NOVELTY AND INFRINGEMENT OF SECOND MEDICAL USE CLAIMS: *MYLAN HEALTH PTY LTD V SUN PHARMA ANZ PTY LTD* [2020] FCAFC 116

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INTRODUCTION

- An enlarged bench of the Full Federal Court of Australia unanimously rejected Mylan's appeal against Justice Nicholas' findings that three of Mylan's Australian Lipidil® (fenofibrate) patents were invalid, and therefore could not be infringed by Sun Pharma's proposed generic fenofibrate formulations.
- The appeal decision provides useful guidance and discussion of:
    - circumstances in which a patent may be invalidated by clinical trial related information and "reasoned hypotheses" published before the priority date of a patent;
    - differences between the Australian and European approach to "Swiss-style" and purpose-limited pharmaceutical patent claims; and
    - infringement of patent claims limited by a specific therapeutic purpose (e.g. "Swiss-style" claims or method of treatment claims)

THE PATENTS

- The dispute related to three patents directed to fenofibrate and its use for the prevention and treatment of diabetic retinopathy.
- Diabetic retinopathy is a complication of diabetes that damages blood vessels inside the retina of the eye. Symptoms include blurred or distorted vision, eye strain, headaches and blindness.
- As the licensee of the following three patents, Mylan sold fenofibrate products under the brand name Lipidil®:
    - Patent No. 2006313711 (**the 711 patent**), which related to the manufacture of a medicament comprising fenofibrate;
    - Patent No. 2003301807 (**the 807 patent**), which broadly related to nanoparticulate fenofibrate formulations, and the use of surface-stabiliser compounds to prevent agglomeration (clumping) of such formulations; and
    - Patent No. 731964 (**the 964 patent**), which provided an immediate-release, micronised fenofibrate composition

PRIMARY JUDGMENT

- At first instance in *Mylan Health Pty Ltd v Sun Pharma ANZ Pty Ltd* [2019] FCA 28 Nicholas J ultimately held that all three patents were invalid.

- In summary, his Honour held:
    - The 711 patent was invalid for want of novelty and inventive step, and that Mylan had not established threatened infringement;
    - The 807 patent lacked inventive step; and
    - Some claims of the 964 patent were invalid, however he was not satisfied that Mylan had established its case on threatened infringement for the other valid claims.

NOVELTY – THE CLINICAL TRIAL HYPOTHESIS

- At trial, Nicholas J held that the 711 patent was deprived of novelty by the "ACCORD Protocol", a clinical trial protocol.
- Amongst other hypotheses, the "Relevant Hypothesis" of the ACCORD Protocol was:

> *"a therapeutic strategy that uses a fibrate to lower triglyceride levels and raise HDL cholesterol levels in patients already receiving a statin drug for treatment of LDL cholesterol levels, will reduce the rate of development or progression of [diabetic retinopathy]…"*

ARGUMENTS RE: CLINICAL TRIAL HYPOTHESIS

- Mylan submitted that the Relevant Hypothesis was nothing more than a "reasoned hypothesis", arguing that the disclosure of a reasoned hypothesis that is yet to be evaluated does not:
    - constitute "clear and unmistakable direction" to perform the method;
    - "teach" the invention; or
    - deprive the patent of novelty as an anticipatory disclosure.
- Mylan further contended that the ACCORD Protocol merely taught the administration of fenofibrate for the purpose of *evaluating its efficacy for the claimed therapeutic purpose*, rather than making such a disclosure for the *deliberate administration of fenofibrate for that purpose*.

FULL COURT FINDINGS: CLINICAL TRIAL HYPOTHESIS

- Rejected Mylan's submissions that a documentary disclosure containing a hypothesis could not be an anticipatory disclosure and thus deprive an invention of novelty; and
- Affirmed that "prior documentary disclosure will not be anticipatory if it merely provides information at a level of generality which, while encompassing that which is claimed as the invention, nevertheless fails to identify the invention with sufficient specificity";
- Clarified that even where the disclosing document is sufficiently specific, "it might not go far enough to disclose all the essential features of the invention";
- Confirmed that for novelty, "the question, simply put, remains: what does the prior document disclose?"

