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The Importance of Having Clear Guidance in Establishing the Groundwork for a Patent Opposition

Nufarm Australia Limited v Corteva Agriscience LLC [2024] APO 12 (7 March 2024)

Background

Corteva Agriscience LLC is the Applicant of patent application AU2017261483, which concerned compounds derived from herbicidal carboxylic acids and ammonium hydroxides. The application was opposed by Nufarm Australia Limited ("the Opponent") prior to its grant. The Applicant sought to amend the application under Section 2014, the request for which was granted. However, the Opponent opposed allowance of the amendment, leading to the Applicant filing a request to have the opposition dismissed, withdrawing the first amendments filed and filing in place of this, a second set of amendments.

The second set of amendments were allowed, and the Opponent filed a subsequent notice of opposition, to which the Applicant requested dismissal.

A hearing was then set for the dismissal request.

A statement of grounds and particulars (SOGAP) was filed, to which the Delegate emphasised forms the basis of the opposition and therefore the dismissal proceedings. The Opponent in preparing the SOGAP would then be bound by that and its case confined to the issues identified therein, unless it is amended under regulation 5.16. Noticeably however, regulation 5.16 does not permit amendment of the SOGAP whilst a request for dismissal is pending.

The grounds raised in the SOGAP included that (i) the amended specification teaches the reader something new, (ii) does not disclose the invention clearly or completely enough; and that (iii) the claims are unclear. Noticeably, the Opponent in this case omitted the grounds that the claim does not in substance fall within the scope of the claims of the specification before amendment, which consequently could not be added to the SOGAP due to the pending proceedings.

Dismissal Proceedings in Australia

The principles that govern dismissal proceedings have previously been discussed in the cases of Les Laboratoires Servier v Apotex Pty Ltd [2008] APO 11 and also in Eigen Technology Pty Ltd v CTA Australia Pty Ltd [2022] APO 44, which stated that for a dismissal of an opposition to be granted, one must assess whether there is any reasonable prospect of success. Since a dismissal precludes the possibility of filing evidence, it would be inappropriate to grant a dismissal where evidence is required to decide a case. Furthermore, a dismissal would not be appropriate if there is some ambiguity in the technical construction of terms. Consideration should also be given to any potential injustice caused as a result of dismissal.

In their request for dismissal, the Applicant submitted that the claims as amended had the exact same wording as one of the accepted claims, which meant that any issues with the wording of the claims now (as amended) were necessarily also present before the amendment. The Opponent rebutted on this point, contending that there are omissions and inconsistencies between the accepted claim and the claims as amended. Specifically, certain features have been removed from the claims, including the terms "a herbicidally effective amount", "or mixtures thereof" (both of which were omitted from claim 8), and "further comprising" (omitted from claim 9).

In assessing these points, the Delegate examined the meanings of the terms of the claims before and after amendment, identifying further changes such as the inclusion of the phrase "one or more other herbicides", in claims 2, 3 and 7 after amendment. The Delegate was satisfied that the meaning of amended claims differed from that prior to its amendment. Although, the Delegate did not consider the Opponent to have established a real case for proceeding to the evidentiary stage, based on the particulars in the SOGAP and the fact that the information or defects associated with the amended claims were already present in the accepted claim, prior to amendment.

Therefore, the opposition to the amendments was dismissed, each party of which bore their own costs of the proceedings.

The case emphasises the importance of ensuring that any SOGAP filed in an opposition clearly outlines from the outset all issues to be addressed.

Patent Invalidity Challenge Saved by an Exercise of Discretion

Resmed Pty Ltd v Fisher & Paykel Healthcare Limited [2024] APO 30 (5 July 2024)

Background

This Australian decision concerned an opposition under section 59 to grant of a number of patent applications. The applications that form the subject of the opposition concerned Australian application 2020223628, which is the parent application to applications 2021201838, 2021201840, 2021201841, 2021201842 and 2021201843 which are all divisional application filed from the parent application. The applications are all related to a portfolio of patents and applications that have either been granted, lapsed or are the subject of separate opposition proceedings. The subject applications in this case were all advertised as accepted on 22 July 2021 and notices of opposition were filed by the Opponent, Resmed on 21 October 2021, the day before expiry of the opposition period. For each of the oppositions, the same evidence was filed by the Opponent.

At the end of the evidentiary period, the Applicant filed submissions that declarations filed as Evidence in Reply were not properly in reply to the Evidence in Answer. With respect to the new material in the Evidence in Reply, the Delegate chose to exclude these from the evidence.

Regulation 5.23 The Applicants then sought to file evidence under Regulation 5.23 to address the remaining (allowed) evidence.

Regulation 5.23 permits the filing of evidence outside of the evidentiary period, admissibility of which is at the discretion of the Delegate (even when a request for an extension of time is denied).

The further evidence filed by the Applicant was allowed and the Opponent was given 1 month to file evidence in reply. Upon reviewing the Opponent's evidence, the Applicant again contended that the Opponent's response was not properly in reply and requested the evidence either be dismissed or they file further evidence under regulation 5.23. Ultimately, the Applicant filed further evidence.

With reference to Regulation 5.23, it was confirmed by the Commissioner that "it is not sufficient that the new information simply be of relevance to the issues in the opposition. The nature of the information must be such that it is likely, if not certain, to change the outcome of the opposition in a significant way". Other considerations in favour for the exercise of discretion under Regulation 5.23 includes considering the circumstances in the lead up to the evidence not being filed earlier and the balance of interests, including in the public interest.

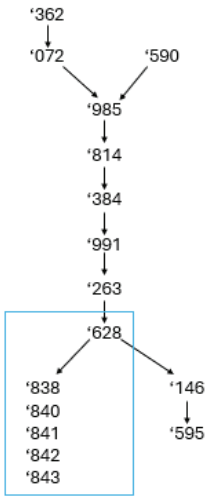
The evidence filed by the Applicant and by the Opponent under Regulation 5.23 primarily concerned fitment of the mask. Specifically, whether or not the side portions extend across the sides of the nose. Apart from the further evidence initially filed by the Applicant, which was allowed, the Opponent's evidence in reply and the Applicant's reply to that which followed were both disregarded by the Hearing Officer, because the evidence contained deficiencies in putting forward a clear case in relation to the fitting of the mask at the relevant time.

