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The 2023 Pharmaceutical Patent Review

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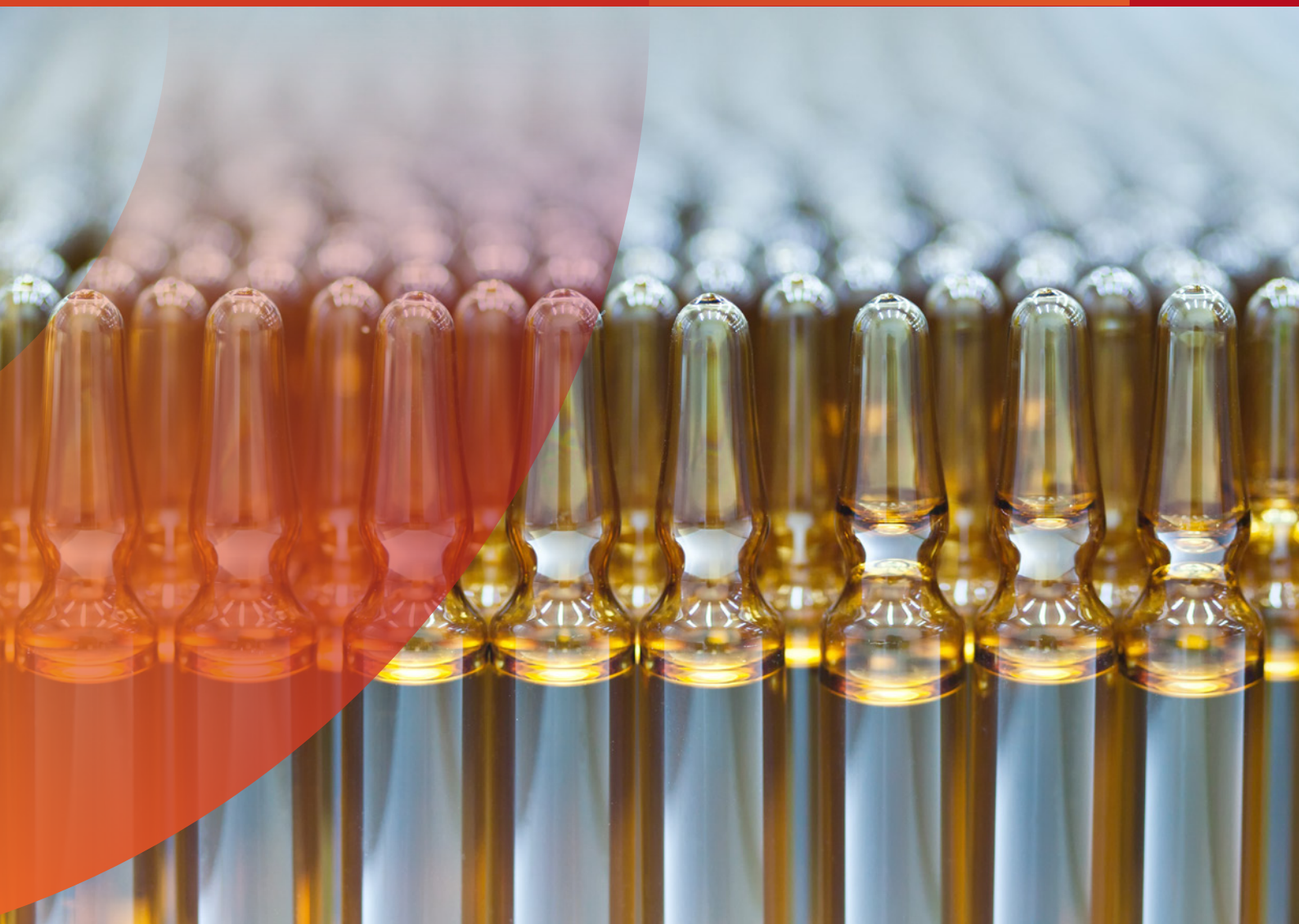

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Introduction

Welcome to Spruson & Ferguson's wrap-up of the most notable developments in pharmaceutical patent law in Australia in 2023. The past year saw a number of important Federal Court decisions delivered, with the key question of 'Commonwealth Government damages' now on its way to the High Court. We continue to see pharmaceutical patent cases making their way to trial, and legal issues which have seen recent attention, such as the validity of patent term extensions and the best method requirement, show no let up with a number of these cases currently before the Courts. Amongst the highlights:

- In the keenly awaited judgment in *Commonwealth of Australia v Sanofi*, the Full Court of the Federal Court of Australia has upheld the trial judge's decision that the Commonwealth is not entitled to damages arising from the grant of a 2007 interlocutory injunction preventing Apotex from launching generic clopidogrel products, on the basis of a patent which was later found invalid. The High Court has granted special leave, meaning that it will now proceed to consider an appeal. It is expected that the hearing will take place this year.
- The Federal Court of Australia has heard an appeal from a Patent Office opposition decision forming part of the global patent litigation concerning Amgen's PCSK9 antibody patents. In contrast to outcomes in the United States and Europe, the Australian Patent Office upheld the patent applications including against claims of lack of fair basis, sufficiency and best method (*Sanofi v Amgen*). It remains to be seen how the Court will approach these issues.
- The Federal Court of Australia has delivered judgment in Australia's landmark CRISPR patent dispute, finding that none of the claims in ToolGen Inc.'s patent application for platform CRISPR technologies are valid. ToolGen has subsequently applied to amend its claims and a hearing is scheduled to consider that application in May 2024 (*Toolgen v Fisher*).
- The Federal Court considered construction and inventive step issues in *Sandoz v Bayer*, providing important comments about the preparation of expert evidence in patent cases.
- We review recent developments in relation to patent term extensions. After a focus in recent years on the 'first regulatory approval' requirement, we expect there to be ongoing judicial consideration of the subject matter requirement that a PTE cover a 'pharmaceutical substance *per se*'.
- We tackle the thorny issue of 'best method'. Australia is one of the few major patent jurisdictions which has maintained in its patent law a discrete requirement that a patentee disclose the "best method" known to it of performing the invention. Rather than remain in the background or even fade away, best method challenges have assumed an increasingly prominent role in Australian patent disputes and can significantly affect the conduct and strategy of Federal Court litigation, in particular. Potential pharmaceutical patent litigants should be mindful of the substantive and procedural implications best method issues can have in the Australian iteration of global disputes.
- We provide an update on key pharmaceutical policy issues and an update on ongoing pharmaceutical patent litigation in the Courts.

As we continue into 2024, we hope this review provides a useful practical resource. Please do not hesitate to take the opportunity to contact our authors, all subject-matter experts in their respective fields, for advice on the issues raised by these important decisions.

2023 Case Law

No pay day for Commonwealth in Sanofi pharma damages claim: Commonwealth of Australia v Sanofi

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Background

In the keenly awaited judgment in *Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis)* [2023] FCAFC 97, the Full Court of the Federal Court of Australia upheld the trial judge's decision that the Commonwealth is not entitled to damages arising from the grant of a 2007 interlocutory injunction preventing Apotex from launching generic clopidogrel products, on the basis of a patent which was later found invalid.

In the financial year 2008, Sanofi's PLAVIX clopidogrel products (also sold in Australia as ISCOVER by Bristol-Myers Squibb), a medication inhibiting the formation of blood clots, was the third most heavily Government subsidised prescribed drug in Australia. Commonwealth costs for that year extended to approximately $170 million.

In August 2007 Apotex commenced legal action to revoke Sanofi's Australian patent 597784 covering the product, and was quickly met with an interlocutory injunction application. That injunction was granted, and remained in force until the patent was ultimately found wholly invalid by the Full Court and special leave for appeal to the High Court was refused. Apotex's clopidogrel products were launched on 1 May 2010.

On grant of the interlocutory injunction, Sanofi was required to give the 'usual undertaking as to damages', by which it undertook to compensate any person adversely affected by the operation of the injunction. After the patent was revoked, both Apotex and the Commonwealth brought claims pursuant to the undertaking, seeking damages for their losses resulting from the delayed launch of Apotex's products. Apotex's claim was settled. The Commonwealth continued with its claim which was based on its lost opportunity for pricing decreases for clopidogrel products which would have been triggered by a first generic entry, including an immediate mandatory price reduction, and further price disclosure related price reductions which would have occurred in the years following. The Commonwealth's claim on this basis exceeded $325 million plus interest.

Key findings and implications

- The Full Court upheld the decision of the trial judge that the Commonwealth did not succeed in making out its case. Ultimately this finding arises from a failure to make out the 'counterfactual' that Apotex would have launched in the circumstances at play at the relevant time, had Sanofi not obtained an interlocutory injunction.
- The appeal decision highlights once again the complexities in establishing that 'counterfactual' to the required standard. Combined with this difficulty, the Full Court did not re-consider the trial judge's finding that it was more likely than not that the Commonwealth would have been prepared to reverse statutory reductions in the reimbursed price for Sanofi's products triggered by the generic listing on the PBS, if sale of the generic product was subsequently restrained by a permanent injunction. Both of these matters are likely to continue to be raised in interlocutory injunction hearings as factors requiring a re-evaluation of the delicate balance between the interests of both parties in such a scenario.
- The decision highlights again the need for compelling evidence (supported by contemporaneous documents) from the ultimate decision-makers at the generic party and the Commonwealth to convince the Court that, but for the grant of the interlocutory injunction, the generic product would have been launched and listed on the PBS in the face of the significant damages risk if patent infringement was later made out.
- In overturning the judge's conclusion that the Commonwealth's losses were not a direct consequence of the interlocutory injunction (because it did not restrain PBS listing), the Full Court has released some pressure on the need to explicitly include such a restraint in interlocutory injunction orders.

First instance decision against the Commonwealth

The first instance decision delivered in May 2020 was the first case dealing with a Commonwealth claim for damages in these circumstances. We reported on this decision here. The Commonwealth had previously settled claims for compensation against Wyeth, relating to extended release formulations of the antidepressant venlafaxine (EFFEXOR-XR), and against AstraZeneca relating to the "super statin" rosuvastatin (CRESTOR). The judgment also followed the late 2018 Federal Court decision relating to venlafaxine, in which the generic party claims were upheld, including third party generic companies who were not party to the proceedings: *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth [2018] FCA 1556*.

