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Contents

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Inclusive construction of comprising: is broader always better?

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This article considers construction of the term "comprising" by Rofe J in *Boehringer Ingelheim Animal Health USA v Zoetis Services LLC*[1] and the implications that construction may have in relation to the standard use of comprising statements in patent applications, as well as to the validity of patent claims, in view of the supplementary reasons handed down in March 2024.

Key points

- A comprising statement can support a non-exhaustive construction of "comprising" (and variations thereof); however, the breadth of the disclosure will nevertheless influence the scope of the claimed monopoly.
- The broader scope afforded by an inclusive construction of "comprising" must be balanced with the breath of support disclosed in the specification as a whole to ensure the claimed monopoly is valid under ss 40(2)(a) and 40(3).

Introduction

In *Boehringer Ingelheim Animal Health USA v Zoetis Services LLC (No 2)*,[2] Rofe J provides supplementary reasons in relation to the validity of the dependent claims of three patent applications in the name of Zoetis Services LLC (Zoetis) directed to a Mycoplasma hyopneumoniae vaccine (M hyo vaccine), ie, Australian Patent Application Nos 2013243535, 2013243537 and 2013243540 (the '535, the '537, and the '540, respectively, and "the Applications" collectively).

In the primary reasons, Rofe J found all claims in each of the Applications, except claim 2 of the '535, successfully opposed.[3] This decision was influenced in part by his Honour's construction of the term "comprising" in the independent claims and in view of the Applications containing a "comprising statement" defining "comprising" (and related terms) as including stated integers but not excluding other integers. Here, construction of the term "comprising" by Rofe J in *Boehringer Ingelheim Animal Health USA v Zoetis Services LLC* and the implications that construction may have in relation to the standard use of comprising statements in patent applications, as well as to the validity of patent claims, is considered in view of the supplementary reasons.

Background

Opposition hearing

Opposition of the Applications was first considered in a hearing before a delegate of the Commissioner of Patents.[4] At the hearing, Boehringer Ingelheim Animal Health USA (Boehringer) opposed the Applications on the grounds that the claims lack clarity, a manner of manufacture and an inventive step. In considering the lack of clarity ground, Delegate Wagg stated that he considered the term "comprising" "to be non-exhaustive as is the usual practice when construing claims";[5] however, the decision did not turn on his interpretation of the term. Ultimately, Boehringer achieved limited success at the hearing with the delegate being persuaded solely by Boehringer's lack of inventive step arguments and only in relation to select claims of the '535 application.[6]

Appeal and cross appeal to the Federal Court

On appeal to the Federal Court of Australia, however, the meaning of the term "comprising" was influential in Rofe J finding the '535 and the '537 successfully opposed on the grounds of lack of support[7] and lack of disclosure[8]. Notably, Rofe J concluded that the term "comprising" (as used in claim 1 of the Applications) and "further comprising" (as used in claims 3 and 8 of the '535 and the '537, respectively) was justifiably given an inclusive construction extending only so far as permissible following a commonsense approach.[9] That is, the scope of the claim should not be given "'an unbridled operation' to contort a claimed invention into a substantially different invention to that described in the specification".[10]

Regarding dependent claims 3 (of the '535) and 8 (of the '537), this construction of "comprising" led Rofe J to conclude that the claimed immunogenic composition

may include within its scope the M hyo antigen(s) and (for the '537) the PCV-2 antigen as well as any one or any combination of the antigens selected from a specified list of 5 pathogens but no additional antigens "beyond those listed in the respective claims".[11] Moreover, the commonsense approach to the construction of "comprising" led Rofe J to consider the scope of the claimed immunogenic compositions which elicit a protective effect includes vaccines.[12]

Since the specifications did not provide enabling support across the full spectrum of combinations of M. hyo antigen(s) [and the PCV-2 antigen] with those listed in claim 3 (of the '535) or claim 8 (of the '537),[13] Rofe J found that the claims failed to satisfy the support requirement pursuant to s 40(3) of the Patents Act 1990 (Cth).[14] Furthermore, Rofe J concluded that since the specifications of the '535 and the '537 did not provide an enabling disclosure of an immunogenic composition consisting of such combinations, developing a vaccine for a M hyo and the 5 pathogens would involve undue burden,[15] hence claims 3, 8 and 12 of the '535 and claims 8, 13, and 17 of the '537 failed to comply with s 40(2)(a) of the Patents Act.[16]

Supplementary reasons

The construction of "comprising" discussed in the primary reasons was reaffirmed in the supplementary reasons, with Rofe J asserting once more that the "breadth of claim [3 of the '535 or 8 of the '537] being the spectrum of possible antigen combinations . . . owe nothing to the disclosure of the specification".[17] Hence, the immunogenic composition and associated method of manufacture claims of that scope, as well as subsequent dependent claims, "suffer from a lack of support and disclosure".[18]

Impact of comprising statements on the construction of "comprising"

The findings of Rofe J, having been maintained in the supplementary reasons, confirm that providing a definition of "comprising", ie, a comprising statement, can support an inclusive construction of the term so long as that construction is not contradictory in the context of the specification as a whole. Moreover, his Honour's decisions affirm earlier principles of construction, particularly those laid out by Allsop CJ, Nicholas and Yates JJ in *Actavis Pty Ltd v Orion Corp*[19] regarding an inclusive construction of comprising not giving the word and its variants "unbridled operation".[20] Rather, the scope of the claimed monopoly yields to the description of the invention such that the breadth of what is claimed does not fundamentally alter the nature of the disclosed invention.