Hearing

At the Hearing, the Opponent pursued grounds of novelty, inventive step, clarity, support, succinctness, utility and manner of manufacture. The Opponent had also sought to rely on a device, which they had brought to the hearing, claiming that the device was already in the evidence and that the Applicant had already viewed it. The device was found inadmissible because the evidence already contained photographs of the physical devices and therefore reliance on the physical device should not be necessary. It was stated that if there was different information that could be derived from the physical product, then a request should have been made earlier in the proceedings together with details of the additional information.

Extensive discussions were made as to how to construe certain terms used in the claims, to which reference was made to Eli Lilly and Company Limited v Apotex Pty Ltd [2013] FCA 214; 100 IPR 451 at [139], in which it was stated that the task of construing the specification should be undertaken from the point of view of the skilled person and the prevailing common general knowledge, at the priority date.

In light of the multiple patent applications, many of which are divisional applications, consideration was also given to whether the applications correctly claimed priority. The relationship between each of the applications in the portfolio is summarised in the flow diagram below:



The blue box shown in the figure above depicts the subject patent applications. In brief, application ‘628 which is the parent of the subject divisional applications, is itself a divisional application in a series of divisional applications originating from ‘985, which was filed on 10 May 2010. Application ‘985 claimed priority from two earlier applications, ‘072 and ‘590.Application ‘072 claims priority from an earlier application ‘362, filed on 12 May 2008.

The Hearing Officer discussed considerations for multiple priority documents in a simplified example, which has been reproduced below:

- Application 1: having Invention A
- Application 2: having Inventions A and B
- Application 3: having Invention B

It was stated that Application 2 could validly claim priority from Application 1 for Invention A, if Application 2 was filed within 12 months of the earlier application.

Since Application 2 further discloses Invention B, this second application would be the first application in a Convention country for Invention B.

Application 3 could therefore make a valid priority claim for Invention B based off Application 2, as long as Application 3 was made within the prescribed timeframe. However, an important consideration is whether Invention B is the same invention as Invention A. When determining this, one should consider whether all the essential features of the invention claimed in the later application were disclosed in the earlier application.

Since ‘985 was filed within 12 months of ‘072, which was the first disclosure of the invention as claimed in each of the subject applications, all applications were considered to be entitled to the earliest priority date of 12 May 2009 of application ‘072.

Novelty

With respect to novelty, a number of documents were raised by the Opponent as being relevant to the subject invention. In light of the finding that the earliest priority date is 12 May 2009, the Hearing Officer disregarded one of the listed prior art documents , since the subject application predates that particular document.

None of the Opponent’s submissions in relation to lack of novelty were successful, as clear and unmistakable disclosures of the features in the present claims were missing.

Inventive Step

With respect to inventive step, the Hearing Officer commented that the Opponent’s submissions failed to provide a clear position and in some areas were not considered to be focused on the issues at hand. Specifically, the submissions appeared vague in some areas and the meanings of some of the terms used in the claims were not properly determined, which led to the Hearing Officer questioning whether the Opponent had understood what the invention is.

The Hearing Officer referred to principles established under Section 7(2) of the Act, with reference to the case of Hood v Bush Pharmacy Pty Ltd [2020] FCA 1686 at [116]-[117], which discussed the meaning of the term “obvious” as used in the provisions of the Act. Specifically, something that is obvious is “plain or open to the eye or mind” or something which “would at once occur to anyone acquainted with the subject and desirous of accomplishing the end.” It was also emphasised that a claimed invention is not obvious merely because the person skilled in the art would consider it “worthwhile to try”. The modified Cripps question requires that there be a reasonable expectation of success, the success of which is not guaranteed.

Common general knowledge in the field was also discussed by the Hearing Officer, to which it was considered that side portions of the mask for sealing against the outer surfaces of the sides of the nose to support and therefore stabilise the seal, which was a feature of the claims, was not common general knowledge. In fact, designing a mask with those features was understood to be undesirable, given it could exert a pinching or blocking sensation to the user.

The Opponent was ultimately unsuccessful on the grounds of inventive step.

Related to the Opponent’s submissions under inventive step appearing weak with respect to understanding the meaning of some of the terms used in the claims, unsurprisingly the Opponent’s submissions on the grounds of lack of clarity also failed.

Lack of Support

The Opponent did not press on the grounds of lack of sufficiency but instead chose to pursue lack of

support, which the Hearing Officer acknowledges are "two sides of the same coin". On the grounds of lack of support, the Opponent's submissions were found not to engage with the key considerations under support, as defined by the case of CSR Building Products Limited v United States Gypsum Company [2015] APO 72 at [115]. Again, it was pointed out that since the Opponent appears unable to determine what the invention actually is, it is unsurprising that they would be in a position to provide a definitive opinion on where the technical contribution lies in the invention.

Nonetheless, based on the Applicant's submissions, the Hearing Officer understood the technical contribution to lie in a nasal seal. Specifically, in the arrangement of the central and side portions, and the use of a supple material, which, on inflation of the mask by internal gases, wraps around and seals to the user's nose, including the surfaces of the sides of the nose. This provides for greater stabilisation of the mask during use. Based on this, the Hearing Officer determined that claims of the present application, with the exception of patent application '841, were consistent with this understanding of the technical contribution. Thus, the claims in patent applications '628, '838, '840, '842 and '843 were found to be supported.

The lack of support on application '841 as discovered by the Hearing Officer was due to the absence of the feature of the face-contacting side of the seal being supple to conform under internal pressure to the surfaces of the nose of the wearer, including at the side portions of the seal, to outside surfaces of the sides of the nose.

Succinctness

The grounds of succinctness were also pursued, arguing that there were a "large number of claims", combined with their overlapping nature, in the growing family of patents and applications, which meant that the claims were repetitious. This was argued not to be in the public's interest, since the scope of monopoly cannot be easily determined. However, the Hearing Officer disagreed and referred to Bancroft's Application (1906) 23 RPC 89, where it was discussed that claims will not be clear and succinct if their repetitious nature is such that the difference in scope between two or more claims is not readily apparent. The opposition was also unsuccessful on this ground.