FULL COURT FINDINGS: CLINICAL TRIAL HYPOTHESIS

- At [105], the Court held:

> *It is, of course, true that a study based on the ACCORD Protocol was to be conducted to test the hypothesis. But it is equally true that, by proposing the study, according to the Protocol and its hypothesis, there was a disclosure that fenofibrate was to be deliberately administered with a statin with the aim of preventing or treating diabetic retinopathy in patients in need of such treatment. That is, plainly, the method of treatment that the ACCORD Protocol instructed practitioners participating in the study to carry out. Equally clearly, that was a method of treatment claimed in claim 7 and, more specifically, the method of treatment claimed in claim 10 of the 711 patent. It was also a method of treatment claimed in claim 11 of the 711 … Therefore, the ACCORD Protocol disclosed the claimed method. Nothing additional was required in order for the Protocol to function as an anticipatory disclosure…*

- Their Honours stressed that validation of the hypothesis was "certainly not required" to constitute the requisite disclosure to deprive the patent of novelty (at [106])
- The Court unanimously concluded that the primary judge did not err in his conclusions that the ACCORD Protocol deprived the 711 patent of novelty.

NOVELTY - CLINICAL TRIAL STUDIES

- At trial, Sun Pharma argued that the method claims of the 711 patent lacked novelty in light of two studies: the ACCORD Study and the FIELD Study.
- Nicholas J noted that this line of argument assumed that the investigators in the two studies knew that they were administering fenofibrate, which was impossible given the researchers were undertaking double-blind studies.
- The Full Court held that the collective activity of administering fenofibrate or placebo to study participants in the context of a clinical trial could anticipate the claims, particularly when considered together with knowledge of the aims and methods of the clinical trials in question.
- Their Honours ultimately held that they would "refrain from expressing a final view on the matter".

INVENTIVE STEP - CLINICAL TRIAL STUDY

- Nicholas J found that the invention claimed in the 711 patent was obvious in light of information contained in a further clinical study called ETDRS 22.
- The appeal court confirmed that:
  - an assessment of inventive step involves a "tricky" evaluative judgment;
  - the assessment may be aided by the "reformulated Cripps question"; and
  - the Court does not need to decide whether the PSA's expectation of success was better than "fifty-fifty" or to otherwise assess the chances of success in percentage terms.
- The PSA would have had a reasonable expectation that they might well produce the claimed outcome by following the information in the ETDRS22 prior disclosure.

COMPARISON TO EUROPE

- The Full Court made a comparison between the approach taken to novelty issues in Australia and Europe, and reiterated that the Boards of Appeal of the European Patent Office take a different approach to Australian courts.
- Pursuant to the European Patent Convention 2000, Swiss type claims and purpose-limited product claims will not have their novelty destroyed merely by prior disclosure that a pharmaceutical compound (or combination of compounds) might have the therapeutic effect that the patent in suit claims for that compound or combination.
- In the European cases, anticipation was not established because the prior disclosure did not also disclose that the therapeutic effect *would* be achieved.
- European case law provides that:
    - the actual achievement of the therapeutic effect is a functional technical feature of the claim, as opposed to a mere statement of purpose or intention, therefore the claim is read as *achieving* the therapeutic effect;
    - the claim imports an element of established efficacy; and
    - in order to anticipate, the prior art must disclose the achievement of the therapeutic effect itself or a pharmacological effect directly and unambiguously underlying that therapeutic effect.
- The Full Court concluded that the above principles "are not the principles developed under Australian case law"