At first instance, Nicholas J confirmed that in principle, a claim by the Commonwealth on an undertaking as to damages in these circumstances could be made out. However the Commonwealth failed in its case in several respects:

- The Court found that the Commonwealth's losses were not a *direct consequence* of the interlocutory injunction granted. In this case the injunction prohibited commercial activities such as manufacture and sale, but did not explicitly restrain listing by Apotex of its products on the Commonwealth's Pharmaceutical Benefits Scheme (**PBS**). There had been some debate at the original interlocutory injunction hearing as to whether such listing would be a patent infringing act and so whether the Court should restrain such an act by injunction. However Apotex in any event gave a separate undertaking to refrain from PBS listing its products, given that practically it would not have been able to meet the guarantee of supply requirements of such listing in the face of an injunction on supply. Crucially the Court found that Apotex's undertaking was not supported by any undertaking as to damages from Sanofi. Accordingly, the Court found that the loss was directly caused by Apotex's decision not to list on the PBS, not by the interlocutory injunction itself;
- Despite Apotex's Australian Managing Director giving evidence that Apotex would "almost certainly" have launched "at risk", Nicholas J was not satisfied that Apotex's CEO and ultimate decision-maker, who did not give evidence, would have authorised a launch if no interlocutory injunction had been granted;
- The Court found that it was more likely than not that the Commonwealth would have been prepared to reverse statutory reductions in the reimbursed price for Sanofi's products triggered by the generic listing on the PBS, if sale of the generic product was subsequently restrained by a permanent injunction.

Full Court upholds decision against Commonwealth

On appeal, the Full Court focussed on two key issues: whether the trial judge erred in finding that:

(a) Apotex would not have sought to PBS list its clopidogrel products even if it had not been restrained by the interlocutory injunction (**Apotex Launch and Listing Issue**); and

(b) the loss claimed by the Commonwealth did not flow directly from the interlocutory injunction (**Directness Issue**).

The Court noted that other issues in the appeal all related to *"further hypothetical causative obstacles sequentially secreted within each other"*, all within the overarching hypothetical scenario where Apotex did list and launch its products in 2008. However these issues did not arise if one of the two key issues above was decided against the Commonwealth. That proved to be the case.

On the Apotex Launch and Listing Issue, the Court reviewed a significant body of both documentary and testimonial evidence relied upon at trial, including a substantial number of emails. Amongst other asserted errors, the Commonwealth argued that the trial judge had failed to have regard to various parts of this material and submissions made at trial, and that he had erred in drawing a *'Jones v Dunkel'* inference against the Commonwealth for failing to call Dr Sherman (the ultimate Apotex decision maker), that is, an inference that evidence from Dr Sherman would not have assisted the Commonwealth. Notably, the Commonwealth also claimed that by reason of his delay in giving judgment (31 months from hearing), the trial judge had lost the advantage usually afforded to a trial judge with regard to the assessment of credit of witnesses.

The Full Court rejected all of these arguments, affirming the trial judge's approach to the evidence. On the question of delay it found that the trial judge had clearly set out his reasons, showing that he was very much alive to the detail of the evidence and its significance. The judge's reasons were described as *"a most thorough and searching excavation of the very complicated factual questions which the case generated".*

The Commonwealth therefore failed in showing that had the injunction not been granted, Apotex would have launched its products. Its failure in this crucial respect was determinative of the case.

However the Court also considered the Directness Issue, on which it found that the trial judge had erred in applying such a strict causative test. Notwithstanding an intermediate causative step (Apotex's undertaking not to PBS list) between the grant of the interlocutory injunction and the loss suffered by the Commonwealth, such loss did flow directly from the injunction.

Further implications

In December 2023 the Commonwealth was granted special leave to appeal the Full Court decision to the High Court. The High Court appeal is expected to be heard this year.

Regardless, it is likely that the implications of this case will be felt not only in future damages cases, but also at the interlocutory injunction stage.

A further Commonwealth claim for damages pursuant to undertakings given by Otsuka and BMS in relation to the antipsychotic aripiprazole (ABILIFY) is also continuing.

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ToolGen unsuccessful in landmark CRISPR patent appeal

Author: Michael Christie | Principal

The Federal Court of Australia has delivered judgment in Australia's landmark CRISPR patent dispute, finding that none of the claims in ToolGen Inc.'s patent application for platform CRISPR technologies are valid *Toolgen Inc v Fisher (No 2)* [2023] FCA 794 (ToolGen FCA). The proceeding is an appeal from a decision of the Commissioner of Patents in which the first respondent – a "strawman" named Grant Fisher – successfully opposed the grant of ToolGen's application.

The patent application

The case concerned ToolGen's application for CRISPR/Cas systems and the use of those systems to introduce a site-specific, double started break at a target nucleic acid sequence in a eukaryotic cell.

The application was filed on 23 October 2013 and claims priority from three provisional applications:

- US Provisional Patent Application 61/717,324 ("P1") filed 23 October 2012;
- US Provisional Patent Application 61/803/599 ("P2") filed 20 March 2013; and
- US Provisional Patent Application 61/837,481 ("P3") filed 20 June 2013.

The application includes two independent claims:

> **Claim 1.** A composition comprising a Type II Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR)/Cas system for use in introducing a site-specific, double stranded break at a target nucleic acid sequence in a eukaryotic cell, said CRISPR/Cas system comprising (i) a nucleic acid encoding a Cas9 polypeptide comprising a nuclear localization sequence, and (ii) a nucleic acid encoding a guide RNA that hybridizes to a target nucleic acid, wherein the guide RNA is a chimeric guide RNA comprising a CRISPR RNA (crRNA) portion fused to a trans activating crRNA (tracrRNA) portion.
>
> **Claim 10.** A method of introducing a site-specific, double-stranded break at a target nucleic acid sequence in a eukaryotic cell, the method comprising introducing into the eukaryotic cell a Type II Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR)/Cas system, wherein the CRISPR/Cas system comprises:
>
> (a) a nucleic acid encoding a Cas9 polypeptide comprising a nuclear localization signal, wherein the nucleic acid is codon-optimized for expression in eukaryotic cells, and
>
> (b) a nucleic acid encoding a guide RNA that hybridizes to the target nucleic acid, wherein the guide RNA is a chimeric guide RNA comprising a CRISPR RNA (crRNA) portion fused to a trans activating crRNA (tracrRNA) portion, wherein the target nucleic acid sequence comprises a first strand that binds to the crRNA portion and a second strand having a trinucleotide protospacer adjacent motif (PAM),
>
> and wherein the Cas9 polypeptide and the guide RNA form a Cas9/RNA complex in the eukaryotic cell, whereby a site-specific, double stranded break at the target nucleic acid sequence is introduced.

Several grounds of validity turned on the meaning of the words "nucleic acid encoding a guide RNA" in both independent claims. ToolGen sought a broad construction of these words, arguing that they encompass both DNA which is transcribed to RNA in a eukaryotic cell and RNA which is transcribed *in vitro* prior to it being introduced into a eukaryotic cell.[1] ToolGen argued that the verb "encoding" can mean both providing the sequence for producing the guide RNA (through the process of transcription from DNA to RNA) as well as providing the sequence that enables the guide RNA to perform its function.[2] ToolGen placed considerable reliance on claim 19 which, when read with claim 10, requires that the nucleic acid encoding the guide RNA is *in vitro* transcribed RNA:

> **Claim 19.** The method of any one of claims 10-16, wherein the nucleic acid encoding the guide RNA is in vitro transcribed RNA.

Justice Nicholas rejected these arguments, finding that claim 10, when read in the context of the specification as a whole, indicates that the claim is limited to a method in which the nucleic acid encodes the guide RNA, and that the guide RNA is transcribed from nucleic acid in the eukaryotic cell.[3] His Honour found that the term "encoding" should be given its ordinary meaning as understood by those skilled in the art:

> In my opinion, the word "encoding" is used in claim 10 in its conventional sense (i.e. as it would be understood by a molecular biologist) to refer to the production of a Cas9 polypeptide by transcription and translation and the production of a guide RNA by transcription in the cell. The nucleic acid referred to in the claim provides the information which is used in the cell to produce the guide RNA. Claim 10 does not encompass a system in which an existing guide RNA is introduced into the cell.[4]

As a consequence of this construction, claim 19 could not be read sensibly with claim 10 and was found to lack clarity.[5]

1 ToolGen FCA at [114].
2 ToolGen FCA at [122].
3 ToolGen FCA at [130].
4 ToolGen FCA at [143].
5 ToolGen FCA at [145].

The priority date

The hearing of the appeal was conducted on the premise that if the claims were not entitled to priority based on P1, then a deferred date of 20 June 2013 established by the filing of P3 would apply. P2 was solely concerned with a method of using RNA-guided endonucleases in restriction fragment length polymorphism analysis, and was not considered to disclose the invention of any of the claims in the patent application.

P1 is a relatively short document; it does not include any claims and resembles a journal article to which an additional paragraph headed "Summary of the Invention" had been added. The CRISPR/Cas9 system described in P1 was derived from *Streptococcus pyogenes* and used a single chimeric guide RNA comprising a crRNA portion fused to a tracrRNA produced *in vitro*. P1 did not disclose a system in which DNA (or viral RNA) is introduced into the cell in order to transcribe the guide RNA in vivo. P1 also did not describe what other bacterial species have Type II CRISPR/Cas systems or how to determine the endogenous crRNA and tracrRNA sequences for such a species.

The question, then, was whether the disclosure of P1 was sufficient to establish a priority date for any of the claims in ToolGen's application.

The priority date test in Australia is the same as the test for sufficiency of disclosure. That is, each claim is entitled to claim priority from an earlier application, provided the earlier application discloses the claimed invention in a manner that is clear enough, and complete enough, for the invention to be performed by a person skilled in the relevant art.[6]

In relation to the words "nucleic acid encoding a guide RNA", his Honour accepted that it would not be a difficult exercise for a molecular biologist in possession of the information in P1 coupled with the common general knowledge to use a plasmid encoding a guide RNA to produce the guide RNA *in vivo* using standard techniques that were well known at the priority date. His Honour also accepted that it would be obvious to the skilled addressee that he or she could use plasmid DNA encoding a guide RNA as a means of generating the guide RNA in the cell.[7]

However, P1 did not disclose the use of DNA (or viral RNA) encoding a guide RNA, as defined in the claims but, rather, a guide RNA produced *in vitro* which is then introduced into the cell. His Honour found that P1 did not disclose the same invention as that claimed in ToolGen's application, and as such, that none of the claims were entitled to claim priority from P1:

> Claims 1 and 10 (and, with the exception of claim 19, the dependent claims) are directed to an invention in which the guide RNA of the claims is introduced into the cell in the form of nucleic acid (DNA or viral RNA) which then encodes the guide RNA in the eukaryotic cell. P1 does not disclose any such system either explicitly or implicitly. It follows that those claims are not entitled to priority based on P1.[8]

The next question was whether P1 discloses a system for cleaving DNA using a Cas9 polypeptide derived from a bacterial species other than *S. pyogenes* in a manner which is clear enough and complete enough for the claimed invention to be performed by a person skilled in the art. It was common ground among the parties that P1 disclosed a CRISPR/Cas9 system derived from *S. pyogenes*. Nicholas J accepted that P1 disclosed, in a general sense, the existence of Cas9 proteins derived from other bacterial species and the possibility that they may be used to mediate DNA cleavage in eukaryotic cells.[9] However, the possibility of using Cas9 proteins derived from other bacterial species was described as just that – a mere possibility. P1 did not include any further discussion of this possibility, nor did it present any evidence or commentary from which it may be inferred that all, or even some, Type II Cas9 proteins derived from other bacterial species could reasonably be expected to work with particular PAMs to mediate DNA cleavage in eukaryotic cells.