Lack of Utility

The Opponent further argued on lack of utility, the submissions of which were very similar to those under the grounds of clarity. Specifically, the Opponent contended that there was lack of detail concerning the regions that are much stiffer than the supple exterior side of the mask, and that those regions extend into the side portions of the seal. The subject matter of the claims are therefore not useful. The Applicant argued in response that the object of the invention is to provide a patient interface (or aspects thereof) which will at least provide the public with a useful choice. The Hearing Officer agreed with the Applicant that the specification did not make any promises beyond the provision of providing a useful alternative. The grounds for lack of utility were therefore unsuccessful.

Manner of Manufacture

Lastly, the Opponent also pressed on the grounds of manner of manufacture, claiming that the invention "is a mere collocation of integers" and in the absence of any interaction between these components, means that the claimed invention does not achieve an overall useful result. The Applicant argued that there is no requirement for the claims to disclose or specify the interaction between the various features. Aside from this, it was pointed out that significant ingenuity was involved in the design of the nasal seal because there is an interrelationship between the features of the mask, the variations of which can have significant effects. In fact, it was pointed out in one of the expert declarations filed by the Opponent that modifications to thicknesses of silicone seal layers have a certain "flow-on" effect on deformation and the support of the remaining silicone layers, as well as in the interrelationship between the seal and the headgear. The Hearing Officer found the Applicant's arguments persuasive that the different features of the masks have a working interrelationship and are not a mere collocation of parts. Consequently, the claims were found to satisfy the requirements for manner of manufacture.

Key points and lessons learnt

The opposition was therefore unsuccessful and the subject applications, with the exception of '841, subsequently proceeded to grant. The Hearing Officer granted a period of 2 months for the Applicant to amend the support issues found in '841.

It is important to understand what forms the inventive concept of a patent application. An overly ambitious approach in pursuing many different grounds to attack validity of a patent application may not be useful, particularly if there is confusion as to what forms the inventive core of the subject patent application. This case therefore emphasises the importance of expert evidence in supporting a challenge to patent invalidity and further reminds us of the powers of the Delegate in exercising their discretion, which ultimately led to a finding of lack of support as identified by the Delegate herself.

Expert Evidence is not to be Underestimated in Challenges to Patent Invalidity

QIP Nominees Pty Ltd. v Dana-Farber Cancer Institute, Inc. and The General Hospital Corporation [2024] APO 33 (7 August 2024)

Patent application number AU2018206769 was a divisional application filed by the Applicant, the Dana-Farber Cancer Institute, Inc. and The General Hospital Corporation. The subject application successfully proceeded to acceptance and was advertised for third party opposition, to which the Opponent, QIP Nominees Pty Ltd filed a notice of opposition to grant under section 59 of the Act.

In the statement of grounds and particulars, all available grounds of opposition were pursued, citing 1 document for novelty, 5 for inventive step, and another 128 documents which were contended to form part of the common general knowledge.

The subject application relates generally to identifying tumour specific neoantigens and the uses of these neoantigens to produce cancer vaccines. The steps for identifying the tumour-specific neoepitopes were as follows: Firstly, DNA mutations were identified using whole genome, whole exome, or RNA sequencing of tumour cells, comparing these to their non-tumour normal counterparts from each patient. The second step concerned applying an algorithm for predicting peptide-MHC binding to obtain a list of candidate T cell epitopes that could bind patient HLA alleles, based on non-silent mutations present in the tumour cells. The final optional step involved demonstrating antigen-specific T cells against peptides or demonstrating that a candidate peptide is bound to HLA proteins on the tumour surface. The mutated peptides are then screened to predict immunogenicity and the immunogenic epitopes screened prior to its selection for producing the vaccine. The method therefore offers a personalised approach to cancer treatment.

The claims of the invention were directed to "a method of treating cancer..." which the Hearing officer had interpreted to mean that the method of treatment must treat the particular condition, and to which it was considered had no appreciable difference when compared with the terms "a method for...".

Disclosure

The Opponent argued that there was not a clear enough and complete disclosure of how to perform the invention, which leads to an undue burden on the skilled person. Firstly, the Opponent relied on the argument that the method claims, being directed to treating "cancer", could not be used to treat all forms of cancer. The examples included in the specification were based on experiments on chronic lymphocytic leukemia (CLL), which is one of many forms of leukemia. Arguments were submitted that not all haematological cancers can be treated in the same way since there are many different subtypes. The Hearing Officer considered that despite there being many different types of cancers, there is no reason why the technique would not work. This is because the claimed method involved selecting neoepitopes from the cancer, which can generate an immune response. The method does not rely on a specific mechanism of action that only certain cancers have or on a particular biological pathway related to the disease aetiology of a particular cancer. The claimed method relied on mutant peptides being expressed, which can then be screened for neoepitopes.

Further submissions provided by the Opponent on this ground included that "the methodology did nothing to reduce the time needed to identify the candidate peptides", and that "a significant amount of work was required to determine whether those candidate peptides had any useful activity in treating cancer".

The Hearing Officer disagreed with the Opponent's comment, stating that the methodology described brings the claimed invention into the technical field of personalised medicine, for which it is expected that some work will be required on the part of the skilled person. An undue burden would otherwise exist if further experimentation were required just to work the invention because the disclosure of the methodology were lacking, however, the methodology was provided in the specification in this particular case, so the amount of work required to perform the invention would not have been unreasonable. Thus, the disclosure in the specification was considered clear enough and complete enough for a skilled person to have performed the invention.

Inutility

The Opponent also pursued grounds of inutility, claiming that the invention did not meet the promise of treating cancer, particularly as there was no disclosure of the amount of peptides to be used in the claim, there was no certainty that

the peptides with a predicted binding would be effective in a patient, let alone was there any suggestion of a synergistic effect between the "at least 4" peptides, or any suggestion that combining the composition with additional therapeutics or anti-immunosuppressants would lead to working combinations. It was also argued by the Opponent that the invention sought to treat cancer. However, the Applicant disagreed and argued that the promise of the invention was in identifying peptides that might be useful for treating cancer.

