patents and only challenged the validity of the patent when Abbott was "on the threshold of losing the added protection of [the] patent" (at 383). Apotex asserted that any action to challenge the validity of the patent would have been "telegraphing" its intentions and losing its position as an early generic entry into competition with Abbott. Jessop J noted (at [42] 383-384):

The questions in the litigation are whether the patent in suit is valid, and if so, whether it would be infringed by [Apotex] as it proposes. [Abbott's] entitlement to have those questions resolved on a final, rather than on an interlocutory, basis is not, in my view, diminished by reason of apprehensions which [Apotex] entertains along the axis of its interaction with other parties. It is, of course, quite open for [Apotex] to have acted as it has, and I would not presume to express any criticism of that course. However, as between itself and [Abbott], it should not expect that the court would be unsympathetic to an application for an interlocutory injunction in circumstances where [Apotex] has, it seems, consciously held back from making a timely challenge to the validity of the patent in suit. It seems that [Apotex's] decision to proceed in that way was essentially a tactical

one and, while I recognise the sense of that decision from the [Apotex's] own perspective, I remain of the view that [Abbott's] discretionary case for interlocutory relief has been made the more persuasive by reason of [Apotex] having acted as it has.

Jessop J was also sympathetic to Apotex's contention that Abbott's damage (by *not* granting an interlocutory injunction) was more easily calculated than Apotex's because Abbott had "an established trading pattern over a number of years, and access to details of [Abbott's] sales which, together, should provide a reasonably firm basis for the calculation of damages" (at 386). In contrast, Apotex's damage (by granting an interlocutory injunction) "might be most problematic to estimate [as to] what sales [Apotex] might have achieved had it been permitted to enter the market" (at 386). Jessop J rejected this contention after accepting that damages were not an adequate remedy for Abbott and the short period left for the patent term, but then stated (at [46] 386):

It would, in my view, be naïve to expect [after Apotex entered the market] that the reputation of [Abbott's branded drug], and the habits of doctors, pharmacists and consumers, could ever be restored to present levels thereafter. It is the circumstance that the patent in suit has only a further 2 years or thereabouts to run that, in effect, confines [Abbott's] losses to that defined period. However, I am not prepared to take the pessimistic approach of assuming that no part of that 2-year period would be available to [Abbott] after a presumptively successful result for them in this proceeding. The task of assessing damages will not, therefore (or at least not necessarily), be confined to the backward-looking process of comparing [Abbott's] lost sales with the sales of [Apotex's] generic product. It would, I predict, be necessary also to address the future damage arising during the course of [Abbott's] attempt to restore the market position of [Abbott's branded drug], and/or to consider whether, in the circumstances then obtaining, it ought to be regarded as entitled to view the remaining period of its statutory monopoly as too short to justify the making of such attempts and to look to [Apotex] for damages with respect to that period.

The end result was that Jessop J favoured Abbott's circumstances and awarded an interlocutory injunction against Apotex, with the proviso that the injunction would cease if Abbott entered the market with a generic and that they provide prior notice to Apotex if this was to happen (at 386-387).

Medrad Inc v Alpine Pty Ltd

In *Medrad Inc v Alpine Pty Ltd* (2009) 82 IPR 101, Medrad (and its Australian subsidiary) sought an interlocutory injunction to prevent Alpine from selling and offering for sale a syringe system that Medrad asserted had essential integers that infringed its patent. In response Alpine challenged the validity of Medrad's patent. In essence the Medrad's invention was a computer controlled injection device for holding a syringe and then injecting a substance into a patient according to computer program regulating the rate the substance entered the patient. Medrad supplied the injection systems (including the disposable syringes) for use in computer tomography and cardiovascular applications. The disposable syringes in dispute supplied by Alpine were a direct substitute for the disposable syringes provided by Medrad for use in Medrad's injection system (at 102-105).

As a part of their business model Medrad relied on the ongoing sale of disposable syringes to maintain contact with their customers and in setting the sale price for their injection systems with "the costs of the syringes over the life of the injector system ... significantly exceed[ing] the initial cost of the injector system" (at 104-105). In short, the dispute was about Alpine offering substitute syringes at a 20% cost reduction and whether this might be prevented by Medrad asserting its patented injector system included the compatible syringes as an essential integer of its invention. Medrad asserted that their patent was infringed and that "the syringe is an integrated component of the entire system, the characteristics of which are important to the accurate and safe operation of the system" (at 104).

Alpine asserted that their syringes did not infringe Medrad's patent claims, but if it did, then the patent was invalid because the disputed ridges/grooves for holding the syringes in the injection system and reinforcing the syringes were known features use in syringes and were therefore obvious (at 109, 115).

Kenny J accepted that the issue of infringement was a serious question and that there was no serious question to be tried about validity. Kenny J was also satisfied that "the inadequacy of damages and the balance of convenience favour the grant of an interlocutory injunction" (at 116). She reasoned that Medrad "have been in the business of selling syringes and medical injector systems for many years. They have a considerable business interest at stake" compared to Alpine that "has not been engaged in selling the impugned syringes for very long and the quantities involved are comparatively slight" (at

116). Further, any loss of Alpine's reputation as a reliable supplier "will be able to offer suitable explanations to its relatively new customers" (at 116).

As to damages, Kenny J reasoned that Alpine was not certain to be able to pay the damages and that Alpine would interfere with Medrad's "trade patterns" (at 116).⁴⁶ That is, the competition would compel a permanent price reduction of about 20% to maintain goodwill, custom and future injection system sales and a loss of reputation for their injection system if Alpine's syringes were defective.

Importantly, Kenny J noted (at [82]-[83] 117):

I accept that evidence about the nature of the competition in the medical injector systems and associated consumables market and the effect of new entrants might well be complex. Obtaining complete evidence of this kind would be expensive and probably unjustified for this application. It is undisputed that the applicants occupy a large proportion of the present market, and derive a large proportion of their revenue from the sales of consumables for the contrast injector systems ...

Although the respondent disputed the propositions advanced by [Medrad], ultimately, the respondent fails to take its case beyond the level of mere disagreement. The evidence of [Alpine] was very limited in that it concerned her experience in a different and not necessarily comparable business. None of [Alpine's] evidence seriously undermined the assessment made by [Medrad's] managing director and a person with apparently considerable experience in the relevant market. As things presently stand, the [Alpine] has not demonstrated that [Medrad's] assessment of the effect of the respondent's sales of the impugned syringes is significantly wrong in any material respect.

Kenny J also considered the argument that Alpine entered the market selling syringes "with its eyes wide open" either knowing or should of known about Medrad's patent (at 118). Importantly, Kenny J stated (at [85] 118):

There would indeed appear to be some force in the applicants' criticism of the respondent's conduct in this regard. The evidence on this point is slight, however, and I would not therefore be inclined to give this factor much weight in determining the outcome of the applicants' interlocutory injunction application.

The outcome was for Kenny J to award the interlocutory injunction. Perhaps importantly, "it is apparent that at least some of the harm that would be done to [Medrad] if an interlocutory injunction were not granted would not readily be met, if met at all, by an award of damages" (at [84]117).

Alphapharm Pty Ltd v Wyeth

In *Alphapharm Pty Ltd v Wyeth* (2009) 82 IPR 71, Wyeth sought an interlocutory injunction against Alphapharm to stop Alphapharm allegedly infringing a method patent for chemically treating central nervous system disorders (like depression) according to a dosage formulation. Alphapharm became aware of Wyeth's patent just before it proposed releasing its chemical and sought an order that Wyeth's patent was invalid. Wyeth then cross claimed seeking an interlocutory injunction to stop Alphapharm's anticipated infringement (at 73).⁴⁷

Jagot J dealt with the infringement and validity claims, finding that Wyeth had a serious case to try about infringement and that Alphapharm had a serious case to try on validity (at 82, 93). The matter then turned on the "balance of convenience" (and adequacy of damages considerations). Alphapharm "implicitly acknowledged" the analysis in *Sigma Pharmaceuticals (Aust) Pty Ltd v Wyeth* (2009) 81 IPR 339, and instead focused specifically on Wyeth's activities in changing the status quo in the market. In short, Wyeth's market was shifting from sales reliant on its method claim patent to another recent Wyeth chemical patent. The significance of this change in Wyeth's market was that its predominant product (venlafaxine hydrochloride) was out of patent (expiring in 2008), its method patent only covered certain dosages of venlafaxine hydrochloride (marketed as "Efexor-XR"),⁴⁸ and its new chemical patent covered a metabolite of venlafaxine hydrochloride (desvenlafaxine, and marketed as "Pristiq") independent of dosages that was not open to the same competition from generic substitutions as venlafaxine hydrochloride (at 74, 93-94).

This, asserted Alphapharm, was reflected in Wyeth's shifting marketing arrangements, and the rapidly declining market for Wyeth's older product "Efexor-XR", so that (at [110] 74):

in these circumstances, first, Wyeth could not assert a stable status quo warranting protection by an interlocutory injunction. Second, the public interest in competition is a discretionary factor weighing in Alphapharm's favour. Third, Wyeth is seeking an interlocutory injunction for a purpose outside the scope of the protection of the method patent, namely, to shelter itself from competition, a factor which also weighed in Alphapharm's favour. Fourth, Wyeth's conduct undermined its submissions about the risk of patient confusion in the event that Enlafax-XR [Alphapharm's product] is permitted to enter the market ... In summary, Wyeth

may not both approbate and reprobate by obtaining an interlocutory injunction to protect its proposed product switching from Efexor-XR to Pristiq on the basis of claims against any such switching to a generic substitute for Efexor-XR.

Alphapharm also asserted that an injunction would irreparably damage its market for its product and its investment because of the delay in hearing and the "inevitable appeal" taking up to two years. Alphapharm proffered various undertakings and argued that the likely price drop from generic competition was minimal and exaggerated by Wyeth, and that an account of profits from Alphapharm and other generic competitors was feasible and possible. Alphapharm argued that various undertakings by Wyeth were not adequate to protect Alphapharm's position and that foretelling the market with Wyeth's introduction of its new patent protected product Pristiq. And finally, Alphapharm asserted that its late knowledge about Wyeth's patent meant that it did not proceed with its "eyes wide open" when making its investments (at 95-96).