Moreover, there was nothing disclosed in P1 which would indicate that *S. pyogenes* was likely to be representative of other bacterial species with a Type II CRISPR/Cas system or that the results of the experimentation with *S. pyogenes* derived components provided any reasonable scientific basis for inferring that Cas9 polypeptides derived from other bacterial species could also be expected to cleave DNA in eukaryotic cells.[10] In that context, the evidence showed there was considerable uncertainty as to whether or not a CRISPR/Cas9 system derived from any particular bacterial species other than *S. pyogenes* would work in eukaryotic cells, and that significant experimental work would need to be done to validate the use of the system in eukaryotic cells.[11]

His Honour found that the work that the person (or team) skilled in the art would need to undertake at the priority date to perform the invention of claims 1 and 10 using a bacterial species other than *S. pyogenes* would involve a significant research project:

> In my opinion the skilled team would be required to carry out prolonged research and experimentation and would most likely encounter significant difficulties along the way. Much of the work would be non-routine and would be carried out in circumstances where P1 provided no meaningful guidance or direction and no assurance of success.
>
> I am persuaded that as at the priority date, P1 did not enable a skilled team including a molecular biologist specialising in genome editing in eukaryotic cells and a microbiologist with expertise in CRISPR/Cas systems in prokaryotes, to make the compositions of claim 1, or perform the methods of claim 10, using a bacterial species other than *S. pyogenes*, without undue burden.[12]

6 *Patents Act 1990* (Cth) s 43(2) and (2A); *Patents Regulations 1991* (Cth) regs 2.12(4) and 3.13A.
7 ToolGen FCA at [207].
8 ToolGen FCA at [212].
9 ToolGen FCA at [221].
10 ToolGen FCA at [320].
11 ToolGen FCA at [325], [327]-[328].
12 ToolGen FCA at [362]-[363].

With regard to the guide RNA itself, P1 disclosed a single chimeric guide RNA comprising a crRNA portion fused to a tracrRNA portion without providing any information as to how it was designed or how its length might be altered.[13] Nicholas J considered that it would be an undue burden for the skilled person to redesign the single guide RNA disclosed in P1 or to design and construct a single guide RNA using a bacterial species other than *S. pyogenes*.[14]

His Honour found that P1 failed to disclose the claimed invention in a manner that was clear enough, and complete enough, for the invention to be performed by a person skilled in the relevant art. None of the claims were entitled to claim priority from P1.

Enablement

Section 40(2)(a) of the *Patents Act 1990* (Cth) states that a complete specification must disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the relevant art. The requirement for enablement is similar to that applicable in other jurisdictions, particularly Europe and the UK.

The respondents accepted that the patent application, unlike P1, discloses an invention that comprises "a nucleic acid encoding a guide RNA". They did not contend that the invention of the claims is, in this particular respect, not sufficiently enabled.

However, none of the examples disclosed in the patent application used CRISPR/Cas9 components from any species other than *S. pyogenes*. The respondents submitted that the patent application did not enable an invention comprising a system derived from a bacterial species other than *S. pyogenes* without undue burden. His Honour accepted that submission essentially for the reasons given in relation to P1.[15]

Similarly, in relation to the guide RNA, there was considered to be no material difference between the disclosures of P1 and the patent application regarding the design of the sgRNA including its tracrRNA component. Accordingly, his Honour found that the patent application did not provide an enabling disclosure of a sgRNA having a length different from that disclosed in the patent application.[16]

Support

Section 40(3) of the *Patents Act 1990* (Cth) states that the claims must be supported by the matter disclosed in the specification. This provision requires that the technical contribution to the art disclosed by the specification justify the breadth of the claim.[17]

In considering the overlapping requirements of enablement and support, his Honour noted that there may be instances where a claim might meet the requirements of section 40(2)(a) by providing an enabling disclosure, but not meet the requirement of section 40(3). However, he found it difficult to see how a claim to an invention for which there was no enabling disclosure could meet the support requirement because, in such circumstances, the scope of the monopoly defined by the claim could not be justified by the technical contribution to the art.[18] Having found that the invention was not sufficiently enabled under section 40(2)(a), his Honour found that all of the claims lacked support under section 40(3).

Novelty and inventive step

Three journal articles published after the filing date of P1 but before the filing date of P3 were relevant to the issues of novelty and inventive step:

- Cong et al, "Multiplex Genome Engineering Using CRISPR/Cas Systems" (2013) Science 339, 819-823 and Supplementary Materials;
- Mali et al, "RNA-Guided Human Genome Engineering via Cas9" (2013) Science 339, 823-826 and Supplementary Materials; and
- Wang et al, "One-Step Generation of Mice Carrying Mutations in Multiple Genes by CRISPR/Cas-Mediated Genome Engineering" (2013) Cell 153, 910-918 and Supplementary Information.

Having decided that ToolGen's application was not entitled to the priority date established by P1, his Honour found that claims 1 to 20 lacked novelty and an inventive step, and that claim 21 lacked an inventive step in light of the prior art.

ToolGen has subsequently applied to amend its claims and a hearing is scheduled to hear that application in May 2024.

Author

Michael Christie
Principal

13 ToolGen FCA at [366]-[377].
14 ToolGen FCA at [369]-[370].
15 ToolGen FCA at [387].
16 ToolGen FCA at [388].
17 *Merck Sharp & Dohme Corporation v Wyeth LLC* (No 3) [2020] FCA 1477 [547].
18 ToolGen FCA at [410].

Sanofi's challenge to Amgen PSK9 antibody patents heard in Federal Court

Author: Michael Christie | Principal

The global patent litigation concerning Amgen's PCSK9 antibody patents has highlighted the divergent approach taken by major jurisdictions in assessing the validity of functionally defined antibody claims. In the US, Amgen's patent claims were ruled invalid by the Federal Circuit for lack of enablement.[1] In corresponding European opposition proceedings, the claims of Amgen's patent were found to be enabled, but were subsequently invalidated by the Board of Appeal for lacking an inventive step.[2]

In 2022, a Delegate of the Commissioner of Patents ruled in Amgen's favour, finding that five of its patent applications are valid and should proceed to grant.[3] Sanofi appealed the decision to the Federal Court. This article summarises the Delegate's 2022 decision and provides an update on the Federal Court appeal, which was heard in November 2023.[4]

Patent Office Opposition

The opposed applications

The opposed applications stem from international patent application no. PCT/US2008/074097. The Australian national phase application has granted, and its term was extended under Australia's pharmaceutical patent term extension provisions.

Amgen filed several divisional applications, five of which were accepted and subsequently opposed by Sanofi in 2016. The opposed applications cover Amgen's cholesterol-lowering antibody, evolocumab (REPATHA), and potentially cover Sanofi's competitor antibody, alirocumab (PRAULENT).

The applicable law

The opposed applications are all subject to *Patents Act 1990* (Cth) as it existed prior to the introduction of the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012*, which came into effect in 2013.

The so called "Raising the Bar" amendments were introduced by the Australian Parliament with the express intention of aligning Australia's written description requirements with those of its major trading partners, particularly Europe and the US. Under the current Act, the requirements of support and sufficiency apply, meaning that, as in Europe, the claims must be commensurate with the technical contribution to the art, and the specification must enable a skilled person to perform the invention across the full scope of the claims without undue burden or further invention.

Under the "old" Act, however, the requirements of "full description" and "fair basis" apply. The standards set by full description and fair basis are much lower than those set by support and sufficiency, and challenging a patent on these grounds has been notoriously difficult (and more often than not, unsuccessful).

The claims

The Delegate broadly grouped the disputed claims into three classes, namely:

> i) epitope claims, which define an isolated monoclonal antibody by its ability to bind an epitope of PCSK9, the epitope comprising nominated residues;
>
> ii) residue claims, which define an isolated monoclonal antibody by its ability to bind one or more specific residues of PCSK9;
>
> iii) competition claims, which define an isolated monoclonal antibody by its ability to compete for binding with a structurally-defined antibody.[5]

The claims also include functional language referring to the ability of the antibody to block or reduce binding of PCSK9 to the LDL receptor (LDLR). The Delegate then set out a detailed construction of certain terms in the claims that were critical to Sanofi's opposition.

Clarity

Sanofi opposed the claims of the applications for lack of clarity. The issues raised in their submissions essentially related to the use of inexact language in the claims, for instance terms such as binds, blocks, reduces, neutralizing and competes. The Delegate rejected these submissions, finding that each term could be given meaning and that the claims provide a workable standard.[6]

Fair basis

Sanofi asserted that the claims of each application were not fairly based on the matter described in the specification.

The question of fair basis has been expressed by Australia's High Court as whether there is a real and reasonably clear disclosure in the body of the specification of what is claimed, so that the alleged invention is broadly, that is in a general sense, described in the body of the specification.[7]

Sanofi argued that only two antibodies disclosed in the applications were actually made, tested and shown to block the binding of PCSK9 to LDLR, and thereby lower plasma LDL levels. Sanofi asserted that it is those two antibodies for which the specification provides a real and reasonably clear disclosure.[8]

The Delegate rejected those arguments and pointed to statements in the specification which described the invention in broader terms. Although generic and not tied to specific examples, those paragraphs indicated to the Delegate that the invention extends beyond the specific antibodies isolated and characterised in the applications.[9] The invention as described by the specification was considered to include antigen binding proteins that bind to the same or an overlapping region of PCSK9 as bound by the EGFa domain of LDLR or the two exemplified antibodies.[27]

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1 No. 20-1074, Fed. Cir. 2021.
2 T 0845/19.
3 *Sanofi v Amgen Inc.* [2022] APO 67 (*'Sanofi v Amgen'*).
4 *Sanofi v Amgen Inc* NSD876/2022.
5 *Sanofi v Amgen* at [51].
6 *Sanofi v Amgen* at [109].
7 *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* [2004] 58 at [69]
8 *Sanofi v Amgen* at [136].
9 *Sanofi v Amgen* at [134] and [137].