The Hearing Officer referred to the case of Rescare Ltd v Anaesthetic Supplies Pty Ltd (1992) 25 IPR 119 at 142-143 and also Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd (No 3) (2011) 92 IPR 320 at -245], point 8, which stated that "a claim may have utility even if a promised advantage cannot be achieved in all cases or with the same degree of success". Thus, inutility would not be found merely because the method did not work for a small proportion of patients, especially since a skilled person would not reasonably expect that claimed method to be effective for every patient. The grounds of inutility therefore failed.

Novelty

With respect to novelty, a lack of clear and unmistakable direction was found in the prior art document that would lead a skilled person to produce the claimed invention. Specifically, at most the prior art document speculated what an "ideal" vaccine would look like, without providing instructions for how to reach this ideal. Furthermore, the prior art document was silent as to using "at least 4 peptides" in the vaccine, which was otherwise required for the claimed invention, and did not disclose any threshold for predicted binding of the peptides.

Similar to the above, in a further prior art document which was a review article, the suggestion made therein that the "ultimate strategy" would be to incorporate whole genome sequencing of both tumor and patient cells also did not provide clear and unmistakeable directions as to how to achieve this, other than simply pointing out that it was a potential option. The grounds of novelty therefore failed.

Inventive Step

With respect to inventive step, the Hearing Officer made reference to the reformulated "Cripps question" endorsed by the High Court in Aktiebolaget Hassle v Alphapharm Pty Ltd [2002] HCA 59; 212 CLR 411, which looked at whether the notional person "in all the circumstances, which include a knowledge of all the relevant prior art and of the facts of the nature and success of the prior art, be directly led as a matter of course to try the invention, in the expectation that it might well produce a useful alternative to or better (drug) than the prior art, or a body useful for any other purpose?". The Hearing Officer commented that it is clear from this test that only routine steps need to be considered and that there is an expectation that a useful result might come therefrom. In other words, the reformulated Cripps question does not require a certainty of outcome, but rather the skilled person should be directly led as a matter of course to try the claimed invention, in the expectation that it "might well produce" a useful result.

As mentioned, the Opponent in this instance raised many prior art documents as being relevant to common general knowledge. However, no evidence was provided as to why the disclosures in those documents were widely known and accepted. Nevertheless, on review of the documents cited, the Hearing Officer noted that use of neoantigens in cancer vaccines, whole genome sequencing and the prediction of epitopes for HLA proteins were areas of interest at the priority date. However, the Hearing Officer did not agree that those documents formed part of the common general knowledge, as there was no evidence of how widely known or used they were.

Manner of Manufacture

Finally, the Opponent also submitted that the claims lacked manner of manufacture as the invention used known materials in the manufacture of known articles for the purpose of which its known properties make that material suitable. The Hearing Officer again disagreed with this, pointing out that the grounds of novelty and inventive step had failed and there is nothing on the face of the specification to suggest a lack of inventiveness. The mere assertion that a person skilled in the art would have thought about using neoantigens for a cancer vaccine was not sufficient to lead to a finding of lack of manner of manufacture.

Key points and lessons learnt

The opposition failed on all grounds and the application proceeded to grant.

This case reminds us that an assessment of inventive step does not require a certainty of outcome, but rather a reasonable expectation that a skilled person could produce the claimed invention. Furthermore, we are also reminded that citation of an excessive number of prior art documents is not an effective approach towards convincing a Hearing Officer that an application is invalid. Instead, one should consider how and why a certain document may be representative of common general knowledge, as mere suggestions towards an idea is not sufficient in proving that the idea is widely known amongst those **skilled in the art. Ultimately, it is apparent in this case is that a lack of sufficient expert evidence led to loss of the invalidity challenge by the Opponent.**

Lessons for Best Method and Support Requirements

Boehringer Ingelheim Animal Health USA Inc v Zoetis Services LLC (No 2) [2024] FCA 291 (26 March 2024)

The above-mentioned case is a follow-on from the judgment handed down last year (Boehringer Ingelheim Animal Health USA Inc v Zoetis Services LLC [2023] FCA 1119) in which it was concluded in the previous judgment that all claims of the three Australian patent applications (the '535, '537 and '540 applications), except claim 2 of the '535 application were invalid on various grounds, including lack of inventive step, lack of support, insufficiency, best method and lack of manner of manufacture. The Australian patent applications, the subject of the present case, were directed to vaccine compositions for treating enzootic (mycoplasmal) pneumonia.

Following publication of the reasons for invalidity, the parties subsequently requested supplementary reasons be provided in relation to the validity of the dependent claims.

Inventive Step

When assessing inventiveness of dependent claims, the Judge did clarify that when determining inventiveness, one should not consider not the additional integer in isolation, but rather consider the combination of integers, taking into consideration features of the independent claim as well, when determining inventiveness. To this effect, it is therefore incorrect to conclude that a dependent claim is obvious simply because the broader claim on which it depends, is obvious.

As mentioned above, in the preceding case, claim 2 in relation to application '535 was the only claim that was considered to have an inventive step. However, when assessing claim 8 of the '537 application in the present case, which was a dependent composition claim to earlier claims 1 to 7 and which comprised at least one additional antigen selected from a defined list, covering 5 pathogens, it was found that claim 8 was also inventive. Experts provided evidence that the process of developing a vaccine is not predictable; significant trial and error is required to find a working composition since it is impossible to predict a composition that will develop an antibody response in the target animal which will be both safe and efficacious. This is especially so because where there is a combination of antigens, there is also the prospect of interference between those antigens which could lead to a poor immune response. Dominant antigens for example, could distract the immune system from raising an appropriate response to another antigen when using multivalent vaccines. Thus, the claim was found to be inventive.