In response, Wyeth asserted that any harm to Alphapharm would be insignificant compared to Wyeth's as Alphapharm's trade was merely proposed, and given Alphapharm's diverse business compared to Wyeth's concentrated business, a loss "of a different order". Further, Alphapharm had not been "assiduous in its inquiries" about competitors' "relevant patents", and taken three months to bring a revocation action, during which time "commercial preparations have been undertaken with knowledge of the method patent" (at 96).

Wyeth asserted that its losses would be significant and irreparable: a price reduction to compete with Alphapharm's product (and other generic competitors following Alphapharm into the market), loss of goodwill, brand and patient confusion, price reductions under the Pharmaceutical Benefits Scheme, and diversion of resources to promote Wyeth's product. Wyeth also asserted that its new patent protected product, Pristiq, merely added to the range of antidepressant medicines and was not replacing or substituting the market for Wyeth's other products (at 96-97).

Jagot J considered that Alphapharm's position was similar to Sigma's in the earlier decision that granted Wyeth an interlocutory injunction with an "unpredictable and irreversible" effect on Wyeth's market if Alphapharm was allowed to compete, and also considered Pristiq as a new product without an existing market, and that it was only being advertised to a broader market of new patients or existing patients who might have better medical outcomes (such as avoiding side effects or efficacy) with the new product. Jagot J said (at [127]-[128] 98-99):

The risk that the market may alter in the interim period to Alphapharm's detriment must be weighed against the evidence of the materiality of that risk (which I consider substantially overstated by Alphapharm ...) and the reasons the risk exists. The risk exists because Alphapharm was insufficiently diligent about maintaining a watch over the compound patent and both continued to take commercial decisions to supply [Alphapharm's product] and (at least to some extent) failed to take action immediately to challenge the validity of the method patent on becoming aware of the method patent ...

... As Wyeth submitted, it is one thing for a patentee to obtain a patent for a new product and place that new product on the market anticipating that it may have some effect on its existing product. It is another altogether for a patentee with a reasonably strong prima facie case for infringement to be exposed to competition against its existing product by an allegedly infringing product while the claim is resolved. This is particularly so in a case such as the present where there is evidence of up to five generic suppliers likely to enter the market (if not restrained) within the period before resolution of the infringement claim. Accordingly, there is a status quo which Wyeth is entitled to seek to protect in circumstances where it has made good a prima facie case for infringement of its method patent.

Jagot J then concluded, awarding an interlocutory injunction (at [131] 99):

I do not accept that Wyeth is acting other than to protect its method patent, which is its right. I accept that Wyeth, if an injunction is not granted, will suffer irreparable harm for which damages are not an adequate remedy. I also consider that, as Sundberg J said [in Sigma], Wyeth is "much more likely to suffer from a disturbance of the status quo" than Alphapharm. I am not satisfied that the existence of the prima facie case of invalidity of the method patent, as found above, is sufficient to disentitle Wyeth from obtaining the relief sought, having regard to the balance of convenience and the strength of Wyeth's prima facie case for infringement.

Sigma Pharmaceuticals (Aust) Pty Ltd v Wyeth

In [Sigma Pharmaceuticals \(Aust\) Pty Ltd v Wyeth](#) (2009) 81 IPR 339, Sigma sued Wyeth seeking a declaration that its patent for a method of treating central nervous system disorders (such as depression) with a chemical (venlafaxine hydrochloride) was invalid. Wyeth cross-claimed, alleging

infringement and sought an interlocutory injunction. Sigma conceded that there was a serious question to be tried on infringement, but asserted that this was overcome because the patent was invalid.

Sundberg J considered Wyeth's infringement allegation, "because the comparative strength of the prima facie case is relevant to the balance of convenience", and concluded that they were "reasonably strong". He then considered the invalidity contentions, finding a prima facie case of invalidity (inventive step; manner of new manufacture (at 346; 347)), albeit others were deficient in some respect (validity; fair bases, novelty (at 344; 348)). Turning to the "adequacy of damages" and the "balance of convenience", Sundberg J considered that an account of sales by Sigma was "irrelevant" as (at [49] 349):

The ability of a party to effectively prevent infringements of its patents must necessarily affect the value of those patents and its commercial standing vis-à-vis others with whom it deals in relation to those patents, and this is not a matter to be ignored, particularly as this kind of injury does not lend itself to ready calculation in monetary terms.⁴⁹

Sundberg J accepted that in the market for venlafaxine hydrochloride Sigma was marketing to pharmacies where there was an incentive to substitute Sigma's product for the Wyeth product. As a result Sigma's product "has the ability to quickly take market share from [Wyeth's product]" "with consequent considerable and irreparable damage to Wyeth's business" (at [51] 349) and reduce the price paid for Wyeth's product. Sigma offered various undertakings, including not seeking listing of its product on the Pharmaceutical Benefits Scheme. Wyeth contended that this would still allow Sigma to affect Wyeth's market detrimentally and that other generic suppliers would soon follow, making any assessment of damages complicated. The result (at [58] 350):

Once Sigma is in the market, it is likely that other generic manufacturers will also come in. I doubt whether, if Sigma is not restrained and Wyeth succeeds at trial, Wyeth will ever be able to resume the position it now occupies ... In my view it is likely that Wyeth will suffer irreparable harm for which damages will not adequately compensate it, unless an injunction is granted.

In addressing the "balance of convenience" Sundberg J accepted that Wyeth had an established trade and that Sigma's was, at best, just starting. Further, Sundberg J accepted Sigma's failure to identify Wyeth's relevant patents and then its "persistence with its commercial operations" meant that it entered the market "with its eyes wide open",⁵⁰ there was also a "public interest point" that "vulnerable people, those with mental health issues, including depression, and elderly patients with a variety of medications" (at[65]) should not be confused by switching between Wyeth and Sigma products, and that the possible losses to Wyeth were "of a different order" to those likely to be suffered by Sigma.⁵¹ Other accepted factors were other generic suppliers entering the market and the difficulty in assessing damages. Taking into account these factors, Sundberg J considered "that the balance of convenience favours the grant of interlocutory relief" (at 353).

Wake Forest University Health Sciences v Smith & Nephew Pty Ltd

In [Wake Forest University Health Sciences v Smith & Nephew Pty Ltd](#) (2009) 81 IPR 530,⁵² Wake Forest sought an interlocutory injunction to stop Smith & Nephew allegedly infringing the patent for an apparatus invention that applied negative pressure to a wound dressing with the patent holder asserting infringement whereupon Smith & Nephew counterclaimed for invalidity. The wound dressings in dispute supplied by Smith & Nephew were a direct substitute for the dressings provided by Wake Forest for use in Wake Forest's negative pressure apparatus.

Ryan J found (at 534-542) that there was a credible case of infringement asserted by the applicant and a credible case of invalidity asserted by the respondent. The remaining questions were then the "adequacy of damages" and the "balance of convenience" (at 543-547). Ryan J favoured the applicant's assertions that early entry into the market of a comparable and competing product would disturb the patent monopoly for that product and "would be likely to alter the market in ways which are not readily predictable or for which an award of pecuniary damages would not afford adequate compensation" (at 543). The irreparable damage was asserted by the applicant to be (at [51] 542-543):

- loss of sales and rental income, flowing from the need to compete with a cheaper product on the market;

- price depression, flowing from downward price pressure which would be exerted by purchasers ... if a cheaper version of the same product were available;
- loss of goodwill which would be caused to [the applicants] if it were to seek to maintain the prices ... at a level above those for a comparable product; and
- loss of goodwill should an injunction be granted at trial and [the applicants] seek to enforce its monopoly and return to its present price structure (in other words, [the applicants] would come to be seen as "the villain" in the market).

Having concluded that there was a serious question to be tried and that damages were not adequate, Ryan J then framed the "balance of convenience" as whether the status quo should be retained. The evidence and conclusions supporting the conclusions about a serious question and the adequacy of damages were "powerful reasons for preferring an interim maintenance of [the applicants] monopoly" (at 544).

Further, it was significant for Ryan J that the respondents entered the market in Australia knowing of the patent and the potential for an infringement action in Australia similar to litigation already underway in other jurisdictions and without seeking to revoke the patent. The respondent also submitted that it would suffer damage in the form of lost sales, reputational damage, increased costs to its likely customers, lost opportunities to participate in tenders for the sale of its products, lost opportunities for its products to be directly compared with the applicant's products in evaluations by potential customers, and an adverse effect of the morale of sales staff (including "losing credibility and have received expressions of frustration and irritation" from potential customers) (at 544-546).

Ryan J was not persuaded by these submissions, awarding an interlocutory injunction and concluding (at [72] 546-547):

I have been persuaded, on balance, that the status quo before the entry of [the respondent] into the market for foam wound dressing kits should be maintained until trial or further order. I have been reinforced in that conclusion upon ascertaining from the docket judge that a speedy trial of this action can occur if the parties are able to attend, with reasonable expedition, to the pleadings and other interlocutory steps. In the result, I shall order that [the respondent] be restrained until the hearing and determination of the action or further order from selling or disposing of its [products]. However, I consider that it would unduly distort the balance of convenience and would be inimical to the public interest if [the respondent] were restrained from submitting its [products] for evaluation as part of a tender process to be conducted by a public health authority or purchasing entity or other substantial purchaser or prospective purchaser of [the products]. I shall therefore add to the restraint which I propose, a proviso excepting from it the supply without charge of [the respondent's products] solely to enable those [products] to be evaluated as part of a tender process to be conducted by a purchaser or prospective purchaser of [the products].

On appeal to the Full Federal Court in [Smith & Nephew Pty Ltd v Wake Forest University Health Sciences](#) (2009) 82 IPR 467 at 470 the parties argued about the competing interests of infringement and validity, albeit the matter was decided that on a proper construction of the disputed claim it was invalid,⁵³ and so there could be no infringement and no serious question to be tried (at 474).⁵⁴ The Full Federal Court did, however, address the assertion that the judge at first instance gave too much weight to the failure to seek revocation of the patent and that potentially infringing conduct was undertaking knowing that infringement proceedings might follow (at 474). Finn, Bennett and Middleton JJ stated (at [52] 475):

We do, however, accept that it would be an error in considering whether the grant of an interlocutory injunction, in the context of an infringement claim, where the validity of the patent is in issue, to impose on a person who seeks to launch an alleged infringing product, an obligation to "clear the way" by revoking the patent. Equally, the fact that a new entrant is prepared to take the risk of being restrained with its eyes wide open, should not be elevated beyond being a factor in the assessment of the many factors relevant to whether to grant an injunction.