With regard to the epitope and residue claims, Sanofi asserted that there is no proof that the antibodies of the invention bind to one or more of the identified residues. However, the Delegate emphasised that fair basis is a consideration of the disclosure provided in the specification, namely what the body of the specification read as a whole describes as the invention. It was not necessary for there to be scientific proof of non-covalent binding between the claimed antibodies and the identified amino acid residues.[10]

The Delegate accepted that the specification does not demonstrate that the amino acid residues identified as part of the interaction interface are directly involved in non-covalent interactions that effect binding between PCSK9 and LDLR or the two characterised antibodies.[11] Instead, the specification described X-ray crystallography experiments identifying those residues on the antigen that are located closest to the antibody when the two molecules are bound. The Delegate considered it a reasonable extrapolation to infer that amino acid residues within the identified region are involved in the non-covalent interactions that effect binding between PCSK9 and antibody.[12] Accordingly, the Delegate was satisfied that the specification provides a real and reasonably clear disclosure of the antibodies encompassed by the epitope and residue claims.

As for the competition claims, the Delegate again pointed to statements in the specification which described the invention in broad and general terms, and to paragraphs disclosing means for identifying competitively binding antibodies. Having construed the invention in these broad terms, the Delegate was satisfied that the specification also provides a real and reasonably clear disclosure of the antibodies encompassed by the competition claims. Consequently, this ground of opposition failed.

Full description (sufficiency)

The test for sufficiency of the description (under the pre-Raising the Bar law) has been articulated by Australia's High Court as whether the disclosure of the specification will enable the addressee to produce *something* within each claim without new inventions or additions or prolonged study of matters presenting initial difficulty.[13]

Sanofi submitted that the opposed applications do not disclose an antibody that falls within the scope of any of the claims, and that a skilled person could not reproduce the antibodies disclosed in the applications. With regard to the epitope claims, Sanofi argued that the applications do not disclose a single antibody that binds an epitope comprising the residues recited in the claims.

The Delegate re-framed the test for sufficiency by asking whether, based on the disclosure provided, the addressee will be able to produce an antibody that binds:

a) an epitope that comprises stated amino acid residues; or

b) to the specific amino acid residues specified;

or whether to do so would require new inventions or additions or prolonged study of matters presenting initial difficulty.

With regard to the epitope claims, the Delegate was satisfied that the specification described the binding site or interaction interface between PCSK9 and LDLR, and that the specification showed how two exemplary antibodies interact with this region to block binding between PCSK9 and LDLR. The Delegate again noted that the epitope, as construed earlier, will include specific amino acids that directly contact the antibody and also amino acids that are covered by the antibody. In that context, the Delegate considered that the residues of PCSK9 that the specification demonstrates with crystallographic experiments to be within the region *covered* by the antibody, can be considered the epitope, and therefore the epitope claims are fully described.[14]

With regard to the residue claims, the experts for both parties agreed that the term "binds to" means that the claimed antibody forms a non-covalent interaction with at least one of the nominated residues of PCSK9. But the parties' experts presented opposing views as to whether the residues specified in the claims are in fact directly involved in binding. Sanofi did not present any evidence that the two exemplified antibodies would not bind at least one of the residues set out in the claims.[15] Amgen's expert, however, performed an analysis using crystal data in the specification and concluded that specific residues identified in the claims very likely form non-covalent interactions with the exemplified antibodies or with LDLR.[16]

The Delegate accepted Amgen's submission that the specification discloses the interaction interface or epitope, and that the residues identified form non-covalent interactions between PCSK9 and the antibodies.[17] The question then became whether the addressee could take this information, along with the other information provided in the specification, to generate antibodies that fall within the scope of the claims.

Sanofi submitted that, to make antibodies that will bind to the relevant residues (or epitope comprising the relevant residues), the skilled person would have to undertake one of two research projects. The first was said to require making a biosimilar of the antibodies disclosed in the application using transgenic techniques. The second approach would be to seek to obtain antibodies either by hyperimmunization of transgenic mice or by other means such as phage display and then carry out experiments to characterise the antibodies.

Amgen, on the other hand, submitted that the state of antibody arts was advanced and mature at the priority date and that armed with the teachings of the application it would be routine for the addressee to make antibodies of the claimed invention. The Delegate favoured the proposition presented by Amgen, and in particular, that antibodies within the scope of the claims could be produced using well understood mammalian expression vector methodologies such as cloning the CDRs of the exemplified antibodies into the framework region of a known antibody, and that this approach would not require new inventions or additions or prolonged study of matters presenting difficulty.[18]

10 *Sanofi v Amgen* at [139].
11 *Sanofi v Amgen* at [139].
12 *Sanofi v Amgen* at [139].
13 *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Limited* [2001] HCA 8 at [25].
14 *Sanofi v Amgen* at [159].
15 *Sanofi v Amgen* at [160].
16 *Sanofi v Amgen* at [161]-[163].
17 *Sanofi v Amgen* at [165].
18 *Sanofi v Amgen* at [172].

The Delegate was not satisfied that the work required to produce one antibody embodying each claim using the information provided in the specification requires anything more than what is routine in the art, even if such work may be complex, time consuming and expensive.[19] Similarly, in relation to the competition claims, the Delegate found that the skilled addressee could use well-established techniques to produce a library of antibodies that is then screened using standard techniques to assess for competition with the reference antibodies.[20] Consequently, this ground of opposition also failed.

Best method

The *Patents Act 1990* (Cth) also requires the complete specification to describe "the best method known to the applicant of performing the invention".[21]

Sanofi alleged that the specification failed to disclose the residues of PCSK9 with which the antibody will form non-covalent interactions or that form the epitope of the claimed antibodies. It submitted that by withholding this information, Amgen concealed the best method by which to achieve the result which constitutes the invention.

The Delegate rejected this submission, finding that the specification discloses exemplary antibodies that represent the invention and provides information that would allow the skilled addressee to produce antibodies with the same CDRs, and therefore binding properties, as these antibodies. The Delegate also noted that there was no evidence that Amgen knew of a better method than what is disclosed in the specification.[22]

Utility

Sanofi also submitted that the invention as claimed failed to achieve what was "promised" by the specification and therefore lacked utility.[23] Sanofi argued that none of the claims are limited to isolated monoclonal antibodies that: a) lower, maintain or prevent an increase in plasma cholesterol of the subject to which they are administered or are useful as a diagnostic tool (The Promise); or b) have a biological effect of achieving The Promise. They asserted that only two exemplified antibodies have the picomolar affinity for PCSK9 and the resultant ability to block binding of LDLR to PCSK9 to the extent that the antibody is capable of lowering plasma LDL levels.

The Delegate did not agree with Sanofi's characterisation of the "promise" as being limited only to those antigen binding proteins that will be capable of lowering plasma LDL levels. Rather, the specification was found to more broadly disclose antigen binding proteins that bind to particular regions of PCSK9 to prevent binding to LDLR. The claims, by virtue of the functional characteristics defined in each of the epitope, residue or competition claims, were considered to necessarily encompass those monoclonal antibodies that achieve the more broadly stated promise of the invention.[24] As such, Sanofi's opposition on this ground was unsuccessful.

Federal Court Appeal

Sanofi appealed the Delegate's decision to the Federal Court. In the run up to the Federal Court hearing, which commenced in November 2023, Sanofi filed two interlocutory applications.

Sanofi v Amgen Inc. [2023] FCA 264 concerned Sanofi's interlocutory application seeking orders for discovery and leave to rely on experimental evidence. In relation to the experimental evidence, Sanofi sought to rely on experiments conducted for the purpose of proceedings in other jurisdictions. The Court refused Sanofi's application for discovery and permitted reliance on some but not all of the experimental evidence.

In refusing leave to rely on certain experiments, Nicholas J considered that the experiments were of little relevance to Sanofi's alleged grounds of invalidity. His Honour also observed that there was significant debate in corresponding European proceedings about the conclusions that could be drawn from the experiments, and that introducing those experiments to the Australian proceedings would likely give rise to a substantial and undue waste of time and costs.

Experimental evidence for which leave was granted was considered to be directly relevant to Sanofi's alleged grounds of invalidity.

In *Sanofi v Amgen Inc.* (No 2) [2023] FCA 1156, Sanofi filed a further interlocutory application seeking orders to limit the evidence which Amgen could adduce at the hearing. Amgen had proposed to rely on declarations made by three experts in the Patent Office opposition, as well as supplementary affidavits from those same experts. Sanofi sought to exclude some of that evidence on the grounds that it was substantially duplicative. Justice Yates rejected Sanofi's application in its entirety noting that Sanofi could have raised its concerns at the first case management hearing but did not do so.

The appeal continues.

Author

Michael Christie
Principal

19 *Sanofi v Amgen* at [174].
20 *Sanofi v Amgen* at [175]
21 Section 40(2)(a)
22 *Sanofi v Amgen* at [181].
23 *Patents Act 1990* (Cth), s 18(1).
24 *Sanofi v Amgen* at [191].

Reading between the lines: Sandoz challenge to rivaroxaban patents unsuccessful

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Summary

In *Sandoz AG v Bayer Intellectual Property GmbH* [2023] FCA 1321, Sandoz AG challenged the validity of two Australian patents (AU2004305226 and AU2006208613) directed to rivaroxaban (an anticoagulant) compositions and their uses, for which Bayer Intellectual Property GmbH is the exclusive licensee. Justice Rofe found that both patents were valid, and that claims 3 and 4 of patent AU2006208613 were threatened to be infringed by Sandoz's intended activities. A key issue at hand was the construction of the phrase "in hydrophilized form" and the extent to which the skilled person would refer to materials cited in the specification to clarify the scope of essential claim features.

Background facts

Bayer Intellectual Property GmbH is the exclusive licensee of two Australian patents, AU2004305226 (the '226 patent) and AU2006208613 (the '613 patent). The '226 patent is directed to compositions comprising rivaroxaban, processes for preparing said compositions and uses of the composition for treatment of thromboembolic disorders. The '613 patent is directed to uses of rivaroxaban in rapid-release tablet form for treatment of thromboembolic disorders. Rivaroxaban is one of a class of factor Xa inhibitors claimed in a former Bayer patent, WO2001/47919 (WO 919).

Sandoz is the sponsor of several rivaroxaban therapeutics on the Australian Therapeutic Goods Register (ARTG), and intends to exploit these products in Australia after November 2023 without Bayer's approval. Sandoz sought revocation of both the '226 and '613 patents and Bayer made a cross-claim seeking an injunction to prevent the threatened infringement of its patents by Sandoz.

Legal issues and outcomes

Infringement

Bayer alleged that Sandoz's intended activities threatened to infringe various claims of both patents.

Subject to the validity of the '613 Patent, Sandoz Australia admitted to threatening infringement of that patent.