Best Method

Whilst Boehringer initially did not initiate a challenge to claim 2 of the '535 application on the grounds of best method, in their second Further Amended Notice of Contention, they challenged the validity of claim 2 on the grounds of best method. The Judge considered the reasoning provided in the first opposition with respect to lack of best method was also applicable to claim 2. I It was discussed briefly in the first decision that the requirements for sufficiency and best method are separate and different requirements. Reference was made to Les Laboratoires Servier v Apotex Pty Ltd (2016) 117 IPR 415 at [64], which stated that for there to be the best method, what needs to be disclosed is a methodology that would allow the public to quickly and more easily utilise the invention for which the monopoly is granted. It was argued in this case that Zoetis had not disclosed the best method because they used relative units for the antigen concentration or content without identifying a reference product. They did not provide enough information to allow a skilled person to ascertain the concentration or content in absolute terms, and in some cases, did not describe the IVPs at all. The Judge ultimately agreed and concluded that whilst it appears that details including concentration are provided for the IVPs in the examples, it is only when the skilled person goes looking for the concentration information for the reference sample, which is key to deciphering the relative concentrations claimed, that one realises that this crucial information is not disclosed anywhere in the subject applications. This means that a skilled person looking to make the invention upon expiry of the patents granted on the applications would need to spend time and resources on determining the best starting point for the range. Since the information was known to the patentee at the time the applications were filed, claim 2 of the '535 application was therefore found invalid for failure to disclose the best method.

Support

This leaves the only standing claim so far to be claim 8 of the '537 application. However, when assessing for support, it was considered that there was a lack of support and disclosure for claim 8, for the same reasons as given in the previous case.

Briefly, in relation to support the Judge had referred to cases such as CSR Building Products Ltd v United States Gypsum Company [2015] APO 72 at 252-253, which stated that when deciding whether the claims are supported by the description:

> *"it is necessary to ascertain what is the invention which is specified in the claims and then compare that with the invention which has been described in the specification…the mere mention in the specification of features appearing in the claim will not necessarily be a sufficient support. The word "support" means more than that and requires the description to be the base which can fairly entitle the patentee to a monopoly of the width claimed."*

It is further stated in the same case that consideration should also be given to the technical contribution to the art, disclosed by the specification, which must justify the breadth of the monopoly claimed. In other words, the monopoly claimed should not be more extensive than the contribution to the art made by the relevant disclosure. With reference to the case of Warner-Lambert LLC v Generics (UK) Ltd t/a Mylan [2018] UKSC 56, plausibility was discussed. Specifically, it was stated at [37] that "the claimed therapeutic effect may well be rendered plausible by a specification showing that something was worth trying for a reason, not just because there as an abstract possibility that it would work but because reasonable scientific grounds were disclosed for expecting that it might well work."

Since the scope of claim 8 in the '537 application was broader than the technical contribution of the specification, it was considered that a skilled person could not work across the scope of the claim without there being an undue burden. The claim therefore fell on lack of support. Since it was considered that a skilled person could not work across the scope of the claim without there being an undue burden.

Key points and lessons learnt

Boehringer was therefore successful in its opposition in invalidating all claims of the three patent applications. This case emphasises the importance of ensuring that the claims in a patent application are not only properly and fully supported by the disclosures contained within a specification, but also that the details provided in the specification are fully disclosed to avoid a finding of invalidity. Both lack of best method and lack of support were the downfalls of the subject patent applications, which may otherwise have led to the finding of some novel and inventive claims in the '535 and '537 applications.

Swiss-Style Claims and Method of Treatment Claims Provide Useful Protection for Applicants Facing Potential Infringement

Neurim Pharmaceuticals (1991) Ltd v Generic Partners Pty Ltd (No 5) [2024] FCA 360 (12 April 2024)

This case concerned Australian patent 2002326114, which was owned by Neurim Pharmaceuticals ("Neurim") and expired on 12 August 2022. The claimed invention related to a method for treating primary insomnia and had both Swiss-style claims and method of treatment claims contained therein. Neurim commercially sold the patented medicament under the name Circadin®, which was intended to be used as a short-term solution for treating primary insomnia in patients aged 55 or over.

Generic Partners developed a generic version of Neurim's medicament, around April 2017, which was called Melotin®, developed for the same indications as for Circadin®. Generic Partners supplied Melotin® to Apotex from March 2020 and from April 2020, Apotex was the distributor of Melotin® in Australia.

Neurim sought action against Generic Partners and Apotex (the Respondents), claiming that each of the Respondents had infringed their granted patent by authorisation and common design (Melotin®) of their patented melatonin product, Circadin®. Both Generic Partners and Apotex cross-claimed on the grounds that the patent was invalid on numerous grounds including that of novelty, inventive step, support, clarity and fair basis.

Similar to method of treatment claims, Swiss-style claims are "purpose-limited claims in the sense that the medicament resulting from the method or process is characterised by the therapeutic purpose for which it is manufactured, as specified in the claim." (Mylan Health Pty Ltd v Sun Pharma ANZ Pty Ltd (2020) 279 FCR 354). By limiting the scope of the claim to its therapeutic purpose, this ensures that the scope of the claim is not unduly broadened to old subject matter, given that Swiss-style claims are directed to methods or processes whose products are for a second therapeutic use.

Infringement

For there to be a finding of direct infringement, the method would need to be used for treating a patient diagnosed with primary insomnia, characterised by non-restorative sleep, such that the quality of the patient's sleep may be improved. A medical practitioner would not infringe the claims if prescribing Melotin® for treating other forms of sleep complaints, for example the lack of sleep arising from the inability to stay asleep.

The term "non-restorative sleep" as used in the claims was discussed, to which it was considered that its meaning refers to a subjective complaint of restless, light or poor quality sleep that is non-refreshing. It is a term used to describe the quality of the patient's sleep rather than the quantity of sleep. However, distinguishing non-restorative sleep from other complaints, such as difficulties in sleep onset, sleep maintenance or sleep duration, was considered somewhat challenging, as it is difficult to separate the symptoms both for clinicians and patients.

Nevertheless, for there to be a finding of infringement by supply of the products, this involves assessing whether the criteria under Section 117 of the Patents Act 1990 have been met. Namely, this involves assessing whether Melotin® is a staple commercial product (Section 117(2)(a)). If not, is there a reason that Melotin® would be prescribed or recommended by medical practitioners to patients diagnosed with primary insomnia, characterised by non-restorative sleep, for the purposes of improving the quality of their sleep (Section 117(2)(b)) and, are there any instructions or inducement to use Melotin® for treatment as claimed (Section 117(2)(c)).