As the Full Federal Court found that there was no infringement there was no basis for seeking an interlocutory injunction and the trial judge's award was overturned (at 469, 474).

Interpharma Pty Ltd v Commissioner of Patents

In [Interpharma Pty Ltd v Commissioner of Patents](#) (2008) 79 IPR 261 at 262-263, Eli Lilly sought an interlocutory injunction against Interpharma alleging infringement of its chemical patent for gemcitabine hydrochloride used in the treatment of various cancers and its process patent for a manufacturing process of the chemical.

Jessop J considered the various arguments and evidence finding that both parties had serious cases to try on infringement and invalidity. The decisive matters were therefore the "adequacy of damages" and the "balance of convenience" matters (at 278-283).

Eli Lilly contended that the price of its product would decline and other competitors would enter the market making assessing lost sales into the future "increasingly problematic". While Jessop J accepted that calculating damages "will be attended by some uncertainty", his main concern was that upsetting the status quo might have consequences that were "unpredictable and irreversible" so that "the real problem is whether it would ever be possible to restore the cross-claimants to the position they now occupy, should they succeed at trial but not secure the interlocutory restraints they seek" (at 279-280).

This was a concern for the longer term, and as a consequence, Jessop J distinguished between adequate damages for the chemical patent which only had approximately four-month term remaining with infringement (if established) with no likely generic competitors other than Interpharma, and the longer term process patent expiring in some six years. As a result damages were likely to be an adequate remedy for infringement of only the chemical patent (at 280).

Turning to the "balance of convenience", Eli Lilly relied (at 281) on a proposition in *Plimpton v Spiller (1876) 4 Ch D 286* that was endorsed in *Beecham* :

Well, now, if you assume that the defendant is in the right, there is no doubt that an injunction is a great hardship upon him; but if you assume that the plaintiff is right, then the mere keeping of an account by the defendant seems to me to be a great hardship on the plaintiff, for he would be driven to commence actions against the purchasers from and customers of the defendant, which would obviously lead to a multiplication of suits. There will be a hardship on the one side or on the other, and the question is, on which side does the balance appear to lie? Now if the trade of a defendant be an old and an established trade, I should say that the hardship upon him would be too great if an injunction were granted. But where, as here, the trade of the defendant is a new trade, and he is the seller of goods to a vast number of people, it seems to me to be less inconvenient, and less likely to produce irreparable damage, to stop him from selling, than it would be to allow him to sell and merely keep an account, thus forcing the plaintiff to commence a multitude of actions against the purchasers.

Jessop J accepted Eli Lilly's contention as a "valid starting point" and that Interpharma would only forego its preparatory and start-up expenses because it was a new entrant. Interpharma "does not appear to be able to say that its present position would be worsened if injunctions were granted" (at 281). In effect this conclusion rejected Interpharma's contention that its commercial focus was cancer pharmaceuticals and that the chemical was important to its ability to supply the "full suite" of available chemical therapies.

Jessop J also accepted Eli Lilly's contention that Interpharma had entered the market with its "eyes wide open" so that it knew, or should have know, about the Eli Lilly patents when preparing to enter the market: "These circumstances, in my view, significantly compromise its attempt to resist an injunction which goes no further than to maintain the status quo" (at [77] 282). While this statement was made in reference to the chemical patent, a similar proposition was stated for the process patent (at 282).

The final consideration in the "balance of convenience" assessment was weighing the relative strength of seriousness of triable issues of infringement against invalidity with Eli Lilly asserting "a very strong case on the merits" (at 282). In considering the chemical patent Jessop J was not persuaded that (at [80] 282):

"either side has the self-evidently stronger case at the level of infringement" and did not "take the merits of the matter into account at that level, beyond noting that the cross-claimants have a prima facie case."

On invalidity, however, Jessop J considered that Interpharma had a stronger case "which should be placed on the scales in favour of [Interpharma]" (at [80] 282). The result, taking into account the short time remaining for the patent and the adequacy of damages, was: "On balance, I am not persuaded to grant the interlocutory restraints sought by [Eli Lilly]" (at [83] 282).

In considering the process patent, Jessop J was persuaded that Eli Lilly had the stronger case on infringement, that the longer term of the patent meant that "there are likely to be all manner of difficulties restoring them to the position of advantage that they now occupy", and that Interpharma

had not shown sufficient "conscientious concern" to discover Eli Lilly's patent (at 282). This was sufficient for the award of an interlocutory injunction for the process patent.

Merck & Co Inc v GenRx Pty Ltd

In [Merck & Co Inc v GenRx Pty Ltd](#) (2006) 70 IPR 286 at 287, Merck commenced proceedings alleging that GenRx's pharmaceutical products infringed its patent protected pharmaceutical product. To address GenRx's imminent import of the allegedly infringing pharmaceutical products Merck also sought an interlocutory injunction restraining GenRx from "infringing claims 16-27 of the patent by supplying, ordering to supply, importing or keeping for the purpose of doing any of those things the products branded Apo-Alendronate, GenRx Alendronate, Chemmart Alendronate, Terry White Chemists Alendronate and Alendronate-DP". The injunction application also sought to prevent GenRx from "continuing to list or apply to list any one or more of those products for supply under the Pharmaceutical Benefits Scheme". GenRx argued that Merck's patent was invalid because a prior disclosure before the priority date in another patent obviated "novelty" (at 288).

In granting an interlocutory injunction, Moore J stated (at [19] 292):

There can be little doubt that GenRx has engaged in this conduct deliberately and with the knowledge that Merck's patent would be infringed unless it was able successfully to impeach its validity. It could have done so by revocation proceedings. It has not and now calls in aid the consequences of not being able to give effect to the arrangements now in place. That includes commercial loss to it and others and potentially, loss of reputation. For my part I give little weight to these complaints or concerns. As just discussed, GenRx has placed itself in this position quite deliberately and knowingly. To use the language of some of the authorities, its "eyes were wide open".

The terms of the interlocutory injunction were, however, confined to prohibiting the import of the GenRx pharmaceutical products until the infringement issues were determined (at 292). The reasoning of Moore J was unfortunately not presented in detail due to the time limits applying to preparing the reasons (at 287).

The relevant considerations appear, however, to be that:

- the balance of convenience favoured Merck because GenRx were aware of possibly infringing Merck's patent before they commenced seeking regulatory approval and making their arrangements to import the products (at 291-292);
- Merck's losses, albeit just financial, "will be difficult to assess with any real precision what those losses are so as to compensate Merck for its actual loss" (at 292); and
- the *Patents Act* and relevant authorities "create a statutory regime intended to afford patent owners a measure of protection" (at 292).

V. Discussion

The courts recognise that the creation of the patent privilege under the *Patents Act* is distinct from the discretionary equitable remedies available to limit dealings with the patent protected product, method or process.⁵⁵ Where those dealings are in dispute the court's approach to addressing interlocutory injunction claims appears to be settled, and the survey of cases demonstrates that courts have little problem applying the accepted principles.⁵⁶ The cases, however, illustrate that the significant evidentiary elements relied on by the courts in applying the discretions in respect of the "adequacy of damages" and the "balance of convenience"⁵⁷ do not articulate a clear conception of the kinds of evidence that might most usefully assist a court in reaching its decision.⁵⁸

Thus, in the generic chemical cases (Abbot ; Interpharma ; Merck), dosage (method) cases (Alphapharm ; Sigma) and medical devices cases (Medrad ; Wake Forest) the common evidentiary themes in respect of the "adequacy of damages" and the "balance of convenience" were:

- the "interference with ... trade patterns";⁵⁹ prior knowledge of the patent ("eyes wide open" or knowing or should have known about the patent);⁶⁰
- reputation and goodwill;

- long standing business;⁶²
- price and income decline for the patent holder;⁶³
- difficulty accounting for lost sales;⁶⁴
- first mover advantage;⁶⁵ and
- wasted resources on unnecessary setup or promotion.⁶⁶

While these are undoubtedly relevant and useful evidentiary themes, the question is whether a more appropriate and generally applicable conceptual model might be adopted in assessing "adequacy of damages" and the "balance of convenience" and leading to a more consistent and reliable predictor of how a court might reach its decision.⁶⁷

Perhaps importantly, the starting place for developing any relevant conceptual model is to identify exactly what it is that a patent grant is intended to achieve. In the context of interlocutory injunction the broader policy balance in contemplating patents was articulated by Ryan J in *Wake Forest* :

I acknowledge that there is significant public interest in maximising competition, particularly in a market like that for wound dressings [the product] where the major consumers are public hospitals and similar institutions operating under severe budgetary constraints. However, there is also a countervailing public interest recognised by the exclusive right granted by s 13 of the *Patents Act* to a patentee to exploit an invention. That public interest is in encouraging scientific and technological research and innovation and would not be served if a patentee's rewards from the subject invention were suspended or diluted for a period before the determination of litigation in which the patentee is, presumptively, successful.⁶⁸

Similarly broad statements about the need for patents to overcome the public goods problem inherent in the nature of invention are not controversial.⁶⁹ Such generalisations are consistent with the broader objectives of Australia's economic and science policy planners asserting that commercialising Australia's ingenuity, creativity and determination through patent privileges under the *Patents Act* (and the *Trade Practices Act*) will deliver an Australian future of prosperity.⁷⁰ Within these broader objectives there is also a range of general policy initiatives to increase the number of businesses investing in R&D, increase innovation across the economy, encourage a culture of collaboration within the research sector and between researchers and industry, and secure value from the commercialisation of Australian research and development.⁷¹ Intellectual property and patents in particular, are a part of this policy matrix.⁷²

The appropriate purpose for patents, however, remains uncertain.⁷³ This uncertainty is significant because different purposes for patent privileges lead to different theoretical conceptions about what the patent scheme is intended to achieve.⁷⁴ Comparing the "reward theory" and the "prospect theory" illustrates this contention. The "reward theory" views a patent as an incentive to undertake uncertain invention with an opportunity to appropriate greater commercial returns. This is considered to foster socially beneficial inventions, but with significant social costs on short term inefficiencies in the market from the anti-competitive effects of the patent (primarily restricted output and higher prices) appropriating public goods (ideas) that would otherwise be used.⁷⁵ In contrast, the "prospect theory" views patents as promoting the commercial development of inventions with patents granted to early stage inventions facilitating the bringing of a usable invention to the market and acting as an incentive to maximise the commercial value from exploiting the invention with relief from free-riders.⁷⁶

These different theories pose significantly different consequences for short-term competition. The "reward theory" imposes high thresholds for patentability seeking to limit patents to only those inventions that would not have been made with significant concerns about the effects on competition. In contrast, the "prospect theory" imposes lower thresholds giving the patent holder control over the development process and possibly increasing the efficiency of commercialisation (that otherwise may not occur) with less concern (or no concern) about the effects on competition. Thus, in the context of interlocutory injunctions, the "reward theory" and the "prospect theory" posit different sensitivities to competition and how competition factors might be addressed in contemplating an interlocutory injunction remedy.