The key issue in determining infringement of the claims of the '226 patent was the scope of the phrase "in hydrophilized form". This phrase appears in claim 8 (which the remaining claims ultimately depend on or refer to), which reads:

> 8. Solid, orally administrable pharmaceutical composition, comprising 5-chloro-N-({(5S)-2oxo-3-[4-(3-oxo-4-morpholinyl)-phenyl]- 1,3-oxazolidin-5-yl} -methyl)-2thiophenecarboxamide (I) **in hydrophilized form**. (emphasis added)

In the course of the proceedings, both of the primary experts agreed that they had not encountered the term prior to reading the patent, and that it was not part of the common general knowledge in the art. The '226 patent does not include a definition of this term, but does refer to two papers (termed the "Lerk papers"). Those papers describe a process for hydrophilization as a means for increasing oral bioavailability of a drug compound. In short, hydrophilization is described as a process for coating a hydrophobic drug with a hydrophilic excipient in order to render it hydrophilic.

The principal dispute was whether it is legitimate for the skilled person to have regard to the disclosure of the Lerk papers in order to correctly understand the term used in the claims. Referring to Justice Greenwood's decision in *Uniline*[1], Justice Rofe held that "the person skilled in the art may read the prior art Lerk papers to give context to, and better understand, the discussion in the '226 Patent".

Consideration then turned to the scope of this phrase. In both the Lerk papers and the '226 patent, the hydrophilization process involves intensive mixing in the presence of a small amount of hydrophilic excipient in liquid solution. However, Bayer asserted that it was not limited to methods which include a liquid, and could also encompass methods which do not include any liquid, such as that used to produce Sandoz's rivaroxaban products.

Her Honour considered that a skilled person having read the specification and the Lerk papers, would construe the claims as referring to the hydrophilization process described in the Lerk papers, and therefore necessarily including the use of a liquid. Thus Sandoz's rivaroxaban products do not infringe the claims of the '226 patent.

Inventive step

An inventive step challenge was brought against both patents relying on various documents including Bayer's earlier patent (WO 919). WO 919 disclosed rivaroxaban, its method of synthesis, identified it as the most preferred compound of the class and also noted a number of other beneficial traits, such as suitability for oral administration and treatment of thromboembolic disorders.

Under the *Patents Act 1990* (Cth) prior to the Raising the Bar amendments, in order for a document to be prior art under s 7(3) of the Act, it had to be shown that the skilled person could reasonably be expected to have 1) ascertained; 2) understood; and 3) regarded as relevant, the information in the document.

1 *Uniline Australia Ltd v SBriggs Pty Ltd* (2009) 81 IPR 42

Evidence of "ascertainment" in patent litigation is commonly obtained by asking an independent expert witness what search strategy they would use to research the relevant problem, undertaking that search and then asking the expert to identify relevant documents from the results.

In this case, Sandoz had provided WO 919 to its expert before he reviewed the search results and he had considered it in some detail. Rofe J noted that it was perhaps unsurprising that WO 919 was then listed by the expert as a high priority document.

In the absence of clear expert evidence that the document would likely have been ascertained, her Honour considered that as a patent specification, WO 919 was dissimilar to high impact journal articles which would be read by all those in the field to keep up to date. In the circumstances Justice Rofe did not consider that this threshold had been met.

In obiter, Justice Rofe offered further comments, remarking that even were the document ascertained, an inventive step challenge on the basis of WO 919 would still not be successful. Justice Rofe considered that, in contrast to the decision in *Astrazeneca*, where the drug in question was one of a class of commonly prescribed statins with the same mechanism of action, the drug in this case (rivaroxaban) was a first in class compound with a different mechanism of action to existing anticoagulant agents (e.g. warfarin and LMWH).

Accordingly, while the information in WO 919 may lead the skilled person to choose rivaroxaban as a starting point, the hypothetical drug development team would have no guidance from other compounds in the same class, and there was no body of knowledge to refer to in order to reliably predict side effects. Ultimately, Justice Rofe did not consider that the skilled person would have the requisite expectation of success that rivaroxaban would pass all the drug development stages to successful completion of Phase III trials and ultimately be approved for use in human as a safe and effective once per day treatment for thromboembolic disorders. A similar finding was made regarding the '613 patent.

The remaining inventive step challenge against the '613 patent was in relation to documents titled the "Blood Abstracts", which were a set of three abstracts published in advance of the annual American Society of Haematology (ASH) conference in 2003. In this instance, her Honour found that the Blood Abstracts would have been ascertained, understood and regarded as relevant by the skilled person and thus did qualify as valid s 7(3) documents. In contrast to WO 919, experts for both parties acknowledged that they would review the ASH abstracts book, in which the Blood Abstracts made up three of the four abstracts listed under the index keyword "factor Xa inhibitor".

The Blood Abstracts disclosed that test compound "BAY 59-7939" had demonstrable effects in various surrogate tests of thrombosis over a dose range that seemed safe. However, the Blood Abstracts failed to disclose: the structure, chemical class, toxicity, formulation chemical form, excipient details or therapeutic window of BAY 59-7939. Justice Rofe considered that without the structure of BAY 59-7939, or a sample of the compound, the skilled team would not (or could not) proceed any further. Her Honour considered that the skilled person would not have the requisite expectation of success that BAY 59-7939 would pass all the drug development stages to successful completion of Phase III trials and ultimately be approved for use in human as a safe and effective once per day treatment for thromboembolic disorders.

Best method

Sandoz also submitted that the '613 patent failed to disclose the best method of working the invention known to Bayer for making a rapid release tablet containing rivaroxaban, which Bayer admitted was that described in PCT/EP2004/012897 (which is the international phase of the '613 patent). While this PCT application was referred to in the '613 patent, a typographical error had led to the PCT application being mis-numbered. Sandoz argued this meant that the material contained in the PCT application was not disclosed in the '613 patent.

Justice Rofe accepted that the mistake in the '613 patent was an unintentional typographical error and further considered that the evidence established that the skilled person would be able to find the correct reference by searching the patent databases or engaging a patent searcher. Accordingly, her Honour considered that the public had been fairly given possession of the invention described in the '613 patent.

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Current pharmaceutical patent cases before the Federal Court

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1. Otsuka Pharmaceutical Co. v Generic Health Pty Ltd NSD121/2012

In similar fashion to *The Commonwealth v Sanofi*, these proceedings concern a claim for compensation by the Commonwealth and the relevant generic company, pursuant to the usual undertaking as to damages made on grant of an interlocutory injunction in 2012 in connection with Otsuka Pharmaceutical Co., Ltd's (**Otsuka**) claim that Generic Health Pty Ltd had infringed certain patents concerning aripiprazole (Abilify). The patent in suit was later revoked, a finding upheld by the Full Federal Court in *Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd (No 2)* [2016] FCAFC 111. On 6 December 2022, the matter was referred to a referee (Hon Tom Bathurst AC KC), however there has been little progress in the matter during 2023, possibly because of the current status of the *Sanofi* proceedings.

2. H Lundbeck A/S & Anor v Sandoz Pty Ltd NSD647/2014

These complex and long running proceedings between H Lundbeck A/S (**Lundbeck**) and Sandoz Pty Ltd (**Sandoz**) concerning escitalopram (Lexapro) were remitted to the Federal Court following the decision in *H. Lundbeck A/S v Sandoz Pty Ltd* [2022] HCA 4 that (among other things) Sandoz's contractual patent licence did not cover the extended term of the patent. The Federal Court proceedings are currently stayed until the final determination of a review in the Administrative Appeals Tribunal of the decision *H Lundbeck A/S v Sandoz Pty Ltd* [2019] APO 18 concerning the grant of a statutory licence to Sandoz for the extended period.

3. Pfizer Ireland Pharmaceuticals & Anor v Samsung Bioepis Co. Ltd & Ors NSD331/2022

These patent infringement proceedings which concern Samsung Bioepis' biosimilar etanercept product Brenzys, were commenced by Pfizer Ireland Pharmaceuticals against multiple Respondents (Samsung Bioepis, Organon, MSD and Arrow with Biogen MC as an interested party) following protracted preliminary discovery proceedings. There are a number of interlocutory events on foot including an application to amend the patent and an application to strike out the proceeding.

4. Novartis AG & Anor v Pharmacor Pty Limited ACN 121 020 835 NSD506/2023

Novartis AG alleges that Pharmacor has threatened to infringe its patent covering its valsartan product (Entresto) and Pharmacor has cross claimed to revoke the relevant claim of the patent. The proceedings are set down for hearing over several days in April and May this year. Among other interlocutory applications dealt with in 2023, an interlocutory application for the hearing of a separate question (as to relevant time at which a patent applicant's knowledge of the best method is to be fixed for the purposes of s 40(2)(a) of the *Patents Act 1990* (Cth)) was dismissed in August 2023, with that matter to be dealt with together with all other issues at final trial.

5. Cipla Australia Pty Ltd v Bristol-Myers Squibb Holdings Ireland Unlimited Company & Anor NSD911/2023

These proceedings concern two patents owned by Bristol Myers Squibb covering apixaban (Eliquis), an anticoagulant directed at inhibiting Factor Xa in the prothrombinase. These proceedings are still at an early stage with the parties currently dealing with discovery matters.

6. Cipla Australia Pty Limited v Bayer Intellectual Property GMBH VID124/2023

These proceedings concerning two patents covering rivaroxaban (Xarelto) have been stayed, pending the outcome of the proceedings concerning the same patents between Sandoz AG and Bayer Intellectual Property GmbH.

7. Samsung Bioepis Au Pty Ltd v Formycon AG NSD1167/2023

These patent invalidity proceedings concern two patents covering aflibercept (Eylea). They are still at an early stage.

Other cases

The following cases of note are the subject of separate case notes:

- *Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis)* [2023] FCAFC 97 (now on appeal to the High Court)
- *Sandoz AG v Bayer Intellectual Property GmbH* [2023] FCA 1321 (now on appeal to the Full Court)
- *Sanofi v Amgen Inc.* NSD876/2022 (judgment reserved)

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2023 Hot Topics

Skinny labelling in the Australian context: an overview

Author: Andrew Rankine | Principal

Key takeaways

- In Australia, new indications for known pharmaceuticals may be protected by several patent claim formats, including method of treatment claims, Swiss type claims and EPC 2000 claims.
- Various forms of "skinny labelling" may be adopted by suppliers of generic and biosimilar medicines in an attempt to avoid infringement of second medical use patents when supplying a known pharmaceutical product for an off-patent indication in Australia.
- Typically, skinny labelling involves omitting patented indications from the prescribing information (i.e., label) for a generic or biosimilar product, with or without an express statement that the product is not supplied for use in any patented indications. Such measures require regulatory approval. Sponsors of generics and biosimilars may also communicate directly with prescribers and pharmacists regarding the permissible use of their products.
- In a leading Australian case, although such measures were effective to avoid infringement of Swiss type claims, they were not effective to avoid infringement of method of treatment claims because, on the facts of that case, the generic sponsor had "reason to believe" its product would be used for a patented indication despite skinny labelling.
- The more complex regulatory arrangements applicable to biosimilars and other high-cost medicines may provide opportunities for more robust forms of skinny labelling (e.g., omitting patented indications from the scope of regulatory approval and/or reimbursement arrangements), although such measures are yet to be tested before Australian courts.