Section 117(2)(b)

The question of whether Melotin® is a staple commercial product, depends on whether it is a product supplied commercially for various uses. It was considered that use of melatonin is restricted for use as a therapeutic treatment for sleep disorders of various kinds, its purpose of use is therefore very limited. Thus, Melotin® was not considered to be a staple commercial product. However, melatonin was considered useful for treating a variety of sleep related disorders, not necessarily restricted to non-restorative sleep. Thus, it was held that a not insignificant number of psychiatrists would prescribe Melotin® as a treatment for primary insomnia where the patient complained of non-restorative sleep. For this reason, Neurim succeeded in its case of infringement under Section 117(2)(b), as there was reason to believe that

the prescription of Melotin® would likely be for the claimed use.

Section 117(2)(c)

To assess whether there were any instructions or inducement to use Melotin® for treatment as claimed, the Court investigated the product information sheet that was supplied alongside the supply of Melotin®. The information disclosed on the sheet was substantially the same as for Circadin®. There were no disclosures in the information sheet that suggested Melotin® not to be used for the treatment of primary insomnia as characterised by non-restorative sleep. The product information sheet also did not provide a definition for primary insomnia, let alone did it define the term "non-restorative sleep". Given that neither the product information sheet or the approved indication made any reference to non-restorative sleep and the fact that a clinician reading the product information sheet would likely understand the document to generally disclose the sleep promoting qualities of melatonin, it was held that neither the product information sheet nor the approved indication could be said to provide any instruction or inducement to using Melotin® as a treatment for primary insomnia, characterised by non-restorative sleep. Thus, Neurim failed in its case of infringement under Section 117(2)(c).

With respect to infringement by authorisation, Apotex admitted that they had authorised medical practitioners to prescribe Melotin® for the approved indication. However, they contended that such authorisation was not infringement because there was no instruction or inducement to use the product for the claimed purpose. Interestingly, the Court rejected the respondent's arguments and considered that despite the findings that infringement under Section 117(2)(c) was not met, it does not follow that the respondents did not authorise infringement of the method of treatment claims. Instead, it was considered that the respondents authorised use of Melotin® by medical practitioners who the respondents had reason to believe would use the product for the purposes of treating primary insomnia characterized by non-restorative sleep in patients over the age of 55. In other words, it was considered unlikely the respondents would have authorised Melotin® for other off-label indications, such as for patients under the age of 55. Thus, there was found infringement by authorisation.

Swiss-style claims

The Swiss-style claims in the subject patent were directed to use of melatonin in the manufacture of a medicament for treating a patient suffering from primary insomnia that is characterized by non-restorative sleep. For there to be a finding of infringement of a Swiss-style claim, consideration needs to be made to the infringing activities of the manufacturer, as has already occurred, rather than the activities that will be done. As per the case of Mylan Health, a assessing infringement of a Swiss-style claim involves looking at the physical characteristics of the product. This includes its packaging, dosage and product information (see paragraph [222] of Mylan Health).

On assessment of the product information sheet, there were found general statements to the effect of melatonin exerting "control of circadian rhythms" and providing "a hypnotic effect and increased propensity for sleep", which together suggests that Melotin® is a product with broad applications. Based on the statements made in the product information sheet, it was considered reasonably foreseeable that Melotin® will be used by some clinicians for a broad range of sleep related issues, not only for the therapeutic purposes as specified in the Swiss-style claims. For this reason, the Court considered that Melotin® is a medicament that is not specifically manufactured for the therapeutic purposes of the Swiss-type claims. Thus, there was found no infringement of the Swiss-type claims.

Validity

i. Novelty

The respondents argued that the claims of the patent amounted to mere parameterisation, whereby the features of "primary insomnia characterised by non-restorative sleep" and "improvement in the restorative quality of sleep" are a narrower use to that described in the prior art. Neurim submitted that the patent disclosed a new and surprising outcome that melatonin could be used to improve the restorative quality of sleep in a specific group of insomnia patients, which was not something that was addressed in the prior art documents. Therefore, the claims disclosed a new therapeutic use. The Court agreed that the claims in the patent had a technical effect and are directly related to a claimed advantage of the invention. Thus, the grounds of lack of novelty failed.

In an alternative argument for lack of novelty, the respondents referred to a webpage, which they contended provided evidence of prior use. The webpage concerned use of Melatonex to restore melatonin to levels needed for a restful, natural sleep, which the respondents argued amounted to a disclosure of use for insomnia, necessarily including primary insomnia and therefore that as characterised by non-restorative sleep. The Court disagreed with the respondents in that the webpage did not provide clear direction, recommendations or suggestions that use of Melatonex could be used to treat a patient diagnosed with primary insomnia, characterised by non-restorative sleep. There was also no evidence of any actual use of Melatonex

by patients diagnosed with insomnia. Thus, this alternative grounds of lack of novelty also failed.

On further grounds of lack of novelty, a journal article published which investigated the effects of melatonin treatment on melatonin-deficient insomnia in the elderly was considered. The study itself was a randomised and double-blinded study which disclosed that in the treatment group, it was found that the "slow-release preparation (2mg) is able to extend high plasma membrane for 5-7 hours. Thus, a sustained-release melatonin (was used) in order to restore melatonin levels in the elderly throughout the night." From this, the Court considered that the prior art study generally disclosed the use of prolonged release melatonin for the treatment of primary insomnia. However, it was also considered that the prior art publication did not provide clear guidance, recommendations or suggestions as to use of prolonged release melatonin to treat primary insomnia characterised by non-restorative sleep and to improve a patient's quality of sleep. Thus, the publication was not considered to be novelty destroying.