There is a further complication in the theoretical role and place of injunctions as remedies in intellectual property disputes. The *Patents Act* standard patent's exclusive rights (s 3 and Sch 1 ,

"patent", "exploit") are an entitlement (s 13(1)) of the holder of a unique product, method or process⁷⁷ in the form of personal property (s 13(2)), so a "property rule" most probably applies:⁷⁸ "No one can take the entitlement to private property from the holder unless the holder sells it willingly and at the price at which he subjectively values the property".⁷⁹ In contrast,⁸⁰ a "liability rule" posits that an entitlement may be destroyed or transferred and the value of the entitlement determined by an organ of the state (an objectively determined value) rather than the entitlement holder.⁸¹ An injunction is the preferred remedy for "property rules" as they generally serve the equitable remedial function of stopping infringement *as well as* preserving the ability of the entitlement holder to determine both the value and the uses (and benefits) of their property (invention) according to the particular circumstances (and desires) of the entitlement holder.⁸² In contrast, damages are the preferred remedy where "liability rules" apply:

This value may be what it is thought the original holder of the entitlement would have sold it for. But the holder's complaint that he would have demanded more will not avail him once the objectively determined value is set. Obviously, liability rules involve an additional stage of state intervention: not only are entitlements protected, but their transfer or destruction is allowed on the basis of a value determined by some organ of the state rather than by the parties themselves.⁸³

As a generalisation, in a patent dispute in the context of a "property rule" a court will ultimately decide whether there is infringement,⁸⁴ and where infringement has been found the infringer will be enjoined from further infringement subject to negotiating with the patent holder a price and dealing satisfactory to the patent holder (thus buying out the entitlement). For interlocutory injunctions, however, the court's task is to decide that if there is infringement, will the court-assessed damages be sufficient to properly value the patent, essentially addressing the patent dispute in the context of a "liability rule". In short, this a change from a conception of the "property rule" with an injunction to a conception of the "liability rule" with damages. This is perhaps an impossible task as the presumption of a "property rule" for patents is favoured exactly because these assessments are accepted to be too difficult and too complex for a court, and best left to the parties.⁸⁵ However, this theoretical change from a "property rule" to a "liability rule" is required and perhaps accounts for the court's general reluctance to find damages are adequate.⁸⁶

Despite these policy and theoretical uncertainties and hurdles, courts are required to consider interlocutory injunctions when sought by a party.⁸⁷ The contention of this article is that in fulfilling this task and applying the discretions in respect of the "adequacy of damages" and the "balance of convenience" the courts need to conceive their role as (1) resolving uncertain entitlements, and (2) delivering justice. The questions of justice are matters routinely considered by courts dealing with equitable remedies, and will likely include matters of the applicant's and respondent's propriety (such as the "eyes wide open arguments"), capacity to pay damages etc. The remainder of this article addresses resolving uncertain entitlements that are a challenged posed specifically by interlocutory injunctions. This does not propose a restatement of the applicable principles, but rather proposes an alternative way of assessing the relative merits and framing of interlocutory injunction claims in patent disputes.

First, the various policy and theoretical propositions situate patents as economic instruments.⁸⁸ In this context the relevant evidentiary themes should be directed to "markets" and the indicators of "competition" in those "markets" from the perspective of the "consumer".⁸⁹ The "prospect theory", with its limited concern for competition, is most likely to favour awarding an interlocutory injunction where a patent has been granted irrespective of the anti-competitive nature and effect of the business. Meanwhile, the "reward theory" is more likely to distinguish different aspects of the anti-competitive nature and effect of the business, especially where the patent is being used to seek a collateral advantage.⁹⁰

Without any guidance beyond motherhood statements about promoting innovation etc, from government, judges are left to determine their own preference and opinion about how much anti-competitive effect should be sanctioned. Where a judge was sympathetic to the likely anti-competitive effect the relevant evidentiary themes would likely require evidence and an analysis about:

(1) "consumers" of the patent protected product, method or process;

- (2) the "market" for the patent protected product, method or process of both the patent holder (and their licensees and assignees) and the alleged infringer; and
- (3) an analysis of "competition" between the patent holder (and their licensees and assignees) and the alleged infringer in that "market".

Where there is direct competition between the patent holder and the alleged infringer the "adequacy of damages" and the "balance of convenience" is likely to side with the patent holder.

Correspondingly, where there is no, or very limited, direct competition between the patent holder and the alleged infringer then damages are likely to be an adequate remedy. While obtaining extensive evidence about competition in the relevant market would undoubtedly be expensive,⁹¹ the standard can be applied in the context of what evidence is presented and how that evidence is framed. With great respect, whether the parties are competing in the same market is a relatively simple question, albeit the degree and quality of that competition is undoubtedly a complex question.

A useful understanding of "markets" is provided by the *Trade Practices Act* conception of a "market" in assessing various anti-competitive dealings and arrangements,⁹² and in particular, the kinds of consideration that are relevant in assessing lawful mergers and acquisitions.⁹³ The relevant "markets" are the product and geographical spaces in which the patent holder (and their licensees and assignees) and the alleged infringer compete, and determined according to the specific facts and circumstances of the business conducted by each of the patent holder and the alleged infringer.⁹⁴ Essentially, "markets" are defined by the ability to substitute: "in determining the outer boundaries of the market we ask a quite simple but fundamental question: If the firm were to 'give less and charge more' would there be, to put the matter colloquially, much of a reaction?".⁹⁵ The relevant "product dimensions" of the market will include:

- the costs of switching purchases between the patent protected product and the substitute;
- the perspective of buyers about the desirability of the substitute views;
- the practices of buyers switching to the substitute;
- price levels and movements in response to the substitute; and so on.⁹⁶

The "geographic dimensions" of the market will include the kinds of costs and limitations arising from moving, transporting, sourcing, switching etc, as a consequence of products in different geographical spaces.⁹⁷

The interlocutory injunction cases suggest that "markets" and "competition" have been a relevant consideration in some decisions, albeit they have not been considered in the context of substitution or as the final determinant in assessing the "adequacy of damages" and the "balance of convenience".⁹⁸ The following analysis considers the various cases in the context of the "consumer", "market" and "competition" issues. Unfortunately this analysis is cursory and necessarily speculative as the reported decisions have not been directed to these matters. Despite this, the analyses show that such an approach may be useful in considering the "adequacy of damages" and the "balance of convenience", and distinguishing where damages may be a satisfactory remedy where there is not direct competition between the patent holder's (or their licensees or assignees) businesses.

Abbott GmbH & Co KG v Apotex Pty Ltd

Abbott's patented chemical was a weight loss drug⁹⁹ with approximately 36% of the market and competing with two other drugs each with 47% and 15% of the market. Apotex intended to gain regulatory approval for its chemical product as a direct substitute for Abbott's chemical product (at 375, 376) and Apotex accepted that Abbott would suffer some loss of sales (at 375, 382). Abbott also contended that if Apotex was allowed to sell its product then others (including Abbott) would also develop similar products that would compete against Abbott's and Apotex's product (at 375, 383). From the case report it appears that Apotex's chemical product was a direct substitute for Abbott's chemical product (sibutramine hydrochloride) with both being for the indication of management of weight gain and loss (at 375, 376). On the basis of this characterisation Apotex was competing

directly with Abbott in the same market and so an injunction might have been expected to be awarded (and was awarded).

Medrad Inc v Alpine Pty Ltd

Medrad's patent related to a device for controlling the injection of substances using a computer linked with various mechanical means including a syringe (at 102-103). Medrad's market was for the device, servicing the device and the consumables necessary to use that device (including the syringes), and comprised approximately 80% of the market for injector systems and their related consumables (at 103-105). Importantly, for Medrad the sale of the consumables "significantly exceeded the initial cost of the injector system" (at 104). Meanwhile Alpine was not major competitor in the injector systems market, instead being a supplier of syringes some of which could substitute for the Medrad syringes (notably, the Medrad evidence was that the Alpine syringes might not work "properly" in the Medrad injector system) (at 105-106).

It is not apparent from the report what the nature and scope of Alpine's business actually was and whether it was in a broader market for syringes, and that only a part of that broader market was for syringes that would substitute for Medrad's syringes. Both Medrad and Alpine accepted that Alpine's syringes were approximately 20% cheaper (at 105-106). On the basis of this characterisation Medrad and Alpine appear to have been direct competitors in the same market and so an injunction might have been expected to be awarded (and one was awarded).

In the alternative, if Alpine was a general supplier of syringes and related materials for a whole range of different purposes, and not just injector systems, then Alpine might be characterised as in a different market. In those circumstances Medrad and Alpine would not be direct competitors in the same market and so an injunction might be expected to be denied. Medrad's circumstances could be characterised as seeking a collateral advantage in another market that might be better addressed through damages.

Alphapharm Pty Ltd v Wyeth and Sigma Pharmaceuticals (Aust) Pty Ltd v Wyeth

Wyeth's patented chemical was for a method of treating nervous system disorders like depression (Alphapharm at 73; Sigma at 340) with Wyeth supplying the "leading anti-depressant medication in Australia in terms of units sold and value of sales" (Alphapharm at 73, 94).¹⁰⁰ Wyeth asserted that the consequence of Alphapharm's and Sigma's product would be a loss of market share and a price reduction for Wyeth's product and the further entry of other competitors (Alphapharm at 96; Sigma at 350). On the basis of this characterisation Wyeth and Alphapharm/Sigma were direct competitors and so an injunction might have been expected to be awarded (and was awarded).