Interpretation of "comprising" and the impact on claim validity

In view of the foregoing principles, an inclusive interpretation of "comprising" in the context of the claims can be expected to establish what features may reasonably be considered to fall within the scope of that claim. Additional integers which are "not excluded" from the claim may include those related to working the invention or achieving an advantageous property, such as inessential elements which the person skilled in the art would ordinarily use to work an invention of a similar nature. For example, with respect to the immunogenic composition claims of the Applications, Rofe J indicates that although adjuvants and excipients are not recited in the claims, they are within the scope of the claimed invention since a person skilled in the art would understand that without, eg, an adjuvant, an M hyo vaccine would suffer from stability issues.[21]

Additionally, an inclusive construction of "comprising" does not necessitate that the scope of the claimed monopoly encompasses each integer of the appended claims. The integers of the appended claims still must relate to the disclosed invention and not "contort the claim into a substantially different invention".[22] For this reason, Rofe J considered the scope of an immunogenic composition comprising the supernatant of a M hyo culture to include any M hyo antigen found in the supernatant but "not" the additional antigens recited in dependent claim 3 (of the '535) or 8 (of the '537), as inclusion of the latter antigens would be contrary to the embodiments of the invention.[23]

These considerations hold considerable consequences with respect to claim validity. Indeed, the commonsense approach to inclusive construction of comprising adopted by Rofe J, which limited the scope of the independent claims in the Applications, resulted in those claims finding sufficient support and disclosure in the specifications. However, the broader scope afforded the dependent claims (where Rofe J considered an immunogenic composition "further comprising" a spectrum of antigens) resulted in those claims being successfully opposed for lack of support and disclosure.

What next?

Moving forward, practitioners may continue to promote the use of a comprising statement to support inclusive construction of the term and its variants. However, broader does not equate to better in all scenarios. In the wake of the Full Federal Court's importation of the "relevant range" concept into Australian law following the *Jusand Nominees Pty Ltd v Rattlejack Innovations Pty Ltd*[24] decision — and the resulting implication that Australian patent applicants may not be able to rely on a principle of general

application to support a broad claim scope — practitioners are encouraged to evaluate not only what scope an inclusive construction will afford but to what extent a specification provides enabling support and disclosure for that scope. As we have seen in the *Boehringer* decisions, the breadth attributed to a claim following an inclusive construction of "comprising" can be its undoing.

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Footnotes

1. *Boehringer Ingelheim Animal Health USA Inc v Zoetis Services LLC* [2023] FCA 1119; BC202313727.
2. *Boehringer Ingelheim Animal Health USA Inc v Zoetis Services LLC (No 2)* [2024] FCA 291; BC202403448.
3. Above n 1.
4. *Boehringer Ingelheim Animal Health USA Inc v Zoetis Services LLC* [2020] APO 40.
5. Above, at [74].
6. Above n 1, at [196].
7. Above n 2, at [589]–[594].
8. Above n 2, at [612]–[617].
9. Above n 1, at [244] following the reasons of Allsop CJ, Nicholas and Yates JJ in *Actavis Pty Ltd v Orion Corp* [2016] FCAFC 121; BC201607889 (*Actavis*) at [168]–[181].
10. Above n 1, at [234], quoting *Actavis*, above, at [178].
11. Above n 1, at [249] and [255].
12. Above n 1, at [589].
13. Above n 1, at [593].
14. Patents Act 1990 (Cth), s 40(3).
15. Above n 1, at [614].
16. Above n 1, at [617]; above n 14, s 40(2)(a).
17. Above n 2, at [65].
18. Above n 2, at [67] and [107].
19. See *Actavis*, above n 9.
20. *Actavis*, above n 9, at [178].
21. Above n 1, at [247]–[248].
22. Above n 1, at [234].
23. Above n 1, at [236].
24. *Jusand Nominees Pty Ltd v Rattlejack Innovations Pty Ltd* (2023) 300 FCR 408; 176 IPR 336; [2023] FCAFC 178; BC202316170, applying the concept of a "relevant range" from *Regeneron Phamaceuticals Inc v Kymab Ltd* [2020] UKSC 27.

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Doxxing: sharing isn't caring; it's criminal

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Two new offences which specifically criminalise doxxing are proposed to be inserted into the Commonwealth Criminal Code. What precisely is proposed to be criminalised, what will need to be proved in future prosecutions, the advice that should be provided to clients (both those who may be implicated in the offending and victims of doxxing) and whether there is even a need for the offences are discussed in this article.

Key points

- The new offences specifically criminalise doxxing; which is the malicious publishing of personal information online.
- There are two new offences. One relates to doxxing involving a person or persons, and the other relates to doxxing which is targeted at a member or members of certain groups. The offences carry maximum penalties of 6 and 7 years imprisonment respectively.
- The offences appear to be targeted towards criminalising the actions of individuals, rather than corporations. However, corporations (particularly those who's trade involves the use or maintenance of social media or other online platforms) should be provided with advice to assist them in ensuring they are not committing offences and/or safeguarding themselves against being implicated in criminal offending.
- The advice provided shouldn't be anything new or groundbreaking. Doxxing is conduct which can be prosecuted under other existing state and commonwealth offences.
- Clients who are victims of doxxing should be advised to take certain steps to preserve and gather evidence and to report the matter to police.

Introduction

For those unfamiliar, the term "doxing" simply means publishing personal data or information online. The new offences criminalise doxxing when the act is done with malicious intent, or more specifically, in a way which is, in all the circumstances, menacing or harassing.