Reference was also made to a European patent owned by Neurim (the '878 Patent"), which disclosed that melatonin may be used in manufacturing a medicament "for preventing, symptoms of dependence on, tolerance of, or addiction to benzodiazepine drugs, for treating multidrug addicts and to a pharmaceutical formulation, for use in such treatments." Dependence on benzodiazepines was disclosed in the '878 patent as a symptom that often develops in insomniacs, who use the drugs to induce sleep. Furthermore, the '878 patent disclosed that melatonin had preventative properties whereby it would prevent the development of undesirable symptoms that may occur as a result of benzodiazepine, such as addiction or tolerance of the drugs, in patients diagnosed as requiring benzodiazepine. However, the Court considered that the '878 patent lacked clear direction, recommendation or suggestion to use melatonin to treat insomnia, or primary insomnia or that which is characterised by non-restorative sleep. Thus, the grounds for lack of novelty failed.

ii. Inventive step

With respect to inventive step, the Court emphasized that just because a skilled person would consider something "worthwhile to try", it does not necessarily lead to something being obvious. However, in some cases a skilled person may be directly led as a matter of course to try a number of alternatives in the expectation that each may well produce a useful alternative. In other words, just because one option appears to be obvious, this does not preclude other pathways that might be obvious.

The respondents argued that the invention was obvious in light of several cited prior art documents, when each are considered separately in light of common general knowledge.

The Court first looked investigated whether a skilled person would be reasonably expected to have ascertained, understood and regarded each of the cited prior art documents as being relevant to treating a patient with primary insomnia characterised by non-restorative sleep. It was determined that while a skilled person would have ascertained the cited prior art documents, they would not have considered them relevant on an individual basis, since they did not suggest that melatonin could improve the restorative qualities of a patient's sleep, but rather that melatonin had an effect on endogenous circadian rhythms as well as provide some hypnotic effects in persons with insomnia. In fact, there was also a warning disclosed in one of the cited prior art documents, which stated that with the chronic use of melatonin for treating sleep disorders, there may be may lead to some profound effects on the reproductive system, as determined in animals.

Given that the patent application has a priority date of 14 August 2001, prior to commencement of the Patents Amendment Act 2001, Neurim contended that the provisions relevant to the assessment of inventive step, should be those in force at the priority date, even though the application was not applied for until the following year, on 12 August 2002. Before the Amendment Act in 2001, two or more related prior art documents could only be combined if the relationship between the documents was such that a skilled person would treat them as "a single source of information". This requirement was relaxed following commencement of the Act. The Court ultimately agreed with Neurim's views on the provisions applying prior to the Amendment Act, yet it was considered that no combination of the documents could reasonably be expected to be considered as "a single source of information" by a skilled person. This is because the cited prior art documents appeared in different journals over a period of five years. Although one of the cited documents discussed all earlier publications and was the work of the same research group, these factors were considered insufficient to meet the more stringent test prior to the Amendment Act 2001.

With respect to other considerations, the Court stated that for a skilled person who would have ascertained each of the four cited prior art documents, and who would have been interested in obtaining more information concerning safety and efficacy of melatonin as a potential treatment for insomnia, it would be reasonable to expect that the skilled person would combine the information from the four cited prior art documents. This is

because all documents related to trials of a 2mg prolonged release melatonin formulation conducted by the same research group which are said to have established that the formulation was safe for use in patients requiring treatment.

When combing the cited prior documents, one could conclude that a 2mg prolonged release melatonin formulation would be safe to use for treating insomnia at least in the short term. However, the Court did consider that together, the four cited documents did not contain disclosure that melatonin may be used to treat primary insomnia characterised by non-restorative sleep, even if common general knowledge was taken into account. Thus, the claims were held to lack an inventive step.

The grounds raised by the respondents on lack of clarity and insufficiency, in failing to describe the invention fully, were both rejected.

iii. Fair basis

The respondents also contended that the specification did not fully describe the invention and that the claims are not fairly based. Specifically, it was argued by the respondents that the invention would have a different effect as claimed, when using patients below the age of 55, compared with patients over that age barrier. The Court refused this argument, as the specification did contain explicit disclosure that the invention was not to be limited to treating patients over 55 years old. Furthermore, there was no suggestion that only patients of certain ages suffer from primary insomnia, or that patients of certain ages would benefit from the claimed treatment methods. It was therefore considered there is a real and reasonably clear disclosure of the claimed invention in the specification, which is not limited to treating patients over the age of 55.

Key points and lessons learnt

Neurim therefore succeeded in enforcement of their patent, which led to a finding that the respondents are jointly liable for infringement as they worked together to supply Melotin® in Australia.

Importantly, this decision provides clarification on what constitutes direct and indirect infringement with respect to second medical use claims. Furthermore, it is apparent that using both swissSwiss-style claims as well as method of treatment claims would provide a strategic advantage to protecting applicants from potential infringement from third parties.

The Price of Non-Compliance to the Regulatory Requirements Imposed on Australia's Therapeutic Goods

Secretary, Department of Health v Medtronic Australasia Pty Ltd [2024] FCA 1096 (19 September 2024)

This case concerned the supply of the "INFUSE Bone Graft Kit" ("Kit") owned by Medtronic Australasia Pty Ltd ("Medtronic"), which itself was not registered on the Australian Register of Therapeutic Goods (ARTG) but was registered only in combination with a medical device known as the LT-Cage ("Device"). Together the Kit and the Device provided a means to assist patients with stimulating bone growth.

Medtronic's Kit and Device and the Australia Therapeutic Goods Administration

In order for a therapeutic good to be supplied, manufactured, imported into or exported from Australia, it must first be assessed by the Therapeutics Goods Administration (TGA) for its safety, efficacy and performance in the same form that is intended to be sold to patients, prior to it being entered into the ARTG, unless it has received exemption from such. This ensures transparency in the healthcare industry.

When listing goods on the ARTG, companies are expected to provide details as to the product's "instructions for use", which should provide information on the medical device's intended purpose, its indication and intended user, as well as any precautions that need to be considered with respect to use of the product.