Patents for second medical uses

Second medical use patents confer exclusive rights relating to the use of known pharmaceutical substances for new therapeutic indications. An example is provided by the patents granted to Warner-Lambert in several jurisdictions relating to the use of pregabalin (a pharmaceutical previously known and used in the management of seizures) for the treatment of certain types of pain (see *Warner-Lambert Company LLC v Apotex Pty Ltd* [2014] FCAFC 59 (**Pregabalin Case**)).

In Australia, several claim formats may be used to protect a new therapeutic indication for a known pharmaceutical substance, including the following:

- Method of treatment claims typically have the form "a method of treating [disease X] comprising administering an effective amount of [substance Y]" or, alternatively, "the use of [substance X] for the treatment of [disease Y]".
- Swiss type claims are purpose-limited process claims typically in the form "the use of [substance X] for the manufacture of a medicament for the treatment of [disease Y]" or "the use of [substance X] in the manufacture of a medicament for the treatment of [disease Y]".
- So-called EPC 2000 claims are purpose-limited product claims typically having the form "[substance X] for use in treating [disease Y]".

While method of treatment claims are prohibited in some jurisdictions, they are generally permissible in Australia: see *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [2013] HCA 50 (**Leflunomide case**).

Skinny labelling as a defensive strategy

Skinny labelling refers to strategies that a supplier of generic or biosimilar medicines may adopt in an attempt to avoid infringement of a second medical use patent when supplying a medicine for an "off patent" indication. As discussed below, skinny labelling may take a number of different forms.

Amendments to pharmaceutical labelling

In common with many other jurisdictions, Australia's regulatory regime for therapeutic goods requires the supplier of a prescription medicine to publish a document (generally known as "prescribing information" or a pharmaceutical "label") providing information necessary for the medicine's safe and effective use. Among other things, this prescribing information or label records the therapeutic indications for which use of the product has been granted regulatory approval in Australia.

In its simplest form, skinny labelling involves omitting from prescribing information for a generic or biosimilar product one or more indications that remain patent-protected, while retaining those indications that are "off patent". A more elaborate version of skinny labelling involves also including in the generic or biosimilar prescribing information an express statement that the product is not supplied for use in accordance with one or more indications that remain patent-protected. Amendments to prescribing information require the approval of Australia's Therapeutic Goods Administration (**TGA**). Whether the TGA will approve the inclusion of a "disclaimer" in generic or biosimilar prescribing information will depend upon the circumstances of each individual case.

In addition to the strategies mentioned above, the supplier of a generic or biosimilar product may communicate with Australian prescribers and pharmacists to inform them that its product should not be prescribed or dispensed for use in one or more patented indications.

Such strategies have been considered in a number of Australian pharmaceutical patent cases:

- In the Leflunomide Case, Australia's High Court ruled that a disclaimer included in the prescribing information for Apotex's generic leflunomide product was effective to avoid infringement of Sanofi's method of treatment claim covering the use of leflunomide for the treatment of psoriasis, enabling Apotex's product to be supplied for the off-patent rheumatoid arthritis indication.

- In the Pregabalin Case, a skinny labelling strategy, coupled with undertakings to notify prescribers and pharmacists that Apotex's generic pregabalin products were only supplied for use in the treatment of seizure disorders was ineffective to avoid a preliminary injunction restraining supply of the generic product, in light of evidence that the patented pain indication comprised almost the entirety of the relevant Australian market for pregabalin products.
- In *Mylan Health Pty Ltd v Sun Pharma ANZ Pty Ltd* [2020] FCAFC 116 (**Fenofibrate Case**), a skinny labelling strategy, coupled with undertakings to notify prescribers and pharmacists that Sun's generic fenofibrate products were only supplied for use in the off-patent hypercholesterolaemia indication, was effective to avoid infringement of Swiss type claims relating to the use of fenofibrate in the treatment of diabetic retinopathy, but was not effective to avoid infringement of method of treatment claims covering the latter indication.

The Fenofibrate Case serves to highlight an important distinction between Swiss type claims and method of treatment claims under Australian law, as it currently stands. In that case, Australia's Full Federal Court held that infringement of Swiss type claims is governed, not by the manufacturer's intention, but rather by what the medicament is manufactured "for" as indicated by (for example) the physical characteristics of the medicament as it emerges from the manufacturing process, including its formulation, dosage, packaging and labelling. On the facts of the Fenofibrate case, Sun's skinny labelling strategy was sufficient, in the Full Court's view, to establish that its generic fenofibrate products were not "for" use in the treatment of diabetic retinopathy and thus would not have infringed Mylan's Swiss type claims.

By contrast, the Full Court held that Sun would have infringed Mylan's method of treatment claims for the diabetic retinopathy indication (had they been valid). That is because, having regard to all of the relevant circumstances, Sun had "reason to believe" their generic fenofibrate products would be used for the patented indication, despite skinny labelling. Similar findings are likely to be made where (for example) a patented indication comprises the overwhelming majority of the Australian market for the pharmaceutical product in question, as occurred in the Pregabalin Case.

Additional strategies for suppliers of biosimilars and other high-cost medicines

Regulatory marketing approval for small-molecule generic medicines is typically granted on the basis of an appropriate bioequivalence study, without the need for the generic sponsor to provide clinical-trial data demonstrating efficacy. In such cases, regulatory marketing approval granted for the small-molecule generic product typically encompasses *all* of the indications for which the reference (i.e., branded or originator) pharmaceutical product has been granted marketing approval in Australia.

Australia's process for regulatory approval of biosimilars is different. Commonly, data submitted in support of an application for regulatory approval of a biosimilar includes results of one or more clinical trials, demonstrating efficacy of the biosimilar for at least one therapeutic indication, coupled with material supporting an inference that the biosimilar will also be efficacious in other therapeutic indications for which the reference product is approved in Australia ("extrapolation of indications").

This more complex regulatory pathway may afford the sponsor of a biosimilar additional strategies to limit the indications for which its product is granted marketing approval in Australia to "off patent" indications.

In most cases, supply of biologicals and other high-cost medicines in Australia is subsidised by the Australian Government under the Pharmaceutical Benefits Scheme (**PBS**). The indications for which supply of a medicine will be reimbursed under the PBS is determined by the Australian Government, acting on the advice of an expert committee (the Pharmaceutical Benefits Advisory Committee; **PBAC**).

There may be scope for a sponsor of a biosimilar or other high-cost medicine to limit the PBS listing of its product to exclude patented indications. In particular, PBS-subsidies are ordinarily not available where a product is supplied "off label" (i.e., supplied for a therapeutic indication for which that product has not been granted regulatory marketing approval by the TGA).

Exclusion of patented indications from the scope of regulatory marketing approval and/or PBS-reimbursement for biosimilars and other high-cost medicines has the potential to afford the suppliers of such products with a more robust form of "skinny labelling". However, the availability of such strategies will depend upon the approach adopted by the TGA and PBAC in each individual case. Whether such strategies will be effective to avoid infringement of second medical use claims is yet to be tested before the Australian courts.

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Pharmaceutical Patent Term Extension in Australia

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Patent term extensions (PTEs) can be of great commercial importance, and in recent years have become of particular interest in Australian pharmaceutical patent law following a number of Federal Court decisions clarifying the circumstances in which PTEs may be available. We provide here a summary of the requirements and some recent Federal Court decisions in this area.

Under Australian patent law, it is possible to apply for a PTE of up to 5 years for a standard patent that claims a pharmaceutical substance, in recognition of the exceptionally long time and regulatory requirements involved in developing and commercialising a new pharmaceutical substance.

As set out in section 70 of the *Patents Act 1990* (Cth), a patent is eligible for PTE:

i) where the claims of the patent encompass:

a) Pharmaceutical substance(s) per se; or

b) Pharmaceutical substance(s) produced by recombinant DNA technology; and

ii) where that pharmaceutical substance is included in goods which have received regulatory approval at least five years following the effective date of the patent.

The application for PTE must be made in the "prescribed manner" which includes providing evidence to show that the goods containing the substance are currently included in the Australian Register of Therapeutic Goods (ARTG) and submitting the application for PTE within six months of the earliest inclusion in the ARTG of goods containing the pharmaceutical substance, or grant of the patent, whichever is later.

Eligibility Considerations - Subject Matter

Except for substances produced by a process involving the use of recombinant DNA technology, an extension of term is only available in respect of a "pharmaceutical substance *per se*" being within the scope of a claim of the patent. The use of the term "*per se*" requires the claim to the substance to be unqualified by process, temporal, or environmental, components (*Boehringer Ingelheim International v Commissioner of Patents* [2000] FCA 1918).

Patents that claim pharmaceutical substances when produced by a particular process (product by process claims) will not be eligible (unless that process involves the use of recombinant DNA technology). In limited circumstances, a substance could be new and inventive but can only be defined by reference to the process in which it was made (for example, compound X obtainable by process Y) because the chemical structure or composition is undetermined. In such circumstances, a claim which defines the substance by reference to such method steps would be regarded as a claim to the substance per se (see *Zentaris AG* [2002] APO 14, and *Pharmacia Italia SpA v Mayne Pharma Pty Ltd* [2006] FCA).

Additionally, case law has established that pharmaceutical compositions (formulations) comprising a specified amount of an active ingredient and other components (excipients), where the mixture provides a physico-chemical interaction within the human body, can be eligible for PTE (see *iCeutica Pty Ltd* [2018] APO 76 and *Spirit Pharmaceuticals Pty Ltd* v *Mundipharma Pty Ltd* [2013] FCA 658). In the *Mundipharma* case, this extended to a slow release formulation.

Claims which limit the use of a known substance to a particular environment, for example claims drawn to the use of pharmaceutical substances when used in a new and inventive method of treatment, are not considered to be claims to pharmaceutical substances per se (see *Commissioner of Patents v AbbVie Biotechnology Ltd* [2017] FCAFC 129).

In a more recent Federal Court decision, *Biogen International GmbH v Pharmacor Pty Ltd* [2021] FCA 1591 ("Biogen"), which involved a disputed PTE, Biogen had sought an interlocutory injunction against Pharmacor. Pharmacor argued that a PTE granted on the basis of EPC2000 claims in the format "Substance X for use in the treatment of disease Y" was invalid as the claim was not to a pharmaceutical substance per se. The Federal Court was sympathetic to this position and considered that there was *"a sufficiently strong prospect" that the PTE had been "wrongly granted"* (Biogen at [139]) and ultimately declined to grant an injunction. This position diverges from the construction of such claims routinely adopted by the Australian Patent Office (i.e. a product merely suitable for but not limited to the specified use). Unfortunately, this issue was not finally determined on account of settlement of the litigation. However, the decision together with advice in the Australian Patent Examiner's Manual suggests that a claim to "substance X for use ...." may not define a pharmaceutical substance per se that may support a PTE.