While Wyeth's chemical product certainly competed with Alphapharm's, Alphapharm asserted that Wyeth was changing its market to another product market that coincided with another patent protected chemical (Alphapharm at 94). If this was true then there seems avenue to speculate about whether Wyeth and Alphapharm were actually competing against each other. Again, Wyeth's circumstances could be characterised as seeking a collateral advantage in another market that might be addressed through damages.

Wake Forest University Health Sciences v Smith & Nephew Pty Ltd

Wake Forest's invention was a device for sucking out air to make a negative pressure over a wound to which a dressing was applied (at 531). Wake Forest's business was as the dominant supplier of negative pressure wound devices with approximately 50% of its turnover coming from the devices and 50% from the consumables (wound dressings) (at 532). Meanwhile Smith & Nephew's business was the manufacture and sale of dressings, prostheses and various devices (at 532). The concern in this matter was the supply of Smith & Nephew's wound dressings in substitution for Wake Forest's dressings for use in Wake Forest's device (at 535-536).

Again, Wake Forest and Smith & Nephew do not appear to be direct competitors in the same market, with Wake Forest in the wound devices market and Smith & Nephew in the wound dressing market, and so an injunction might be expected to be denied. And again, Wake Forest's circumstances could

be characterised as seeking a collateral advantage in another market that might be better addressed through damages.

Interpharma Pty Ltd v Commissioner of Patents

Eli Lilly's chemical patent and process patents were for a cancer treatment (at 262-263). For Eli Lilly's chemical product Interpharma's product was a direct substitute and listed accordingly by the medicine regulator (at 264-265, 278-279).

On the basis of this characterisation Eli Lilly and Interpharma were direct competitors and so an injunction might have been expected to be awarded (and was awarded).

Conclusion

In conclusion, whether the court awards or denies an interlocutory injunction, one of the parties will suffer damage, and while the aspiration of the relevant principles might be to maintain the status quo between the parties until their rights can be finally adjudicated and determined,¹⁰¹ this is in practice an impossible task where parties are already in the market.¹⁰² Similarly, concerns about disturbing "trade patterns".¹⁰³ The posited analysis of the "consumer", "market" and "competition" demonstrates that important distinctions can be made about the circumstances in which an interlocutory injunction might be claimed. In Abbott, Alphapharm and Sigma there was direct competition between the patent holder's (and their licensee's or assignee's) product and the alleged infringer's product. And arguably in both Wake Forest and Medrad the patent holder was seeking to use their patent to exclude a cheaper substitutable element of their protected invention.

These distinctions provide a useful starting place and accept that promoting competition is desirable and that damages, albeit a lesser resolution between competing property claims, should be awarded unless the parties are directly competing in the same market. The advantage of this approach is to promote, encourage and coerce patent owners to provide access to, and disseminate, their patent protected products, method and processes while respecting core exclusive rights.

Footnotes

- * Associate Professor, Australian Centre for Intellectual Property in Agriculture, Griffith Law School, Griffith University. I acknowledge and appreciate the assistance, guidance and suggestions from Hazel Moir and Stephen Hubicki, although I accept all responsibility for this work. This work was supported by an Australian Research Council grant to research *Promoting Plant Innovation in Australia: Maximizing the Benefits of Intellectual Property for Australian Agriculture* DP0987639.
- ¹ For recent passing mention of patents in the broader equitable injunctions literature: see eg, Gummow W "The Injunction in Aid of Legal Rights – An Australian Perspective" *Law and Contemporary Problems*; Philips J "Interlocutory Injunctions and Intellectual Property: A Review of American *Cyanamid v Ethicon* in the Light of Series 5 Software" *Journal of Business Law*. For a useful historical analysis see Leubsdorf J "The Standard for Preliminary Injunctions".
- ² See [Adam Brown Male Fashions Pty Ltd v Philip Morris Inc](#) (1981) 148 CLR 170^[PDF] at 176-177 (Gibbs CJ, Aickin, Wilson and Brennan JJ).
- ³ Notably, the High Court (Australian *Constitution*, s 75(v)) and the Federal Court (*Judiciary Act 1903* (Cth), s 39B(1)) also have original jurisdiction with respect to any matter in which an injunction (or writ of mandamus, certiorari or prohibition) is sought against an officer of the Commonwealth so that, eg, decisions of the Patent Commissioner (or delegate) made under the *Patents Act 1990* (Cth) may be reviewed and an injunction awarded to prevent the Commissioner of Patents from going beyond power in the determination of rights and entitlements.
- ⁴ For example, in [Pharmacia Italia SpA v Interpharma Pty Ltd](#) (2006) 67 IPR 397 at 399, Pharmacia Italia SpA sought an interlocutory injunction that, in part, restrained Interpharma Pty Ltd, "whether by itself, its officers, employees, agents or otherwise from importing, making, selling, supplying or otherwise disposing of, or offering to import, make, sell, supply or otherwise dispose of, or using or keeping for the purpose of doing any of those things, the imported [patented injectable ready-to-use solutions containing an anti-tumour anthracycline glycoside]".
- ⁵ For example, in [Pharmacia Italia SpA v Interpharma Pty Ltd](#) (2006) 67 IPR 397 at 398-399, Pharmacia Italia SpA sought an interlocutory injunction that Interpharma Pty Ltd, in part, procure the removal of the allegedly infringing product from the schedule of pharmaceutical benefits that attract a subsidy under the *National Health Act 1953* (Cth) pharmaceutical benefits scheme. See also [Alphapharm Pty Ltd v Wyeth](#) (2009) 82 IPR 71 at 95, 100.
- ⁶ See eg, [Australian Broadcasting Corp v O'Neill](#) (2006) 227 CLR 57^[PDF] at 68 (Gleeson CJ and Crennan J), 82 (Gummow and Hayne JJ); [Australian Broadcasting Corporation v Lenah Game Meats Pty Ltd](#) (2001) 208 CLR 199^[PDF] at 218 (Gleeson CJ), 233 (Gummow and Hayne JJ), 268 (Kirby J), 296 (Callinan J).
- ⁷ See [Beecham Group Ltd v Bristol Laboratories Pty Ltd](#) (1968) 118 CLR 618^[PDF] at 623-624 (Kitto, Taylor, Menzies and Owen JJ); Ricketson S, *The Law of Intellectual Property* (Law Book Co, 1984) p 991. See also Duft B "Patent Preliminary Injunctions and the United States Court of Appeals for the Federal Circuit" *Journal of the Patent Office Society* and references therein. But see Dorr R Duft B "Patent Preliminary Injunctive Relief" *Journal of the Patent Office Society* (demonstrating that preliminary injunctions were not as rare as the literature might have suggested, albeit different courts had dramatically different rates of award).
- ⁸ See also Morrison W "The Impact of the Creation of the Court of Appeals for the Federal Circuit on the Availability of Preliminary Injunctive Relief Against Patent Infringement"; Foster J "The Preliminary Injunction – A New and Potent Weapon in Patent Litigation" *Journal of the Patent and Trademark Office Society* (both arguing that the establishment of the United States Court of Appeals for the Federal Circuit moved towards treating patent preliminary injunctions like any other case and increased the prospects for their award).
- ⁹ Notably, quia timet injunctions may also be available to restrain or apprehend a threatened legal wrong, but they are not considered further here: see [Telstra Corp Pty Ltd v Premier Media Group Pty Ltd](#) (2007) 72 IPR 89 (Allsop J); [CSL Ltd v GlaxoSmithKline Australia Pty Ltd](#) (2006) 70 IPR 128 (Weinberg J); [Diesel SpA v Hwang](#) (2006) 67 IPR 568 (Tamberlin J).
- ¹⁰ *Patents Act 1990* (Cth), s 61 and Sch 1 . This contrasts with innovation patents (s 62 and Sch 1).
- ¹¹ See eg, [CSL Ltd v GlaxoSmithKline Australia Pty Ltd](#) (2006) 70 IPR 128 (Weinberg J) where the dispute about marketability and merchantability was framed as a claim that an advertising information sheet did not present

a fair and accurate profile about the competing patented products under the *Trade Practices Act 1974* (Cth), s 52 (misleading and deceptive). See also Duns J "The Statutory Injunction: An Analysis" (1989) 17 MULR 56.