While many people remember the Ashley Maddison scandal, most wouldn't automatically identify what occurred as doxxing. Indeed, many may not even consider the persons who were revealed to be members as victims. This is a prime example of doxxing, even if the malicious intent were primarily directed at the company itself.

The practice of doxxing isn't new but it is becoming more common. The personal data published typically includes identity information such as a person's name, address, date of birth, address, telephone numbers and, in some cases, even financial information. However, it could also include personal information whereby that person is target based on their race, gender, religion, health status, sexuality or other characteristics.

Revealing the identity and personal information of persons online can compromise the privacy and safety of the person and can harm their reputation. It's not uncommon for offenders to encourage others to intimidate, harass or troll their targets in order to fuel the marginalisation or hatred of the person or a particular group of people.

Proposed offences

Following a Commonwealth review of the Privacy Act 1988 (Cth),[1] the Privacy and Other Legislation Amendment Bill 2024 (Cth)[2] was introduced to parliament on 12 September 2024 and is presently progressing through to third reading debates.[3] While the primary function of the bill is to amend the Privacy Act[4] in a number of material respects (which are important but not the subject of this article), if passed, the Bill will create two new offences which specifically criminalise doxxing.

In keeping with the rest of the Criminal Code Act 1995 (Cth),[5] the proposed offences will be implemented with the short, sharp and succinct headings that follow:

- "Using a carriage Service to make available etc personal data of one or more individuals" pursuant to s 474.17C of the Criminal Code (maximum penalty 6 years imprisonment)[6] and
- "Using a carriage Service to make available etc personal data of one or more members of certain groups" s 474.17D of the Criminal Code (maximum penalty seven years imprisonment)[7]

Sarcasm aside, the text of the sections will operate to criminalise the act of uploading or publishing the

personal data of one or more people (the s 474.17C offence[8]) or the personal data of one or more members of certain groups (the s 474.17D offence[9]).

Any practitioner working with client's affected by these changes will no doubt need to provide advice on more than what the offences are. They will need to understand what is actually criminalised and what is required to be proved and apply that to their client's situation (or hypothetical situation).

For those unfamiliar with criminal proof for Commonwealth offences, the prosecution is required to prove the element itself, as well as an associated fault element. This can be rather complicated, and advice from a specialist lawyer or barrister may be worthwhile.

To prove the offences, the prosecution need to establish the below, beyond reasonable doubt that:

- the accused used a carriage service to make available, publish or otherwise distribute information and
  - — "the fault element" that they intentionally did so (that is, they meant to engage in the conduct)
- the information was personal data of:
  - — an individual or individuals (for the s 474.17C offence); or
  - — a member or members of certain groups (for the s 474.17D offence); and
    - "the fault element" that they were reckless in doing so (that is, they were aware of a substantial risk that their conduct could be menacing or harassing and proceeding was unjustifiable in light of that risk)
- with respect to the s 474.17C offence only — the conduct was engaged in, in whole or in part because of the person's belief that the targeted group is distinguished by race, religion, sex, sexual orientation, gender identity, intersex status, disability, nationality, national or ethnic origin and
  - — "the fault element" that they were reckless in doing so
- they did so in a way that reasonable persons would regard (in all the circumstances) as being menacing or harassing towards:
  - — the individual or individuals (for the s 474.17C offence) or
  - — a member or members of certain groups (for the s 474.17D offence) and
    - "the fault element" that they were reckless in doing so

The presumption in s 475.1B of the Criminal Code[10] applies to the first element and has the effect that if the prosecution prove beyond reasonable doubt that the accused engaged in that particular conduct (ie made available, published or otherwise distributed information), then it is presumed, unless the person proves to the contrary, that they used a carriage service to engage in that conduct.

"Personal data" means information about the individual that enables the individual to be identified, contacted or located and includes a person's name, a photograph or other image of them, their telephone number, email address, online account, residential address, work or business address, place of education or place of worship.[11] It is not an exhaustive list.

Application to corporations

The Criminal Code applies to corporations in the same way it does to individuals. Corporations can be charged criminally for the conduct of their employees, agents and officers provided such conduct is within the scope of their employment or engagement.

When one reviews the sections themselves, the explanatory memorandum and the absence of a separate maximum penalty for corporations, the new offences appear to be targeted at individuals rather than corporations. However, there's no reason why a corporation couldn't be charged, and shouldn't be provided with relevant advice about such.

The charging of corporations with criminal offences is relatively rare. Further, if an employee or agent of a corporation engages in doxxing while at work, or using their workplaces online or social media platform, a real question as to whether such was within the scope of the persons employment or engagement arises. Unless there was a direct and clear order, request or employment-based responsibility to do so, establishing corporate liability would be difficult. An additional layer of complexity arises when one comes to establishing that the fault elements of the offences are made out.

Nevertheless, practitioners with corporate clients who create, use or manage online platforms (including social media platforms) ought turn their mind to how the new offences may affect their clients and advise accordingly. The advice provided will of course be dependent on the client's circumstances, but may involve advice about:

- ceasing any conduct which amounts to doxxing
- considering whether to cease or change any business activities which facilitate doxxing (such as allowing personal information to be published on their online platform), and whether such conduct could result in criminal liability
- introducing security measures to ensure employees, agents, contractors or other persons cannot access and/or publish personal information

- changing company policies and procedures and/or
- training and education of employees

While one cannot predict what will or won't occur with certainty, the fact that the legislative intent upon a reading of the explanatory memorandum and second reading speeches appears to be to ensure the prosecution of the individuals who engage in this conduct, it's most likely that law enforcement will be pursuing those individuals, rather than corporations who facilitate the commission of the offences through the maintenance of online or social media platforms.