Eligibility Considerations – First Regulatory Approval Date

Under section 70(3) of the *Patents Act 1990* (Cth), in order to be eligible for a PTE the period beginning on the date of the patent and ending on the first regulatory approval date for the pharmaceutical substance must be at least 5 years.

In two appeal judgements handed down concurrently in March 2022 (*Commissioner of Patents v Ono Pharmaceutical Co. Ltd* [2022] FCAFC 39 (*Ono*) and *Merck Sharp & Dohme Corp. v Sandoz Pty Ltd* [2022] FCAFC 40 (*MSD*)), the Full Federal Court has clarified that a PTE for a patent should be based on the earliest Australian regulatory approval date of a pharmaceutical substance which is disclosed and claimed in the patent, irrespective of whether the substance was developed by the patentee or a competitor.

In *Ono*, the claims of the patent encompassed two pharmaceutical substances, one belonging to the patentee (Opdivo®: registered later and afforded a longer extension), and the other belonging to a third party (Keytruda®: registered earlier and requiring an extension of time in order to timely file the PTE application). In *MSD* the claims of the patent encompassed two pharmaceutical substances both developed and registered by the patentee (Januvia® (sitagliptin alone): registered first and within 5 years of the date of the patent), (and Janumet® sitagliptin and metformin combination): registered (later than 5 years from the patent date).

In both decisions, it was held that the goods which were approved first were those upon which the PTE must be based. Significantly, in *Ono* and *MSD* the Full Federal Court confirmed that the language of the relevant provisions refers to the first regulatory approval date in respect of *any* of the pharmaceutical substances which may be disclosed and claimed in the respective patent. Accordingly, it is not open to the patentee to distinguish between its own goods and those developed by a third party, nor can a patentee exclude from consideration or nominate for itself the goods upon which a PTE is to be based, where more than one product falls within the scope of its patent. It is also clear from *MSD* that if the product the subject of the first regulatory approval is registered within 5 years of the patent date, no PTE will be available for it or any subsequent product falling within the patent scope.

Interestingly, Ono's alternative PTE application filed for AU 2011203119 on the basis of Keytruda® was recently granted, confirming the position that it is possible to obtain a PTE based on a third party's product.

Practical Implications

Claims defining a pharmaceutical substance "for use" require careful consideration and may not be eligible to support a PTE or render any resultant PTE susceptible to challenge.

An application for PTE must be based on the broadest reading of the claim set as a whole. Where the claims of a patent to be extended cover more than one active ingredient, they should also be cross-checked against any goods entered into the ARTG to determine what registered goods are encompassed by the claims, including those of unrelated third parties.

It is advisable to consider filing one or more divisional applications during prosecution so that individual pharmaceutical substances (that are intended to be ARTG registered) are quarantined in separate applications. Proceeding in this way will avoid an earlier registration in respect of one substance precluding a PTE based on later registered goods in respect of a different substance.

Where it is not possible to file a divisional application, patentees may consider pre-emptively filing amendments to exclude earlier ARTG registered goods if appropriate, in order to facilitate eligibility and allowance of a PTE.

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"Best Method" Requirement Increasingly Prominent in Australian Pharmaceutical Patent Disputes

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Australia is one of the few major patent jurisdictions which has maintained in its patent law a discrete requirement that a patentee disclose the "best method" known to it of performing the invention. As outlined in this article, rather than remain in the background or even fade away, best method challenges have assumed an increasingly prominent role in Australian patent disputes and can significantly affect the conduct and strategy of Federal Court litigation, in particular. The table at the end of this article summarises the claims, findings and key issues of selected Australian pharmaceutical patent cases where best method has proven a pivotal issue. Potential pharmaceutical patent litigants should be mindful of the substantive and procedural implications best method issues can have in the Australian iteration of global disputes.

Best in Australia (but nowhere else?)

Australia inherited its best method requirement from the United Kingdom, which itself abolished the corresponding requirement in its own legislation in 1977, coming into line with European patent law. The United States abolished its (perhaps less onerous) "best mode" patent revocation ground as part of the "America Invents" legislative reforms in 2011, although it can still play some role during examination before the USPTO. Similarly, Japan has no formal best method requirement, although similar objections can be raised during examination it is not a ground of invalidity. South Africa abolished its best method requirement in 2002. New Zealand retains a narrow best method with respect to methods which would be entitled to protection in their own right and but (unlike Australia) does not have strict prohibition in relation to post-acceptance amendments (meaning there is more scope to "fix" best method issues).

Best method is a question of fact

The best method requirement under Australian law, now enshrined in section 40(2)(aa) of the *Patents Act 1990* (Cth), is a factual question focusing essentially on what the patentee (or its predecessor in title) actually knew at the time the application for the patent was filed in Australia (PCT filing or direct Australian complete or divisional application), rather than at the earliest priority date, and whether any of that known information about the best method of performing the invention can be adjudged to have been withheld from the patent specification. The obligation is merely to disclose that method known by the patent applicant (not the inventor(s)), including constructively.

Best method of performing "the invention"

The best method requirement pertains to disclosure of "the invention". Therefore, the starting point is to identify the invention, as claimed and described by the specification as a whole. Features which are ancillary to the invention do not form part of the "invention" for the purposes of the best method. Whether a feature is ancillary to the invention depends on whether that feature is "necessary and important" to carry the invention into effect. "Best" means what is best in practice and not in theory. Commercial value or profitability is not of itself a relevant criterion for determining what is "best". What is required is disclosure of the most effective means of carrying out the invention known to the patentee at the relevant time. The best method of performing the invention does not have to be identified as being the best method in the specification.

Best method is similar, but in addition to, sufficiency

The best method requirement is therefore similar, but in addition and in important ways different to, the "sufficiency" requirement to provide clear enough and complete enough description to perform the invention, and the "support" and "clarity" requirements to draw claims that are clear and supported by matter disclosed in the specification. Patents satisfying the sufficiency, support and clarity requirements are increasingly be found invalid for failure to disclose the best method. A tantalising intersection with the law of "sufficiency" is that a patentee is not obliged to disclose information that is already known to the skilled addressee by way of the common general knowledge. It may also be open to the patent applicant not to disclose relevant information on the basis that it is available to the skilled addressee by routine experimentation. This is to be assessed by reference to the importance of the information in question, the practicality of disclosing it, and the extent of the burden imposed on the skilled addressee who is left to rely upon routine experimentation. This difficult argument was run successfully by the patentee in the GlaxoSmithKline case summarised in the table below.

Basis for best method challenges

Invalidity for failure to disclose the best method is not confined to scenarios where the patentee knows two (or more) methods and discloses the inferior method, although that is perhaps most common and often proven through discovered or other contemporaneous documents. Invalidity may also arise where the comparison is between an "umbrella" or general methodology that is disclosed in the specification and "a specific method which was sure to provide the benefits of the invention" which was not disclosed. In either situation, the party challenging validity needs to identify some basis for asserting that the disclosure given in the specification is deficient because it is apparent that the patentee withheld information material to the best method of performing the invention.

When best method challenges typically arise

Given the fact-dependent nature of best method challenges, they arise most often in Federal Court of Australia proceedings (appeals from pre-grant opposition decisions of the Patent Office or post-grant revocation cases), where discovery, subpoenas, witness cross-examination and other compulsive processes are available to parties challenging patent validity – see, for example, the *Servier* decision summarised in the table below. Best method is also increasingly being run as a ground of opposition in pre-grant *inter partes* oppositions in the Patent Office, typically on the basis of detail apparently absent on the face of the specification or in view of publications or statements in a declaration by the inventor (eg, as part of the patent applicant's evidence on inventive step or entitlement). Best method objections are rarely raised during examination, and are discouraged by the Examiner's Manual published and used by IP Australia – although the *Kineta Inc.* decision summarised in the table below is an example of a patent application being refused during examination on the basis of a best method objection.

Impact best method allegations can have on conduct of patent disputes

Because best method is a question of fact, it can provide fertile ground for seeking discovery from the patentee. The Court has adopting an increasingly strict approach to best method pleadings, which must not be general and speculative in the hope of finding a best method case after the patentee gives discovery. The Court may refuse discovery if there is no apparent best method case without discovery. However, if a sound basis can be provided for pleading a specific lack of best method case, discovery orders are often made in Federal Court proceedings and can prove onerous for patentees, particularly if the patent in suit was filed many years ago and the invention was developed during a major R&D programme. Such discovery exercises can significantly expand the timetable for evidence and pre-trial steps, as well as the scope and costs of the proceedings overall. Mindful of this, sometimes the discovery sought with respect to best method is targeted at specific documents expected to exist, such as parts of regulatory dossiers – see the successful application for discovery in the *AUPharma* decision in the table below. The potential complications and case expansion arising from best method discovery and subsequent evidence has also motivated parties to actively consider whether best method issues might be considered as "separate questions" before all other issues of validity and infringement – see the unsuccessful application made by the patentee in the Novartis decision in the table below.