- ¹² Notably, *Patents Act 1990* (Cth), s 122(1) provides: "[t]he relief which a court may grant for infringement of a patent includes an injunction (subject to such terms, if any, as the court thinks fit)".
- ¹³ *Patents Act 1990* (Cth), s 154(1) ; *Judiciary Act 1903* (Cth), s 39B(1A)(c) . Notably, the jurisdiction is also conferred on the High Court: *Patents Act 1990* (Cth), s 154(2) . In certain circumstances, *Patents Act 1990* (Cth), s 155 provides that a "prescribed court" may have jurisdiction, and this will include the "the Supreme Court of a State, the Supreme Court of the Australian Capital Territory, the Supreme Court of the Northern Territory or the Supreme Court of Norfolk Island": *Patents Act 1990* (Cth), Sch 1 .
- ¹⁴ *Federal Court of Australia Act 1976* (Cth), s 23 .
- ¹⁵ *Federal Court of Australia Act 1976* (Cth), s 22 .
- ¹⁶ *Federal Court Rules*, O 25 .
- ¹⁷ Federal Court of Australia, *Usual Undertakings as to Damages*, Federal Court Practice Note 3, 14 June 1999 (Black CJ).
- ¹⁸ Notably, Lord Denning in *Hubbard v Vosper* [1972] 2 QB 84 at 96 in rejecting argument and former (non-binding) decisions that an interlocutory injunction should be granted where the plaintiff has "an arguable case" stated: "[t]he remedy by interlocutory injunction is so useful that it should be kept flexible and discretionary. It must not be made the subject of strict rules". However, this is not entirely unlimited in Australia: see eg, [Jackson v Sterling Industries Ltd](#) (1987) 162 CLR 612^[PDF] at 622 (Deane J).
- ¹⁹ Stating the justification that an asserted patent restricts competition so that the patent holder (or their licensee or assignee) "must give more proof of the right he claims that is afforded by the mere granting of the patent" and citing *Smith v Grigg Ltd* (1924) 1 KB 655 at 659 (Atkin LJ) and *Bonnella v Espir* (1926) 43 RPC 159 (Russell J).
- ²⁰ Citing *Smith v Grigg Ltd* (1924) 1 KB 655 at 658 (Atkin LJ).
- ²¹ Citing *Marshall and the Lace Web Spring Co Ltd v Crown Bedding Co Ltd* (1929) 46 RPC 267 at 269 (Romer J).
- ²² A similar proposition appears to be accepted in Australia: see eg, [Martin Engineering Co v Trison Holdings Pty Ltd](#) (1988) 11 IPR 611 at 117-118 (Gummow J). See also [Interpharma Pty Ltd v Commissioner of Patents](#) (2008) 79 IPR 261 at 267 (Jessup J); [GenRx Pty Ltd v Sanofi-Aventis](#) (2007) 73 IPR 502 at 504 (Gyles J); [AB Hassle v Pharmacia \(Aust\) Pty Ltd](#) (1995) 33 IPR 63 at 69-70 (Ashley J) etc.
- ²³ Albeit that at the time of the hearing the defendants had obtained leave to amend their defence to put validity in issue only to challenge the construction of the patent: *Beecham Group Ltd v Bristol Laboratories Pty Ltd* (1968) 118 CLR 618^[PDF] at 624-625 (Kitto, Taylor, Menzies and Owen JJ).
- ²⁴ See also [Fejo v Northern Territory](#) (1998) 195 CLR 96^[PDF] at 125-126 (Gleeson CJ, Gaudron, McHugh, Gummow, Hayne and Callinan JJ), 141 (Kirby J).
- ²⁵ [Maritime Union of Australia v Patrick Stevedores No 1 Pty Ltd](#) (1998) 77 FCR 456^[PDF] at 460.
- ²⁶ [Patrick Stevedores Operations No 2 Pty Ltd v Maritime Union of Australia](#) (1998) 77 FCR 478^[PDF] at 480 (Wilcox, von Doussa and Finkelstein JJ).
- ²⁷ Notably the joint judgment cited [American Cyanamid v Ethicon Ltd](#) [1975] AC 396 at 407, [Murphy v Lush](#) (1986) 60 ALJR 523 at 524; [Castlemaine Tooheys Ltd v South Australia](#) (1986) 161 CLR 148^[PDF] at 153-154.
- ²⁸ Another High Court decision addressing interlocutory injunctions briefly was [Australian Broadcasting Corporation v Lenah Game Meats Pty Ltd](#) (2001) 208 CLR 199^[PDF] at 216-220 (Gleeson CJ), 231-233 (Gaudron J), 239-242 (Gummow and Hayne JJ), 265-271 (Kirby J), 296-297 (Callinan J).
- ²⁹ Citing [Firth Industries Ltd v Polyglas Engineering Pty Ltd](#) (1975) 132 CLR 489^[PDF] at 492 (Stephen J), [Winthrop Investments Ltd v Winns Ltd](#) [1975] 2 NSWLR 666^[PDF] at 708 (Mahoney JA); [World Series Cricket Pty Ltd v Parish](#) (1977) 16 ALR 181 at 186 (Bowen CJ).
- ³⁰ *Beecham Group Ltd v Bristol Laboratories Pty Ltd* (1968) 118 CLR 618^[PDF] at 622-623.
- ³¹ *Beecham Group Ltd v Bristol Laboratories Pty Ltd* (1968) 118 CLR 618^[PDF] at 622.

- ³² See *Beecham Group Ltd v Bristol Laboratories Pty Ltd* (1968) *118 CLR 618*^[PDF] at 622 (Kitto J).
- ³³ *O'Neill v Australian Broadcasting Corp* [2005] *TASSC 26* at [37] (Crawford J).
- ³⁴ *Australian Broadcasting Corporation v O'Neill* [2005] *TASSC 82* at [46]-[47] (Slicer J dissenting), [48] (Evans J), [83] (Blow J).
- ³⁵ *O'Neill v Australian Broadcasting Corp* [2005] *TASSC 26* at [28] per Crawford J. See also *Australian Broadcasting Corporation v O'Neill* (2006) *227 CLR 57*^[PDF] at 64-65 (Gleeson CJ and Crennan J), 87-88 (Gummow and Hayne JJ).
- ³⁶ *Australian Broadcasting Corporation v O'Neill* [2005] *TASSC 82* at [48] (Evans J), [81] (Blow J). See also *Broadcasting Corporation v O'Neill* (2006) *227 CLR 57*^[PDF] at 65 (Gleeson CJ and Crennan J).
- ³⁷ *Australian Broadcasting Corporation v O'Neill* [2005] *TASSC 82* at [46] (Slicer J). See also *Australian Broadcasting Corporation v O'Neill* (2006) *227 CLR 57*^[PDF] at 66 (Gleeson CJ and Crennan J).
- ³⁸ See, in particular, the criticism of higher courts addressing such matters: *Australian Broadcasting Corporation v O'Neill* (2006) *227 CLR 57*^[PDF] at 90 (Kirby J), 116 (Heydon J).
- ³⁹ See also *Australian Broadcasting Corporation v O'Neill* (2006) *227 CLR 57*^[PDF] at 68, 73 (Gleeson CJ and Crennan J), 88 (Gummow and Hayne JJ), 103 (Kirby J), 160-162 (Heydon J).
- ⁴⁰ Where there is a claim of infringement and an interlocutory injunction sought and a counterclaim of patent invalidity: see eg, *Abbott GmbH & Co KG v Apotex Pty Ltd* (2009) *83 IPR 373*; *Medrad Inc v Alpine Pty Ltd* (2009) *82 IPR 101*; *Wake Forest University Health Sciences v Smith & Nephew Pty Ltd* (2009) *81 IPR 530*; *Roche Therapeutics Inc v GenRx Pty Ltd* (2007) *71 IPR 546*; *Merck & Co Inc v GenRx Pty Ltd* (2006) *70 IPR 286* etc. Where there is a claim of patent invalidity and a counterclaim of infringement and an interlocutory injunction sought: see eg, *Alphapharm Pty Ltd v Wyeth* (2009) *82 IPR 71*; *Sigma Pharmaceuticals (Aust) Pty Ltd v Wyeth* (2009) *81 IPR 339*; *Interpharma Pty Ltd v Commissioner of Patents* (2008) *79 IPR 261* at 266 and 283; *GenRx Pty Ltd v Sanofi-Aventis* (2007) *73 IPR 502* etc.
- ⁴¹ See *Wake Forest University Health Sciences v Smith & Nephew Pty Ltd* (2009) *81 IPR 530* at 533 per Ryan J: "the existence or otherwise of a serious question to be tried can turn either on a perceived difficulty faced by a plaintiff or applicant in making out some element of the cause of action, or on an assessment of the strength or weakness of a defence to the cause of action which the defendant or respondent claims to be available. In some cases, the existence of a serious question may depend on an evaluation of each of these aspects in combination". Notably, a finding that there is a serious case to be tried on invalidity does not necessarily obviate the grant of an interlocutory injunction: see eg, *Wake Forest University Health Sciences v Smith & Nephew Pty Ltd* (2009) *81 IPR 530* at 540, 543; *Sigma Pharmaceuticals (Aust) Pty Ltd v Wyeth* (2009) *81 IPR 339* at 346, 347, 348 (Sundberg J) etc.
- ⁴² For recent examples see, *Abbott GmbH & Co KG v Apotex Pty Ltd* (2009) *83 IPR 373* at 376; *Medrad Inc v Alpine Pty Ltd* (2009) *82 IPR 101* at 109-110; *Alphapharm Pty Ltd v Wyeth* (2009) *82 IPR 71* at 76-77; *Wake Forest University Health Sciences v Smith & Nephew Pty Ltd* (2009) *81 IPR 530* at 532-533; *Sigma Pharmaceuticals (Aust) Pty Ltd v Wyeth* (2009) *81 IPR 339* at 342-343; *Interpharma Pty Ltd v Commissioner of Patents* (2008) *79 IPR 261* at 266-267; *GenRx Pty Ltd v Sanofi-Aventis* (2007) *73 IPR 502* at 503-504. For earlier cases illustrating the less certain application of the relevant principles see eg, *Roche Therapeutics Inc v GenRx Pty Ltd* (2007) *71 IPR 546* at 556-569; *Merck & Co Inc v GenRx Pty Ltd* (2006) *70 IPR 286* at 291.
- ⁴³ See eg, *Sigma Pharmaceuticals (Aust) Pty Ltd v Wyeth* (2009) *81 IPR 339* at 342; *Interpharma Pty Ltd v Commissioner of Patents* (2008) *79 IPR 261* at 266 and 283 etc.
- ⁴⁴ *Patents Act 1990* (Cth), s 61 and sch 1 ("standard patent").
- ⁴⁵ *Patents Act 1990* (Cth), s 13(1) and sch 1 ("exploit").
- ⁴⁶ Citing *Interpharma Pty Ltd v Commissioner of Patents* (2008) *79 IPR 261* at 279-280; *GenRx Pty Ltd v Sanofi-Aventis* (2007) *73 IPR 502* at 506.
- ⁴⁷ A similar dispute about the same patent between Wyeth and Sigma was resolved with the award of an interlocutory injunction against Sigma in *Sigma Pharmaceuticals (Aust) Pty Ltd v Wyeth* (2009) *81 IPR 339* (Sundberg J).
- ⁴⁸ According to Alphapharm "Wyeth's evidence in chief presented a picture of Efexor-XR as the leading antidepressant in Australia with annual sales of \$115 million or about 25% of Wyeth Australia's income": *Alphapharm Pty Ltd v Wyeth* (2009) *82 IPR 71* at 94.