The case for new offences

The Bill's explanatory memorandum argues that:

> . . . if such malicious conduct is not criminalised, it can reduce individuals and the broader community's confidence in engaging substantially online, including in public and political debate, undermining the benefits of such engagement to the individual and community.[12]

However, just because there's isn't presently a specific "doxing" offence doesn't mean it's not criminal. Indeed, it can already be prosecuted. There are a number of offences with which a person or corporation engaging in doxxing can be charged. These include but are not limited to:

- use carriage service to menace/harass/offend[13]
- intimidation (the definition of which specifically includes "cyberbullying amounting to harassment or molestation of the person")[14] and
- dealing with identification information with the intention of committing, or facilitating the commission of an indicatable offence[15]

In addition to the above, if doxxing were engaged in for the purpose of obtaining financial gain or causing a financial loss, a person could be prosecuted for fraud related offences.

Such begs the question; is there even the need for new offences?

While the cost, time and resources that are inevitably consumed in the process of consultation, review and legislative amendment is undoubtedly significant, and adding further similar offences can result in an (even more) unwieldly and needlessly complicated criminal code, the pros arguably outweigh the cons.

As noted in the explanatory memorandum, the introduction of specific criminal offences sends a message to the broader community that doxxing "is harmful, serious and subject to significant criminal penalties".[16] Deterring people from offending promotes the right of protection against interference with privacy and reputation. It also prevents the potential harms caused by doxxing.

Creating specific offences raises awareness of the issue among our law enforcement officers and can promote and encourage them to commence proceedings where they may not have otherwise. This however is contingent on new offences being rolled out with appropriate education and training.

The new offences also have higher maximum penalties that the general offences under which doxxing may presently be prosecuted. The offences of "Use carriage service to menace/harass/offend"[17] and "Intimidation"[18] will typically be the most appropriate "catch-all" offences for doxxing. Both offences carry a maximum penalty of 5 years imprisonment, which is less than the 6– and 7–year maximum penalties for the new offences respectively.

Advising victims of doxxing

Any person who has the unfortunate experience of falling victim to doxing should be encouraged to report the matter to either State or Federal police.[19] They should also be advised about:

- The importance of obtaining and preserving evidence that law enforcement may need (law enforcement will likely do this too, but the earlier they start gathering and/or preserving evidence the better as the "doxxer" may begin deleting accounts, pages or messages).
- Once evidence has been obtained or preserved:
  - if a social media platform has been used in the doxxing, they should report such to the platform (but only once they have obtained a copy as platforms often remove reported posts and pages)
  - block any profiles or users who have engaged in the doxxing
  - if they wish to do so, remove any sensitive information from their own online profiles or take down or deactivate their profiles.
- Reviewing their own privacy and security settings.

From a reporting and review standpoint, the gathering of statistical and empirical data about crimes is also important. Post implementation reviews and reports are commonly prepared, and agencies (such as BOCSAR) often rely heavily on such data.

While some investigations may not result in the identification and prosecution of the offender due to the offender obscuring or concealing their identity online or using other mechanisms to evade detection, the fact such is likely should not be used to dissuade a person from reporting the matter. It is important for law enforcement is able to gather any and all intelligence about crimes.

Reports, even where they do not specifically lead to prosecution, may assist police in piecing together information relevant in other prosecutions, may be relevant for Apprehended Violence Order (AVO) applications or bail applications.

In addition to the above, the police may also give consideration to other protective mechanisms such as making an application for an AVO (if the perpetrator is known) or referring victims onto relevant support services.

As touched on above, it is important to consider whether the person should be provided with any practical advice with respect to the management of their own physical or online safety. Placing profiles on private, undertaking a cull of "followers" or "friends" to remove unknown profiles, removing other publicly available information online and changing banking details, account logins or passwords may assist the victim to feel more protected, self-empowered and reduce the likelihood of further harm being caused to them.

Complaints and referrals can also be made to the eSafety Commissioner, which urges people to report complaints about doxxing and other illegal or inappropriate online activity (including cyberbullying). Complaints can easily be made online here: www.esafety.gov.au/report/forms.

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Footnotes

1. Privacy Act 1988 (Cth).
2. Privacy and Other Legislation Amendment Bill 2024 (Cth).
3. Parliament of Australia, Privacy and Other Legislation Amendment Bill 2024 (Cth), November 2024 www.aph.gov.au/Parliamentary_Business/Bills_LEGislation/Bills_Search_Results/Result?bId=r7249.
4. Above n 1.
5. Criminal Code Act 1995 (Cth), Sch 1 (Criminal Code).
6. Above, s 474.17C.
7. Above n 5, s 474.17D.
8. Above n 5, s 474.17C.
9. Above n 5, s 474.17D.
10. Above n 5, s 475.1B.
11. Above n 5, s 474.17C(2).
12. Explanatory Memorandum, Privacy and Other Legislation Amendment Bill 2024 (Cth) [21].
13. Above n 5, s 474.17.
14. Crimes (Domestic and Personal Violence) Act 2007 (NSW), s 13. See also s 7 in relation to the meaning of "intimidation".
15. Crimes Act 1900 (NSW), s 192J.
16. Above n 11, Statement of Compatibility with Human Rights at [12].
17. Above n 12.
18. Above n 13.
19. Both State and Federal police investigate and prosecute Commonwealth offences.