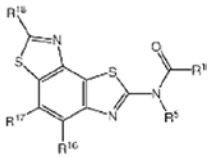
Selected Australian Pharmaceutical Patent Cases Involving Best Method Challenges

Case	Claim(s)	Finding	Notable
Les Laboratoires Servier v Apotex Pty Ltd (2016) 247 FCR 61 (click for judgment)	1. The arginine salt of perindopril and its hydrates. 2. Pharmaceutical composition comprising, as active ingredient, the arginine salt of perindopril and its hydrates, in combination with one or more pharmaceutically acceptable excipients.	*"...in describing only the general method of classical salification rather than a specific method, such as the known 1986 and 1991 method, which would have provided the information to the skilled reader of a method for obtaining a form of perindopril arginine which met the characteristics of the claimed invention, Servier failed to describe the best method known to it of performing the invention".*	Evidence (of inventors) demonstrated **actual patentee knowledge of better methods not disclosed** Amendment to introduce best method (pre-RTB s102) refused on discretionary grounds

Selected Australian Pharmaceutical Patent Cases Involving Best Method Challenges

Case	Claim(s)	Finding	Notable
GlaxoSmithKline Consumer Healthcare Investments (Ireland) (No 2) Limited v Generic Partners Pty Limited (2018) 264 FCR 474 (click for judgment)	1. A pharmaceutical composition comprising a bilayer tablet having an immediate release phase of paracetamol and a sustained release phase of paracetamol, the immediate release phase being in one layer and comprising from about 10 to 45% by weight of the total paracetamol; and the sustained release phase being in the other layer and comprising from about 55% to 90% by weight of the total paracetamol in admixture with a matrix forming polymer or a mixture thereof; said composition comprising from 600 to 700mg of paracetamol per unit dose and a pharmaceutically acceptable carrier, wherein said composition has an in vitro paracetamol dissolution profile (as determined by the USP type III apparatus, reciprocating basket, with 250ml of 0.1M HCl at 37C set at a cycle speed of 15 strokes/min) with the following constraints: • 30 to 48% released after 15 minutes • 56 to 75% released after 60 minutes • >85% released after 180 minutes.	*"...we are not satisfied that the respondents discharged their onus of establishing that the Patent was invalid on the ground that the complete specification failed to specify the particular grade and viscosity of HPMC or granulation end points that might be used to perform the invention according to the best method known to the patent applicant. We agree with the primary judge that the best method was disclosed, albeit at a level of generality that did not include the more detailed but inessential manufacturing and production information described in the MAA applicable to the commercial embodiment."*	Patent survived best method challenge because details not disclosed were inessential to performance because they were common general knowledge / routine

Selected Australian Pharmaceutical Patent Cases Involving Best Method Challenges

Case	Claim(s)	Finding	Notable
Kineta, Inc. [2017] APO 45 (31 August 2017) (click for judgment)	Claim 1 as proposed to be amended is directed to a compound represented by the formula:  For the purposes of this decision it is not necessary to consider the definition of the variables R1, R5, R16, R17 and R18. Later claims are appended to claim 1 and directed to pharmaceutical compositions comprising the compound and methods of treatment comprising administering the composition.	*"The specification does not set out any method of preparing the compounds, and no method is apparent when the specification is read in the light of the common general knowledge. The applicant was aware that the compounds could be obtained from a commercial supplier. I am satisfied that the specification does not comply with section 40(2)(aa) as it does not disclose the best method known to the applicant."*	Patent applicant failed to disclose the best method of performing the invention because it had failed to disclose that the only method known to it of obtaining the compounds of the invention was to commission their synthesis from a particular supplier Patent Office decision upholding objection during examination
AUPharma Pty Limited v Mundipharma Pty Limited [2023] FCA 330 (click for judgment)	*"Each patent relates to an oral controlled-release pharmaceutical composition comprising oxycodone and naloxone, where the oxycodone and the naloxone are present in a ratio within the range of 5:1 to 1:1 (the 469 patent, the 453 patent, and the 011 patent), or within the range of 4:1 to 1:1 (the 745 patent and the 130 patent), and where the composition releases the oxycodone and the naloxone".*	The Court orders that: 1. The respondent produce to the applicant electronic copies of the following modules from the dossier provided to the Therapeutic Goods Administration in relation to each of the respondent's TARGIN® products: a) module 3.2.P.1 titled "Description and Composition of the Drug Product"; b) section 3.2.P.2.1 titled "Components of the Drug Product"; c) section 3.2.P.2.2 titled "Drug Product"; d) section 3.2.P.2.3 titled "Manufacturing Process Development"; and e) module 3.2.P.3.3 titled "Description of Manufacturing Process and Process Controls".	Discovery ordered with respect to specific sections of regulatory dossier where best method challenge related to details of pharmaceutical formulation, in the context of a challenge to a pharmaceutical patent term extension

Selected Australian Pharmaceutical Patent Cases Involving Best Method Challenges

Case	Claim(s)	Finding	Notable
Novartis AG v Pharmacor Pty Limited (No 2) [2023] FCA 963 (click for judgment)	1. A pharmaceutical composition comprising: (i) the AT 1-antagonist valsartan or a pharmaceutically acceptable salt thereof; and (ii) the NEP inhibitor N-(3-carboxy-1-oxopropyl)-(4S)-p-phenylphenylmethyl)-4 amino-2R-methylbutanoic acid ethyl ester or (2R,4S)-5-Bipheny-4-y-4-(3 carboxypropionylamino)-2-methyl-pentanoic acid or pharmaceutically acceptable salts thereof and a pharmaceutically acceptable carrier.	*"On balance, I am not persuaded that the just resolution of the substantive question raised by Novartis's separate question—namely, the date fixed by s 40(2)(a) of the Act (in its relevant form) for determining the patent applicant's knowledge of the best method—in accordance with the overarching purpose, favours the hearing of that question separately from and before any other question in the proceeding. I am satisfied that the substantive question is best determined in the context of the trial itself."*	Application by patentee, after giving discovery, for legal viability of specific best method challenge to be heard as a "separate question" before all other issues of validity and infringement refused by the Court

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Pharmaceutical Policy update

Author: Lucy Hartland | Special Counsel

Federal budget

The most recent Federal budget for 2023-2024 forecast that annual expenditure on the Pharmaceutical Benefits Scheme (**PBS**) would not increase over the next five years, by contrast to expenditure on Medical Benefits which are expected to increase. Such "flat" forecasting for PBS expenditure is not new and is consistent with previous (pre covid) budget forecasts. Notwithstanding that expenditure on the PBS has in fact increased over time, it is clear that efforts to contain the costs of subsidised medicines will continue.

Another item of note in the current budget is the identification of a "contingent asset – unquantifiable" being the expectation of recovery of compensation against pharmaceutical companies in respect of what proved to be wrongly granted interlocutory injunction. We have noted key proceedings involving Sanofi and Otsuka elsewhere in this update. This item has been noted in past budgets and indicates the government's expectation that the compensation to which it claims an entitlement is significant.

Eighth Community Pharmacy Agreement

The Community Pharmacy Agreements (CPAs) are a series of agreements between Minister for Health and Aged Care, the Pharmacy Guild of Australia and Pharmaceutical Society of Australia concerning compensation to pharmacists for dispensing subsidised medicines on the PBS and in connection with various community pharmacy medication management programs and services. The CPAs usually last for 5 years but although the current (seventh) CPA is not due to expire until 30 June 2025, negotiations for the either CPA commenced in mid 2023. On 14 March 2024, the parties announced that they had reached heads of agreement and that they will work in good faith to finalise and implement the agreement (to be effective from 1 July 2024).

The New Frontier – Delivering Better Health for all Australians report

In November 2023, the government delivered its response to the Standing Committee on Health, Aged Care and Sport report "The New Frontier – Delivering better health for all Australians". While there are several recommendations and responses of interest, of note is recommendation 11, which the Government has accepted. This recommendation is that:

> *... the Department of Health conduct a comprehensive consultation process with industry to establish a more flexible way forward for the repurposing of drugs in Australia. This should include:*
>
> *• Establishing a new pathway that incentivises the repurposing of drugs for all diseases, not just rare disease.*

No detail as to the proposed implementation of this recommendation is available yet.

While doing no more than "noting" Recommendation 27, concerning increasing data exclusivity periods to 10 years for vaccines and orphan drugs, the government stated:

> *that additional periods of data exclusivity should be made available for orphan drugs and vaccines, but only where thorough analysis of the issue and evidence demonstrate this is necessary to encourage investment in these important areas. Such analysis would need to consider the potential impacts on access to medicines and the patent system, including the flexibilities available in that system, and the current and ongoing discussions on IP and vaccine accessibility occurring in international fora*

It is therefore possible that this specific issue will be revisited although the timeframe for that is unknown.

Health Technology Assessment Policy and Methods Review

The long awaited review of Health Technology Assessment policy has been ongoing during 2023 and is expected to be completed in April 2024. Affected subsidy/ funding schemes include:

- the Pharmaceutical Benefits Scheme;
- the Medicare Benefits Schedule;
- the National Immunisation Program;
- the Life Saving Drugs Program.

It is hoped that the review will lead to faster and more cost effective access to new health technologies and that it will help make Australia a desirable country for first or early launch of such technologies.

Early notification of generic medicine applications to the innovator

In 2020, the Therapeutic Goods Administration sought feedback on a proposed measure for a system of earlier notification of generic medicine applications to the innovator. At present, an innovator may be notified of an application to register a generic medicine via s 26B of the Therapeutic Goods Act 1989 which requires generic applicants to provide such notification in certain circumstances. However in many cases s 26B is not engaged or if it is engaged. The practical effect is that innovators typically learn of generic medicine applications upon entry onto the ARTG or through market intelligence of an impending launch does not result in a notification to the patentee.

The proposed measure would require first generic sponsors to notify the patentee when their application is accepted for evaluation by the TGA, before the TGA commences the evaluation. In an update in December 2023, the TGA indicated that feedback on this measure was mixed and the measure would not be progressed. We note that the 2023 Special 301 Report on Intellectual Property Protection and Enforcement notes that early notification to patentees remains an area of concern for the United States. It is therefore possible that further consideration of notification of generic applications will occur.

The approval of psychedelics for certain medical uses

Since 1 July 2023, authorised psychiatrists have been able to prescribe medicines containing the psychedelic substances psilocybin and MDMA (3,4-methylenedioxy-methamphetamine) for certain mental health conditions. Under the changes, MDMA may be prescribed for post-traumatic stress disorder (PTSD) and psilocybin for treatment-resistant depression (TRD). In relation to these specific uses, psilocybin and MDMA have been rescheduled to Schedule 8 (Controlled Drugs) medicines in the Poisons Standard. However, all other uses of psilocybin and MDMA remain in Schedule 9 (Prohibited Substances) in the Poisons Standard.

As at the date of writing, there were no psilocybin or MDMA products on the ARTG, however a registered psychiatrist who has been approved as an authorised prescriber will be able to access and legally supply an unregistered therapeutic product containing psilocybin or MDMA to patients under their care for the specific uses referred to above if all other clinically appropriate treatment options on the ARTG have been considered.

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About the Spruson & Ferguson Pharmaceutical Industry Group

At Spruson & Ferguson, our strength lies in our deep expertise in all aspects of intellectual property law and practice spanning across the entire IP life cycle. We also recognise that an understanding of the commercial and regulatory environments in which our clients operate, is vital to maximise the impact of IP strategy.

Our Pharmaceutical Industry Group includes Principals, lawyers and attorneys from across our firm working together to meet the need of our pharmaceutical industry clients. This includes patent and trade mark prosecution experts, and litigators and commercialisation specialists, allowing us to build a team with appropriate skill set for any matter. We all share a strong knowledge of the pharmaceutical industry and ensure that our advice is always commercially appropriate and relevant.

Our team has many decades of experience in intellectual property, and represents one of the largest groups of its kind in Australia. Our patent attorney Principals are PhD qualified, between them representing a huge breadth of specialist scientific expertise in the life sciences. Our litigation and commercialisation team are also highly experienced, our team members having acted in a number of Australia's largest pharmaceutical litigation matters.

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