- ⁴⁹ Citing [Appleton Papers Inc v Tomasetti Paper Pty Ltd](#) (1983) 1 IPR 569 at 580-581 per McLelland J.
- ⁵⁰ The relevant facts being that Sigma became aware of Wyeth's patent on 6 March 2009 despite earlier searches being made on Sigma's behalf, Sigma commenced revocation action on 1 April 2009, Sigma launched its product on 1 May 2009, Wyeth filed a cross-claim on 1 May 2009 and the hearing was on 3 June 2009. Notably other dates are also identified: that Sigma put Wyeth on notice on 14 April 2009 and that Wyeth sought interlocutory relief on 28 April 2009.
- ⁵¹ The comparable quantification was unclear with Wyeth's "potential to affect the 45% of sales ... which currently have a value in excess of \$50 million" compared to Sigma's "approximately 0.4% of its total company turnover": [Sigma Pharmaceuticals \(Aust\) Pty Ltd v Wyeth](#) (2009) 81 IPR 339 at 350, 352.
- ⁵² The Full Federal Court considered an appeal against the granting of an interlocutory injunction and overturned the decision of the lower court deciding that on a proper construction of the disputed claim it was invalid, and so there could be no infringement and no serious question to be tried: [Smith & Nephew Pty Ltd v Wake Forest University Health Sciences](#) (2009) 82 IPR 467 at 474 (Finn, Bennett and Middleton JJ).
- ⁵³ Perhaps importantly, the decision was to set aside the interlocutory injunction based on the validity of a single claim when a number of claims had been made and were asserted to be being infringed. "[W]e have approached the question of the validity of [the claim] by reference to the evidence and submissions made as to the construction of [the claim] put forward by the [applicant for the interlocutory injunction]": [Smith & Nephew Pty Ltd v Wake Forest University Health Sciences](#) (2009) 82 IPR 467 at [54] 475 per Finn, Bennett and Middleton JJ.
- ⁵⁴ The Full Federal Court determined that properly construed there was no working interrelationship of the collocation of integers claimed (that is, between the negative pressure apparatus and the aseptic package).
- ⁵⁵ See eg, [Abbott GmbH & Co KG v Apotex Pty Ltd](#) (2009) 83 IPR 373 at 376; [Medrad Inc v Alpine Pty Ltd](#) (2009) 82 IPR 101 at 109-110; [Alphapharm Pty Ltd v Wyeth](#) (2009) 82 IPR 71 at 76-77; [Wake Forest University Health Sciences v Smith & Nephew Pty Ltd](#) (2009) 81 IPR 530 at 532-533; [Sigma Pharmaceuticals \(Aust\) Pty Ltd v Wyeth](#) (2009) 81 IPR 339 at 342-343; [Interpharma Pty Ltd v Commissioner of Patents](#) (2008) 79 IPR 261 at 266-267; [GenRx Pty Ltd v Sanofi-Aventis](#) (2007) 73 IPR 502 at 503-504 etc.
- ⁵⁶ Perhaps in contrast was the predicament of interlocutory injunctions in the late 1970s where there were no principles were readily apparent: see generally Hammond G "Interlocutory Injunctions: Time for a New Model".
- ⁵⁷ The determination of the patent holder's and alleged infringer's serious case to be tried appears to be readily resolved by evaluating the merits of each party's case (see eg, [Abbott GmbH & Co KG v Apotex Pty Ltd](#) (2009) 83 IPR 373 at 376-382; [Medrad Inc v Alpine Pty Ltd](#) (2009) 82 IPR 101 at 111-116; [Alphapharm Pty Ltd v Wyeth](#) (2009) 82 IPR 71 at 78-93; [Wake Forest University Health Sciences v Smith & Nephew Pty Ltd](#) (2009) 81 IPR 530 at 534-542; [Sigma Pharmaceuticals \(Aust\) Pty Ltd v Wyeth](#) (2009) 81 IPR 339 at 343-348; [Interpharma Pty Ltd v Commissioner of Patents](#) (2008) 79 IPR 261 at 267-278; [GenRx Pty Ltd v Sanofi-Aventis](#) (2007) 73 IPR 502 at 504-506 etc), albeit a conclusion that there is a serious case to be tried over validity does not necessarily lead to a court denying an interlocutory injunction (see eg, [Wake Forest University Health Sciences v Smith & Nephew Pty Ltd](#) (2009) 81 IPR 530 at 540 and 543; [Sigma Pharmaceuticals \(Aust\) Pty Ltd v Wyeth](#) (2009) 81 IPR 339 at 346, 347, 348 etc. See also [Medrad Inc v Alpine Pty Ltd](#) (2009) 82 IPR 101 at 110-111).
- ⁵⁸ A similar concern is evident in other jurisdictions: see eg, Denlow M "The Motion for a Preliminary Injunction: Time for a Uniform Federal Standard" *Review of Litigation*; Vaughn L "A Need for Clarity: Toward a New Standard for Preliminary Injunctions"; Leubsdorf, n 1 etc.
- ⁵⁹ See [Abbott GmbH & Co KG v Apotex Pty Ltd](#) (2009) 83 IPR 373 at 382-383; [Medrad Inc v Alpine Pty Ltd](#) (2009) 82 IPR 101 at 116-117; [Alphapharm Pty Ltd v Wyeth](#) (2009) 82 IPR 71 at 93-94, 96, 98-99; [Wake Forest University Health Sciences v Smith & Nephew Pty Ltd](#) (2009) 81 IPR 530 at 542-543; [Sigma Pharmaceuticals \(Aust\) Pty Ltd v Wyeth](#) (2009) 81 IPR 339 at 349, 352; [Interpharma Pty Ltd v Commissioner of Patents](#) (2008) 79 IPR 261 at 280; [Interpharma Pty Ltd v Commissioner of Patents](#) (2008) 79 IPR 261 at 280.
- ⁶⁰ See [Medrad Inc v Alpine Pty Ltd](#) (2009) 82 IPR 101 at 118; [Alphapharm Pty Ltd v Wyeth](#) (2009) 82 IPR 71 at 96, 98-99; [Wake Forest University Health Sciences v Smith & Nephew Pty Ltd](#) (2009) 81 IPR 530 at 544; [Sigma Pharmaceuticals \(Aust\) Pty Ltd v Wyeth](#) (2009) 81 IPR 339 at 351; [Interpharma Pty Ltd v Commissioner of Patents](#) (2008) 79 IPR 261 at 282.

- ⁶¹ See *Medrad Inc v Alpine Pty Ltd* (2009) 82 IPR 101 at 116; *Alphapharm Pty Ltd v Wyeth* (2009) 82 IPR 71 at 96; *Wake Forest University Health Sciences v Smith & Nephew Pty Ltd* (2009) 81 IPR 530 at 543; *Sigma Pharmaceuticals (Aust) Pty Ltd v Wyeth* (2009) 81 IPR 339 at 349.
- ⁶² See *Abbott GmbH & Co KG v Apotex Pty Ltd* (2009) 83 IPR 373 at 382; *Medrad Inc v Alpine Pty Ltd* (2009) 82 IPR 101 at 116; *Sigma Pharmaceuticals (Aust) Pty Ltd v Wyeth* (2009) 81 IPR 339 at 351; *Interpharma Pty Ltd v Commissioner of Patents* (2008) 79 IPR 261 at 281.
- ⁶³ See *Abbott GmbH & Co KG v Apotex Pty Ltd* (2009) 83 IPR 373 at 382; *Medrad Inc v Alpine Pty Ltd* (2009) 82 IPR 101 at 117; *Alphapharm Pty Ltd v Wyeth* (2009) 82 IPR 71 at 96; *Wake Forest University Health Sciences v Smith & Nephew Pty Ltd* (2009) 81 IPR 530 at 542; *Sigma Pharmaceuticals (Aust) Pty Ltd v Wyeth* (2009) 81 IPR 339 at 350; *Interpharma Pty Ltd v Commissioner of Patents* (2008) 79 IPR 261 at 279.
- ⁶⁴ See *Abbott GmbH & Co KG v Apotex Pty Ltd* (2009) 83 IPR 373 at 382; *Alphapharm Pty Ltd v Wyeth* (2009) 82 IPR 71 at 96; *Wake Forest University Health Sciences v Smith & Nephew Pty Ltd* (2009) 81 IPR 530 at 543; *Sigma Pharmaceuticals (Aust) Pty Ltd v Wyeth* (2009) 81 IPR 339 at 350; *Interpharma Pty Ltd v Commissioner of Patents* (2008) 79 IPR 261 at 279.
- ⁶⁵ See *Abbott GmbH & Co KG v Apotex Pty Ltd* (2009) 83 IPR 373 at 383 (Jessup J); *Alphapharm Pty Ltd v Wyeth* (2009) 82 IPR 71 at 94-95 (Jagot J); *Interpharma Pty Ltd v Commissioner of Patents* (2008) 79 IPR 261 at 281 (Jessup J).
- ⁶⁶ See *Abbott GmbH & Co KG v Apotex Pty Ltd* (2009) 83 IPR 373 at 382-383 (Jessup J); *Alphapharm Pty Ltd v Wyeth* (2009) 82 IPR 71 at 95-97 (Jagot J).
- ⁶⁷ A number of other scholars have proposed various methodologies albeit they have not gained favour: see eg, Brooks R Schwartz W "Legal Uncertainty, Economic Efficiency, and the Preliminary Injunction Doctrine"; Greene K "Motion Picture Copyright Infringement and the Presumption of Irreparable Harm: Toward a Reevaluation of the Standard for Preliminary Injunctive Relief"; O'Rourke M "Rethinking Remedies at the Intersection of Intellectual Property and Contract: Toward a Unified Body of Law"; Hammond, n 56.
- ⁶⁸ *Wake Forest University Health Sciences v Smith & Nephew Pty Ltd* (2009) 81 IPR 530 at [69] 547-548 (Ryan J).
- ⁶⁹ See eg, Landes W and Posner R, *The Economic Structure of Intellectual Property Law* (Harvard University Press, 2003) pp 11-24.
- ⁷⁰ Recent policy statements include Commonwealth of Australia, *Powering Ideas: An Innovation Agenda for the 21st Century* (Department of Innovation, Industry, Science and Research, 2009); Review of the National Innovation System, *Venturous Australia: Building Strength in Innovation* (Cutler & Co Ltd, 2008) etc.
- ⁷¹ See eg, *Powering Ideas*, n 70, pp 25-27. See also Department of Innovation, Industry, Science and Research, *Australian Innovation System Report 2010* (2010) p 8. For an earlier exaltation see Commonwealth of Australia, *Backing Australia's Ability: An Innovation Action Plan for the Future* (Big Island Graphics and Corporate Communications ISR, 2001) p 18.
- ⁷² See *Powering Ideas*, n 70, pp 53 and 56-57. See also *Venturous Australia*, n 70, pp 83-87.
- ⁷³ Most recently the Australian Government posits patents exist to stimulate innovation through providing an opportunity for inventors to profit from their investment in invention and attract foreign R&D investment: *Powering Ideas*, n 70, pp 56 and 64. Earlier purposes variously considered patent privileges seek to stimulate invention and innovation, increase the public availability of information about new technology, encourage entrepreneurs, promote investment or address free-riding on investment in intellectual effort: Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (IP Australia, 2000) pp 136-138. See also Moir H, "What are the Costs and Benefits of Patent Systems", in Arup C and van Caenegem W (eds), *Intellectual Property Law Reform: Fostering Innovation and Development* (Edward Elgar, 2009) pp 29-54.
- ⁷⁴ Notably, a major criticism of the current patent policy is that it is being managed as a legal issue dominated by practitioners and the beneficiaries of the patent system rather than an aspect of economic policy and an important front of micro-economic reform: see *Venturous Australia*, n 70, p 85 and the reference therein. See also Lawson C "Patent Privileges and the National Competition Policy – Patent Scope and Allocation?" (2005) 33 ABLR 7.
- ⁷⁵ There is an extensive literature about this theory: see for example the Subcommittee on Patents, Trademarks and Copyrights of the Senate Committee on the Judiciary, *An Economic Review of the Patent System*, 85th

Congress, 2nd Session (Committee Print, 1958) (also known as the Machlup Report).