The battle of the coffee jars

Fiona Brittain *and* ***Alexandra Chubb*** *GILBERT + TOBIN*

The recent proceedings commenced by Koninklijke Douwe Egberts BV (KDE) and Jacobs Douwe Egberts AU Pty Ltd (JDE AU) against Cantarella Bros Pty Ltd (Cantarella) in the Federal Court represents the latest battle in the ongoing coffee brand trade mark wars being waged in Australian courts (most recently where the Federal Court considered the validity of the Cantarella's ORO mark).

While the claims being made in the case were not unusual (the case involved allegations of trade mark infringement, Australian Consumer Law (ACL) contraventions, and passing off), the trade mark at the centre of the case was somewhat unusual, being a "shape" mark relating to the shape of a container.

The decision[1] of Wheelahan J, handed down on 7 November 2024, provides useful guidance as to the validity of registered shape marks, the use of product containers as trade marks, and an analysis of deceptive similarity in the context of a shape mark.

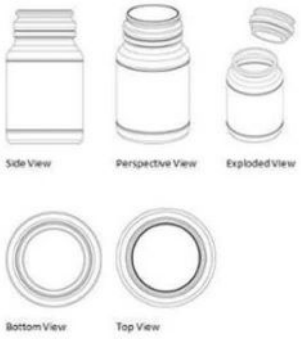
The facts

The case concerned the well-known coffee brands "Moccona" (the applicants' brand) and "Vittoria" (the respondent's brand).

The focus of the case was the shape of a glass jar in which the respondent, Cantarella, had marketed and sold a Vittoria-branded 400-gram instant coffee product since August 2022. A representative image of the Vittoria product is shown below:

The first applicant, KDE, is the registered owner of a shape mark, Australian Trade Mark Registration No 1599824 being a trade mark comprising the three-dimensional shape of a container (the KDE shape mark). The second applicant, JDE AU, sells Moccona-branded instant coffee products in Australia in various packages and containers, including glass jars using the KDE shape mark.

The KDE shape mark is represented on the Australian Trade Marks Register as shown below (noting that dimensions, colour and material do not form part of the registered mark):



An example of a Moccona-branded glass jar using the KDE shape mark is shown below:

The allegations and key findings

The applicants commenced proceedings against Cantarella alleging that Cantarella's jar infringed the KDE shape mark. In addition, the applicants alleged that, by the use of its glass jar, Cantarella had engaged in misleading and deceptive conduct in contravention of the ACL and passing off.

Cantarella denied the applicants' claims and filed a cross-claim seeking cancellation of the KDE shape mark, or removal of the mark from the Register, on various grounds, including (amongst others) a lack of distinctiveness, a lack of intention as at the priority date to use the mark "as a trade mark", and non-use of the trade mark "as a trade mark" since the priority date.

While the court dismissed Cantarella's cross-claim seeking cancellation or removal of KDE's shape mark, the court also dismissed the applicants' infringement claim against Cantarella, finding that:

- Cantarella had not used its jar as a trade mark and
- even if Cantarella had used its jar as a trade mark, the Cantarella jar was not deceptively similar to the KDE shape mark and, accordingly, would not have infringed that mark

Relying largely on the reasoning set out in relation to the analysis of deceptive similarity, the court also dismissed the ACL and passing off allegations against Cantarella.

Reasoning for the decision

Cancellation/removal of the KDE shape mark

Wheelahan J dealt first with Cantarella's claims that the KDE shape mark should be cancelled or removed from the Register. Ultimately, his Honour was not satisfied that any ground of cancellation or removal was established.

In relation to distinctiveness, his Honour found that the KDE shape mark "is not to any extent inherently adapted to distinguish KDE's goods" from those of other traders,[2] and that:

> . . . the KDE shape mark is both primarily functional and, to the extent that it is not functional, it draws on features of the common heritage [that is, features of old-fashioned jars] that are not apt to distinguish the goods of any one trader.[3]

Wheelahan J then went on to consider whether the KDE shape mark had acquired distinctiveness through use as a trade mark in relation to relevant coffee products before the priority date, and in so doing, summarised the existing case law in relation to shape marks. His Honour noted that:

> . . . it does not follow that consistent use of a container will constitute the use of its shape as a mark. More is required, in that the shape of the container must be used to distinguish the goods from those of other traders.[4]

Examining the evidence of use of the KDE shape mark in the decades before the priority date, his Honour found that it had acquired distinctiveness, including for the following reasons:

- the Moccona jars using the KDE shape mark were aesthetically distinct, with the most notable characteristics "involving the combination of the shoulder, the opening of the jar, and the stopper lid, which are depicted in the visual representation of the shape recorded on the Register"[5]
- over several decades, the applicants had "developed a significant association between their coffee products and the jar shape in which those products were sold"[6]
- in the 2 decades immediately preceding the priority date for the KDE shape mark (being 7 January 2014), "there were no competitors using jars that were apt to detract from the effectiveness of this use as a badge of origin"[7] and
- taking into account the evidence of the applicants' longstanding extensive advertising campaigns in which the KDE shape mark was a prominent feature — including television advertisements featuring Moccona coffee jars and lids significantly not bearing Moccona labels (eg as a candle or keepsake holder) — the applicants had "clearly deployed the KDE shape mark as a badge of origin in the last decade before the priority date"[8]

His Honour concluded that "this amounted to such significant use of the KDE shape mark as a badge of origin before the priority date as to satisfy the test of use"[9] under the relevant section of the Trade Marks Act 1996 (Cth).[10]

It is apparent from the decision that the applicants had spent a significant amount on their advertising campaigns over the years and enjoyed substantial sales and a major share of the instant coffee market in Australia. However, the details in this regard were the subject of confidential evidence.