THE ALLEGED INFRINGEMENT

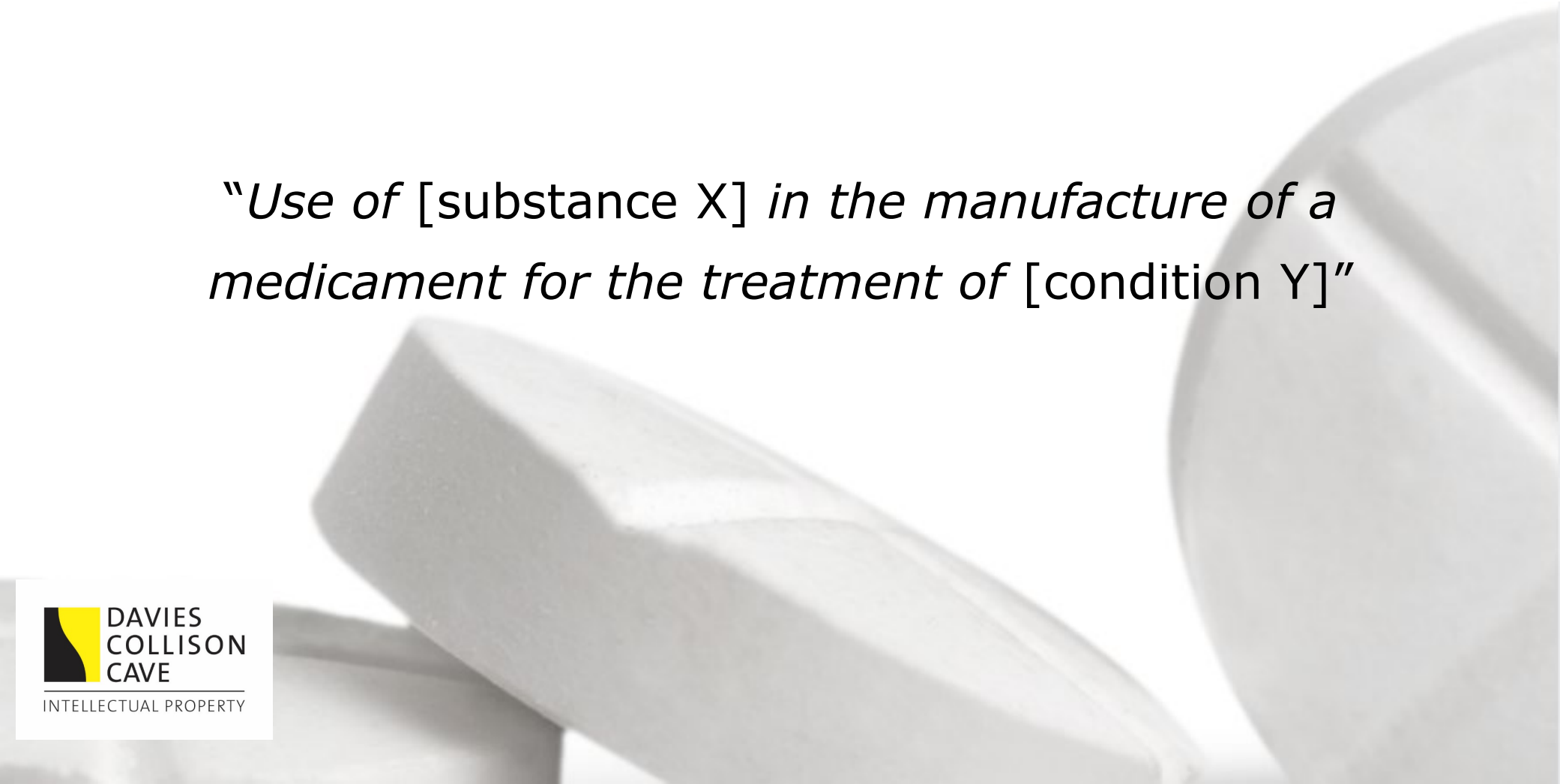
Claim 5 of the 711 Patent

> 1. Use of fenofibrate or a derivative thereof for the manufacture of a medicament for the prevention and/or treatment of retinopathy, in particular **diabetic retinopathy**.
>
> ...
>
> 5. Use according to any of claims 1 to 4, wherein said medicament contains 200 mg, 160 mg, 145 mg or 130 mg of fenofibrate or a derivative thereof.