⁷⁶ There is an extensive literature about this theory: see eg, Kitch E "The Nature and Function of the Patent System" *Journal of Law and Economics* and its later articulation in Merges R "Uncertainty and the Standard of Patentability". See also Abramowicz M "The Danger of Underdeveloped Patent Prospects"; Duffy J "Rethinking the Prospect Theory of Patents".

⁷⁷ The inventor having satisfied the threshold criteria for the grant of a patent: *Patents Act 1990* (Cth), ss 18, 61 .

⁷⁸ "[Intellectual property privilege] cases fit the criteria set up by [Calabresi G Melamed D "Property Rules, Liability Rules, and Inalienability: One View of the Cathedral"] for application of a property rule: (1) there are only two parties to the transaction; (2) the costs of a transaction between the parties are otherwise low; and, most importantly, (3) a court called on to set the terms of the exchange would have a difficult time doing so quickly and cheaply, given the specialized nature of the assets and the varied and complex business environments in which they are deployed. Because each asset covered by an [intellectual property privilege] is in some sense unique – a characteristic guaranteed by various requirements for protectability in intellectual property statutes – it is difficult for a court in an infringement case to properly value the right-holder's loss": Merges R "Of Property Rules, Coase, and Intellectual Property". See also O'Rourke, n 67 at 1143-50; Merges R "Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents"; Polinsky M "Resolving Nuisance Disputes: The Simple Economics of Injunctive and Damage Remedies".

⁷⁹ Calabresi and Melamed, n 78 at 1105. See also Landes and Posner, n 69, p 12 ("Thus a property right includes both the right to exclude others and the right to transfer the property to another").

⁸⁰ On the choice of property and liability rules for intellectual property: see generally Merges , "Of Property Rules", n 78.

⁸¹ Calabresi and Melamed, n 78 at 1092. See also Merges "Bargaining Breakdown".

⁸² See eg, Epstein R , "Steady the Course: Property Rights in Genetic Material" in Scott Kieff F (ed), *Perspectives on Properties of the Human Genome Project* (Academic Press, 2003) pp 171-79; Merges "Bargaining Breakdown"; Merges "Of Property Rules". See generally Epstein R "A Clear View of The Cathedral: The Dominance of Property Rules"; Nance D "Guidance Rules and Enforcement Rules: A Better View of the Cathedral"; Kaplow L Shavell S "Property Rules Versus Liability Rules: An Economic Analysis"; Krier J Schwab S "Property Rules and Liability Rules: The Cathedral in Another Light" (1995) 70 NYULR 440.

⁸³ Calabresi and Melamed, n 78 at 1092.

⁸⁴ There is a further complication as the general theoretical assessment of the "property rule" and the "liability rule" separate the entitlement from the protection of that entitlement, meanwhile interlocutory injunctions require the courts to address these elements concurrently: see Brook and Schwartz, n 67 (addressing indeterminacy of entitlement and a model to provide parties with sufficient incentives to behave efficiently).

⁸⁵ See Merges "Of Property Rules"; Polinsky, n 78 at 1111-2.

⁸⁶ As an exception see [Interpharma Pty Ltd v Commissioner of Patents](#) (2008) 79 IPR 261 at 280 (Jessup J) where the chemical patent would have expired by the date of the trial and damages would have been the only available remedy.

⁸⁷ See *Federal Court of Australia Act 1976* (Cth), ss 22, 23 .

⁸⁸ An economic focus for injunctions has also been adopted in other jurisdictions: see eg, *eBay Inc v MercExchange LLC* 547 US 388 at 396 (2006) (Supreme Court) where Kennedy J (concurring with Thomas J; joined by Stevens, Souter and Breyer JJ) said "[t]he lesson of the historical practice, therefore, is most helpful and instructive ... In cases now arising trial courts should bear in mind that in many instances the nature of the patent being enforced and the economic function of the patent holder present considerations quite unlike earlier cases". In this case the patent owner use the patent not as a basis for producing and selling goods but rather to obtain licence fees.

⁸⁹ Notably, a similar perspective was recommended by the Intellectual Property and Competition Review Committee when considering the granting of compulsory licenses: Intellectual Property and Competition Review Committee, n 73, pp 162-163.

⁹⁰ The conception of a "collateral advantage" is significant in the sense that *Trade Practices Act 1974* (Cth), s 51(1), (3) provides an exemption for certain conditions in a license or assignment contract that "relates to" the patent protected product or process, except misuse of market power (ss 46, 46A) and resale price

maintenance (s 48), *but not for seeking a collateral advantage*: see [Transfield Pty Ltd v Arlo International Ltd](#) (1980) [144 CLR 83](#)^[PDF] at 103 (Mason J); Trade Practices Commission, *Application of the Trade Practices Act to Intellectual Property*, Background Paper (1991) p 13.

- ⁹¹ A notable concern among judges: see eg, [Medrad Inc v Alpine Pty Ltd](#) (2009) [82 IPR 101](#) at 117.
- ⁹² See *Trade Practices Act 1974* (Cth), ss 44ZZRA-51AAA (restrictive trade practices).
- ⁹³ See *Trade Practices Act 1974* (Cth), ss 50, 50A . See also Australian Competition and Consumer Commission (ACCC), *Merger Guidelines* (2008). An alternative might be third party access to services of certain facilities that are considered critical to competition in related markets: see ACCC, *Access Regime: A Guide to Part IIIA of the Trade Practices Act* (1995).
- ⁹⁴ See *Merger Guidelines*, n 93, pp 15-16.
- ⁹⁵ Re Queensland Co-operative Milling Association Ltd; Re Defiance Holdings Ltd (1976) [25 FLR 169](#)^[PDF] ; [1976] *ATPR 17,223 (40-012)* (Woodward J, Mr J Shipton and Professor M Brunt).
- ⁹⁶ See *Merger Guidelines*, n 93, pp 15-19.
- ⁹⁷ See *Merger Guidelines*, n 93, pp 15-19.
- ⁹⁸ See [Abbott GmbH & Co KG v Apotex Pty Ltd](#) (2009) [83 IPR 373](#) at 375, 382-383 (Jessup J); [Medrad Inc v Alpine Pty Ltd](#) (2009) [82 IPR 101](#) at 117 (Kenny J); [Alphapharm Pty Ltd v Wyeth](#) (2009) [82 IPR 71](#) at 94-95 (Jagot J) etc.
- ⁹⁹ Notably the patent identified the chemical as useful in the treatment of depression and presumably the initial regulatory approval for marketing the drug under the *Therapeutic Goods Act 1989* (Cth) was in respect of this indication: [Abbott GmbH & Co KG v Apotex Pty Ltd](#) (2009) [83 IPR 373](#) at 374-375 (Jessup J).
- ¹⁰⁰ See also [Sigma Pharmaceuticals \(Aust\) Pty Ltd v Wyeth](#) (2009) [81 IPR 339](#) at 349-350.
- ¹⁰¹ See eg, [Australian Broadcasting Corp v O'Neill](#) (2006) [227 CLR 57](#)^[PDF] at 68 (Gleeson CJ and Crennan J), 82 (Gummow and Hayne JJ); [Australian Broadcasting Corp v Lenah Game Meats Pty Ltd](#) (2001) [208 CLR 199](#)^[PDF] at 218 (Gleeson CJ), 233 (Gummow and Hayne JJ), 268 (Kirby J), 296 (Callinan J).
- ¹⁰² For examples of the losing parties' damage, see [Abbott GmbH & Co KG v Apotex Pty Ltd](#) (2009) [83 IPR 373](#) at 383-384 (Jessup J) (Apotex's drug registration and first mover advantage); [Medrad Inc v Alpine Pty Ltd](#) (2009) [82 IPR 101](#) at 106, 109, 116 (Kenny J) (Alpine's loss of sales, reputation and stock on hand); [Alphapharm Pty Ltd v Wyeth](#) (2009) [82 IPR 71](#) at 95 (Jagot J) (Alphapharm's possible loss of market share); [Wake Forest University Health Sciences v Smith & Nephew Pty Ltd](#) (2009) [81 IPR 530](#) at 543 (Ryan J) (Smith & Nephew's loss of tender opportunities) etc. But see [Sigma Pharmaceuticals \(Aust\) Pty Ltd v Wyeth](#) (2009) [81 IPR 339](#) at 348 (Sundberg J) (Sigma's damage was not considered, the standard applied being: "Wyeth must also demonstrate that unless an injunction is granted it will suffer irreparable harm for which damages will not be adequate compensation").
- ¹⁰³ See [Medrad Inc v Alpine Pty Ltd](#) (2009) [82 IPR 101](#) at 116 (Kenny J); [Alphapharm Pty Ltd v Wyeth](#) (2009) [82 IPR 71](#) at 97 (Jagot J); [Wake Forest University Health Sciences v Smith & Nephew Pty Ltd](#) (2009) [81 IPR 530](#) at 543 (Ryan J); [Sigma Pharmaceuticals \(Aust\) Pty Ltd v Wyeth](#) (2009) [81 IPR 339](#) at 350 (Sundberg J); [Interpharma Pty Ltd v Commissioner of Patents](#) (2008) [79 IPR 261](#) at 280 (Jessup J).