For the reasons summarised above, his Honour dismissed the claims by Cantarella that the KDE shape mark should be cancelled or removed for lack of distinctiveness, lack of intention as at the priority date to use the mark as a trade mark, and non-use of the mark as a trade mark since the priority date.

Infringement of the KDE shape mark by Cantarella

As mentioned above, the applicants contended that Cantarella had infringed the KDE shape mark by selling its 400-gram instant coffee product in a cylindrical glass jar with a glass stopper lid.

This gave rise to two questions for the court:

- did the use by Cantarella of its jar constitute use of the jar "as a trade mark" and
- was Cantarella's jar substantially identical with, or deceptively similar to, the KDE shape mark?

Was Cantarella using its jar as a trade mark?

In relation to the first question, Wheelahan J found that Cantarella had not used the Cantarella jar shape as a trade mark. Rather, his Honour found that:

> . . . the Cantarella jar shape . . . is simply functioning as the shape of a receptable that fits in with the overall market positioning of the Vittoria 400-gram product, and not as a badge of origin sufficient in itself to distinguish Cantarella's instant coffee from the instant coffee of other traders.[11]

His Honour observed that:[12]

- the Cantarella jar itself was fairly plain, making it less likely that the shape of the jar itself serves to distinguish the Cantarella product to any extent from those of other traders
- Cantarella's advertisements did not explicitly draw attention to the shape of the jar; nor did they expressly ask consumers to use it as a point of distinction from the goods of other traders
- the shape of the jar is "swamped" by the use of the Vittoria branding in numerous locations on the jar (and elsewhere), further undermining the argument that the shape of the jar itself was functioning as a trade mark and
- Cantarella's advertisements for its product were to be contrasted with those deployed by the applicants (discussed above), with the latter prominently featuring the shape of the Moccona jar

Was the Cantarella jar deceptively similar to the KDE shape mark?

In light of Wheelahan J's finding that Cantarella was not using its jar as a trade mark, the applicants' claim that Cantarella was infringing the KDE shape mark was doomed to fail. However, his Honour nonetheless addressed the applicants' claim that the Cantarella jar shape is deceptively similar to the KDE shape mark and concluded that it is not.

Citing the decision of the High Court in *Self Care IP Holdings Pty Ltd v Allergan Australia Pty Ltd*,[13] Wheelahan J stated that:

- "the question of deceptive similarity is concerned with the impression that would be produced on the mind of a potential customer", noting that:

  > . . . The notional buyer is understood by reference to the nature and kind of customer who would be likely to buy the goods covered by the registration — here, coffee and instant coffee . . .[14]

- the:

  > . . . notional buyer has no knowledge about any actual use of the registered mark, the actual business of its owner, the goods the owner produces, any acquired distinctiveness arising from the use of the mark prior to filing, or any reputation associated with the registered mark . . .[15]

  and
- the notional buyer "who sees the impugned mark must be attributed an imperfect recollection of the mark as registered"[16]

Applying these principles, his Honour:

- accepted that purchasers of instant coffee do not spend a long time deciding which product to purchase, and that this informs the level of detail that should be attributed to the notional buyer's "imperfect recollection" of the mark and
- found that the notional buyer on an ordinary shopping trip could not be expected to remember anything more specific about the KDE shape mark than its rough proportions and general shape

Even taking into account this imperfect and rather vague, recollection, Wheelahan J did not consider there to be a real, tangible risk that a notional buyer:

> . . . would be perplexed, mixed up, caused to wonder, or left in doubt, about whether instant coffee sold in the Cantarella jar shape has the same commercial source as coffee sold in the KDE shape mark.[17]

Indeed, his Honour concluded that there were three features that were essential to the imperfect recollection that the notional buyer would have of the KDE shape mark, namely its "cylindrical body with, in roughly its top third, a shoulder that slopes to a thick neck ring surmounted by a two-tiered lid".[18]

In describing the key features of the Cantarella jar, his Honour concluded:

> . . . Having regard to these key features of an otherwise fairly plain shape, the notional buyer would be left with a strikingly different impression from the effect produced by the KDE shape mark. The buyer would view the Cantarella jar shape as noticeably taller in its proportions, with a compressed neck section, and a plain, low lid. Even with the imperfect recollection outlined above, there is no real risk that a buyer could confuse the Cantarella jar shape, in view of its distinct visual impression, with the KDE shape mark.[19]

Expert marketing evidence

The expert marketing evidence filed by the parties was found to be not helpful in the context of key questions such as use of a sign as a mark of origin and deceptive similarity as they are questions of fact for the court.[20]

Key takeaways

The owner of a shape trade mark registration faces particular challenges when seeking to enforce the registration as follows:

- there is a risk that the alleged infringer will counter claim and seek to cancel the shape registration on the basis of lack of distinctiveness or other grounds
- the need to establish that the alleged infringer is using the shape in question as a trade mark/badge of origin (and not merely for functional purposes) noting the applicant recently did not succeed in cases involving a light switch and moulded plastic chair[21] and
- the need to establish that the respective shapes are deceptively similar (which is likely to be more complex in the context of shapes) noting the applicant recently did not succeed in cases involving a dishwasher tablet, soft drink bottle and moulded plastic chair[22] because:
  - — there were significant or obvious differences between the shapes
  - — there were several points of difference between the shapes
  - — there were distinctive features in the allegedly infringing shape that were not present in the registered mark
  - — it was determined that there was a lack of intention to deceive on the part of the respondent or
  - — the relevant goods would be purchased by well — informed consumers reducing the risk of any confusion

Implications

Shape trade marks can be a very valuable asset in connection with protecting a successful product (which may be as diverse as a dishwasher tablet, sneaker, plastic chair, beverage bottle, light switch or chocolate bar). However, there may be considerable challenges in connection with securing and enforcing such registrations. Care and attention must be given to employing long term effective and targeted advertising and marketing strategies highlighting the shape separately and using the shape as a trade mark prior to filing the application to register the shape mark. This case is also a reminder of:

- the challenges involved in establishing that a three-dimensional object is being used as a trade mark and
- the difficulties involved in applying the ordinary legal principles with regard to deceptive similarity to shape marks and three-dimensional objects

Otherwise, who knew that the Moccona coffee jar can be used as a lovely candle jar!

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Footnotes

1. *Koninklijke Douwe Egberts BV v Cantarella Bros Pty Ltd* [2024] FCA 1277; BC202416039.
2. Above, at [257].
3. Above n 1, at [267].
4. Above n 1, at [288].
5. Above n 1, at [293].
6. Above n 1, at [306].
7. Above
8. Above n 1, at [306].
9. Above.
10. Trade Marks Act 1995 (Cth), s 41(3)(b).
11. Above n 1, at [478].
12. Above.
13. *Self-Care IP Holdings Pty Ltd v Allergan Australia Pty Ltd* (2023) 277 CLR 186; 408 ALR 195; [2023] HCA 8; BC202301799.
14. Above n 1, at [482].
15. Above.
16. Above n 1, at [483].
17. Above n 1, at [496].
18. Above n 1, at [501].
19. Above n 1, at [502].
20. Above n 1, at [27].
21. *Clipsal Australia Pty Ltd v Clipso Electrical Pty Ltd (No 3)* (2017) 122 IPR 395; [2017] FCA 60; BC201700384; *Sebel*

Furniture Ltd v Acoustic & Felts Pty Ltd (2009) 80 IPR 244; [2009] FCA 6; BC200900027 (*Sebel*).

22. *RB (Hygiene Home) Australia Pty Ltd v Henkel Australia Pty Ltd* (2024) 420 ALR 173; 179 IPR 178; [2024] FCAFC 10; BC202401384; *Coca-Cola Co v PepsiCo Inc (No 2)* (2014) 322 ALR 505; 109 IPR 429; [2014] FCA 1287; BC201411310; *Sebel*, above.

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Keywords go viral: COVID-19 swept the patent world

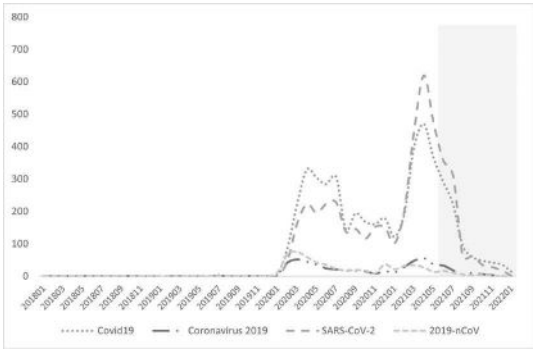
Frazer McLennan *and* ***Michael Christie, PhD*** *SPRUSON & FERGUSON*

Introduction

COVID-19 was not just a once-in-a-lifetime pandemic that swept across the globe causing hardship and sorrow; to a patent searcher like me, it was also a new keyword, and the opportunity to look at a global pandemic through a patent lens is similarly a once-in-a-lifetime event. Although the pandemic is over, COVID-19 has fuelled the ongoing development of RNA vaccines that will better prepare us for future outbreaks.

Searching for COVID-19

When we first searched for patents and patent applications relating to COVID-19 in 2021, we saw the use of keywords relating to COVID-19 rise dramatically, much like cases of the disease. This chart shows how often different keywords were used when we searched in 2021.



The keywords were searched in the title, abstract and claims of patent applications using the search string:

TAC=(covid, covid19, (corona w2 2019), (sars w2 cov w2 2), (sars w2 cov2), ((19, 2019) w2 (ncov, hcov)))*

The first keyword is Covid or COVID-19. COVID-19 was one of the official names designated by the World Health Organisation (WHO) and comes from Corona Virus Disease 2019. It's used widely to refer to the disease, and more loosely to the virus itself.

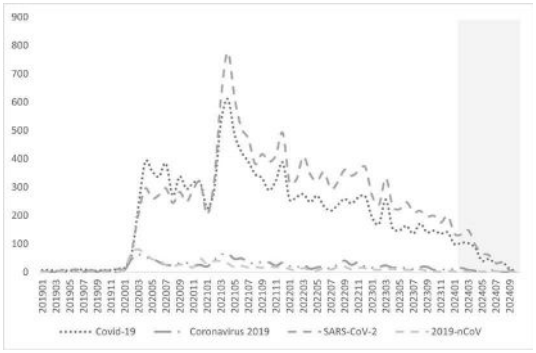
The second keyword is essentially "Coronavirus 2019", coming from the long form text of COVID-19.