The entry on the ARTG for Medtronic's Kit and Device combination detailed that it was intended to be used for skeletally mature patients requiring spinal fusion procedures as a result of degenerative disc disease. The Device component was separate and was intended to be supplied together with the Kit, serving the purpose of ensuring the spine is held securely in its required position during surgery. The Kit comprised of a recombinant human bone morphogenetic protein composition for promoting bone growth, an absorbable collagen sponge for transferring the protein and for acting as a scaffold in promoting new bone growth, a vial of sterile water for injection, some empty syringes, as well as corresponding needles. The Device was packaged separately from the Kit due to the need for clinicians to select their desired size for each Kit and Device. The Kit also had specific storage requirements which did not apply to the Device; for example, the Kit needed to be stored below certain temperatures and had a shorter shelf-life.

Following launch of the product in Australia, Medtronic found that there was a "significant clinical demand" for the Kit itself, including for use together with another cage. In other words, there was no real clinical demand for the Kit and Device together, as approved by the TGA and listed on the ARTG. In light of market demands, Medtronic ended up supplying the Kit for a range of surgical procedures outside of its intended use, which contravened the approval as originally given by the TGA.

The system that was in place at the time to control the supply of Medtronic's products in Australia had the Kit and the Cage listed separately. Notably, there was no requirement set up on the system to inform users that the Kit was to be released only with the Device. In fact, when undertaking due diligence, there was no document found that formalised the instructions that were given by Medtronic to its suppliers of the combined supply of the Kit with the Device.

Since each component (the Kit and the Device) had a "market licence" recorded within the system, this led to each component being capable of separate release from Medtronic's warehouse to its suppliers. In the absence of any monitoring or recordal of supply of products from the warehouse, once the products had been shipped to the supplier for distribution to the hospitals, it meant that the Kit was unintentionally supplied without the Device.

Upon realising this error, which was identified by private health insurers, steps were taken to rectify the situation. New procedures were adopted, updates were made to regulatory processes, and better quality control was implemented, which involved restructuring processes between the products team and with wider operations and supply chain teams. New policies were also developed and further training was given, in particular in relation to the supply of unapproved products or components of products that would contravene the ARTG conditions. Upon reviewing whether Medtronic could continue to supply the Kit as a standalone medical product or as a Kit with alternative Devices,

it was ultimately considered not feasible to resume compliant supply of the Device. Medtronic therefore requested cancellation of the ARTG entry for the Device and ceased supply of the Kit in Australia.

Approximately a year later, in August 2021, the TGA initiated an action against Medtronic Australasia Pty Ltd ("Medtronic") for the unauthorised supply of the Infuse Bone Graft Kit without its second component, the LT Cage, arguing that they were not granted the opportunity to assess the possible risks and efficacy of the Kit, when the Kit was supplied as a "stand-alone" therapeutic good.

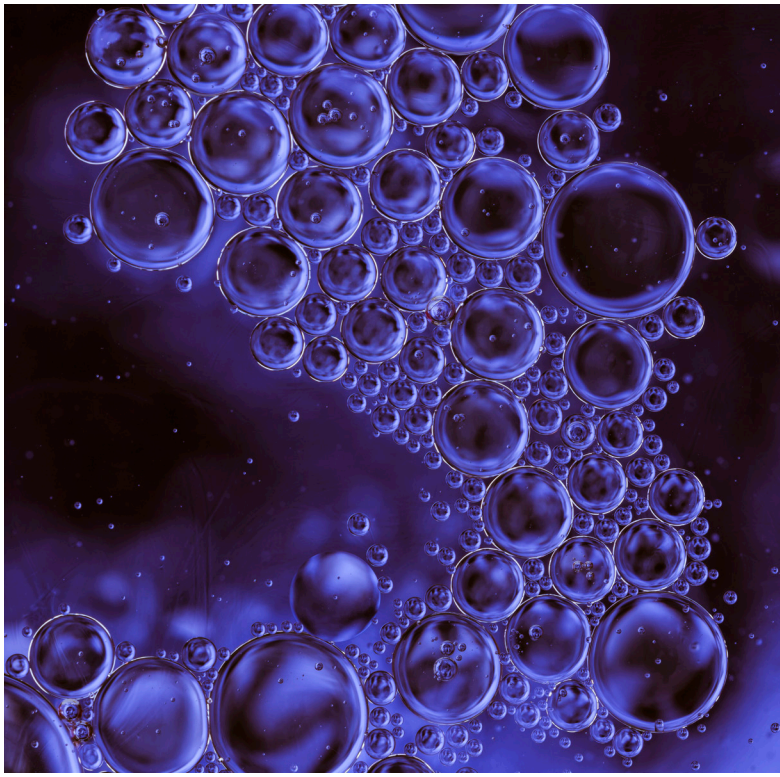
The Court's Findings

When reviewing the evidence, the Court came to the opinion that the breach in compliance was not deliberate, as Medtronic did take steps to address the contraventions once it was realised. It was considered that what did occur were several instances of missed opportunities in identifying the non-compliance. These included instances where quality audits and compliance reviews should have flagged a difference in the supply volumes. There was also a lack of information and training with respect to how to handle the supply of non-approved products. Had Medtronic paid closer attention to their systems, compliance, and training, the damage done would have been minimised.

Medtronic was ultimately ordered to pay significant penalties in the amount of $22 million for their actions in supplying over 16,267 units of their kit to a number of hospitals between September 2015 and January 2020, which is the largest fine that has been imposed under the Therapeutics Goods Act 1989 to date, as well as legal costs of $1 million on behalf of the TGA. The substantial fines were considered necessary to deter others from similar activities in the future and was based on precedence in the case of Australia Building and Construction Commissioner v Pattinson (2022) HCA 13, which stated that the penalty should be fair whilst being "sufficiently high enough that a cynical operator may not take it into account as the cost of doing business".

Key points and lessons learnt

This case comes as a timely reminder to companies, distributors and suppliers to stay vigilant and to take their obligations seriously to ensure strict regulatory compliance with Australia's therapeutic goods industry. This is applicable not only to medicines and medical devices, but also to the aesthetics industry that provide products for sale in Australia. It is recommended that regular review of internal compliance procedures be undertaken to ensure that therapeutic goods are made, supplied, imported and/or exported according to policy and standard operating procedures. This is particularly important as market trends and therefore the demand for a product may vary during the product's lifecycle.



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