- Product Information (**PI**) for Lipidil® on the ARTG included diabetic retinopathy.
- Sun Pharma (formerly Ranbaxy) listed its own fenofibrate products on the ARTG (**Ranbaxy Products**).
  - Bioequivalent to Lipidil®.
  - Diabetic retinopathy not included among the indications listed in the PI.
  - PI amended during the course of proceedings to recite specific indications (i.e., hypercholesterolaemia, various types of dyslipidaemia and dyslipidaemia associated with type 2 diabetes).

SWISS-STYLE CLAIMS

"*Use of* [substance X] *in the manufacture of a medicament for the treatment of* [condition Y]"



"MENTAL ELEMENT" TEST

***Mylan Health Pty Ltd (formerly BGP Products Pty Ltd) v Sun Pharma ANZ Pty Ltd (formerly Ranbaxy Australia Pty Ltd)* [2019] FCA 28**

- Swiss-style claim imports a "**mental element**" with respect to the manufacturer's intention.
- Did the manufacturer of the Ranbaxy Products objectively intend for them to be used in the treatment of retinopathy (particularly diabetic retinopathy)?
- Relevant considerations include:
  - the PI and any product labelling; and
  - the nature, size and other pertinent characteristics of the market into which the product is to be sold.

HELD:

- **Swiss-style claims not infringed** – insufficient evidence to establish the manufacturer's objective intention.
- **Method of treatment claims indirectly infringed** - *reasonably foreseeable* that a significant portion of the Ranbaxy Products would be used by medical practitioners for treating the same indications as Lipidil®.

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INTELLECTUAL PROPERTY

APPEAL DECISION

"Mental element" test rejected

- Proper construction of Swiss-style claims does not involve the addition of a further essential feature, namely, the manufacturer's objective intention.
- Relevant question is whether the medicament is *for* the specified therapeutic purpose.
- Requires consideration of a variety of factors depending on the specific circumstances of the case, no single one of which is determinative of infringement.
- The factors that may be taken into account include:

  - the **manufacturer's intention** in producing the medicament;
  - the **physical characteristics** of the medicament (e.g., its formulation and dosage);
  - the **packaging, labelling and PI** for the medicament; and
  - the **reasonably foreseeable use(s)** to which the medicament would be put after its manufacture.

WERE THE FINDINGS CONSISTENT?

Swiss-style v method of treatment claims

- Mylan contended that a finding of non-infringement of the Swiss-style claims was inconsistent with a finding of infringement in relation to the method of treatment claims.
- Full Court rejected this submission – different considerations inform the question of infringement in each case.
- The question of indirect infringement of method of treatment claims turned on whether it was reasonably foreseeable that a medical practitioner would prescribe the Ranbaxy Products for diabetic retinopathy.

  - Medical practitioners do not usually tick the "brand substitution not permitted" box on prescriptions.
  - Medical practitioners do not typically read the PI for a generic product, but assume that the indications for the generic will be identical to the originator drug.
  - In any case, the PI for the Ranbaxy Products says it is bioequivalent to Lipidil® and does not state any reason why they cannot be used to treat or prevent diabetic retinopathy.

PRACTICAL TIPS

SWISS-STYLE CLAIMS INFRINGED IF THE MEDICAMENT IS "*FOR*" THE CLAIMED THERAPEUTIC USE

- Manufacturer's objective intention not determinative of infringement
- If the alleged infringing product is presented to the market (e.g., PI, packaging, labelling) for a therapeutic use not covered by the patent it may be difficult to establish infringement

INCLUDE BOTH METHOD OF TREATMENT <u>AND</u> SWISS-STYLE CLAIMS IN AN AUSTRALIAN PATENT

- Both allowable in Australia (Note: method of treatment claims not allowable in NZ)
- Provide the broadest scope of protection against potential infringers

FILE A PATENT APPLICATION BEFORE PUBLISHING CLINICAL TRIAL PROTOCOL / CONDUCTING TRIALS

- A "reasoned hypothesis" or double-blind clinical trial can be novelty-destroying
- An invention may be obvious if a skilled person would be directly led to try it in the expectation that it might well produce a useful result, even if the result or outcome is not certain