The third keyword is "SARS-CoV-2". This is an official name for the virus that causes COVID-19, designated by the WHO in February 2020.

The last keyword is "2019-nCoV" (or "2019-hCoV"). This was an early name, originating in January 2020, and comes from the naming conventions for new viruses and diseases, often used to protect groups of people or geographic locations from social stigma.

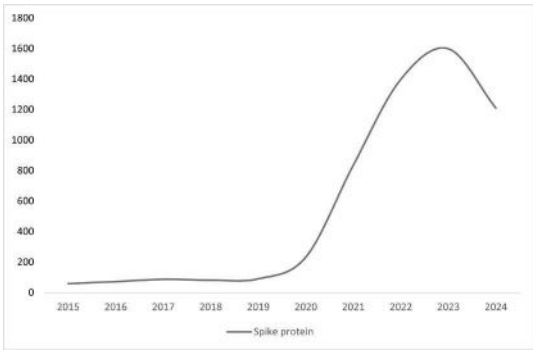
Here is an updated chart showing the number of patent applications filed from January 2019 to October 2024 that mention one of the keywords described above.

We see the two peaks evident in the earlier data, but since then, the number of applications has declined, and continued in a downward trend.



There's a shaded area covering the last 8 months. The data in this region is incomplete because we're waiting for a portion of applications filed 18 months ago to be published.

The basis for most COVID-19 vaccines, and a target for many COVID-19 treatments, is the viral spike protein — a surface protein that facilitates coronavirus entry into host cells. Not surprisingly, then, we also see a sudden increase in patent applications relating to spike proteins shortly after the emergence of COVID-19.

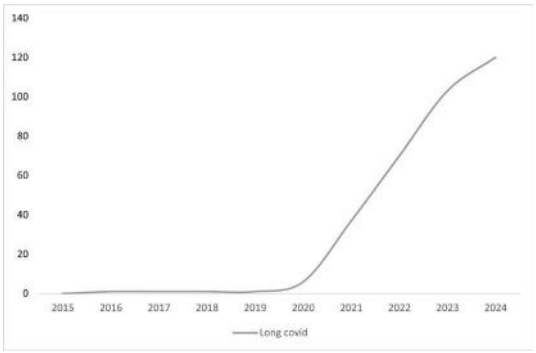


Spike indeed.

COVID-19 patent filings have followed the trajectory of the disease itself, with new filings gradually petering off.

Long COVID

Long COVID is a poorly understood condition that afflicts many individuals who contract COVID-19. It was first described towards the end of 2020 — well after the outbreak of COVID-19 — and the search for effective treatments is ongoing. Patent filings for long COVID reflect this dynamic: we see a sustained increase that lags Covid itself.

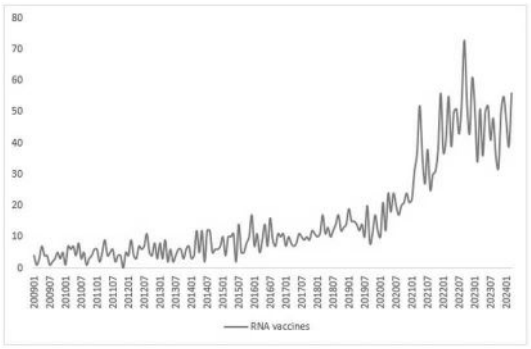


It is interesting to see the continued rise in the number of filings through 2024. Normally, we expect to see a decrease in the last year's data as we wait for publication of applications made in the last 7 or 8 months, but here we don't, indicating a strong, continued growth in patent filings.

Lasting impacts

When we look at patent applications relating to vaccine development more broadly, we see a lasting impact from COVID-19.

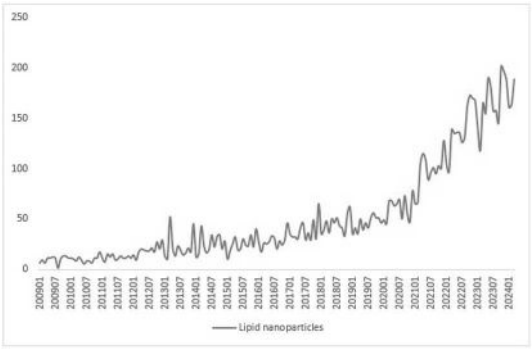
This chart shows the number of patent applications filed since 2009 in the field of RNA or mRNA vaccines.



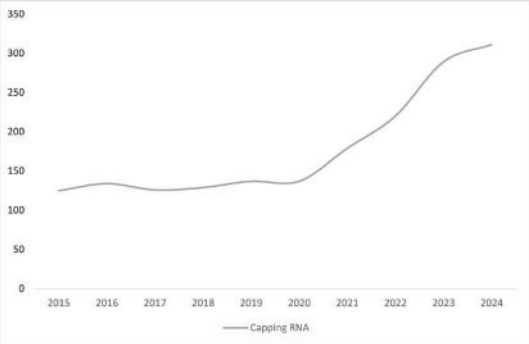
The number of applications in the months post-2019 is easily five-fold compared to the period before COVID-19.

The applications are dominated by some familiar names such as Moderna, Pfizer and BioNTech, while the (Chinese) Academy of Military Medical Sciences is in the top three.

It's not just "RNA vaccines" per se that increased in popularity. We also see a corresponding increase in filings for technologies that enable vaccine development and delivery. Take lipid nanoparticles (LNPs), for example. These tiny droplets of fat have proven to be particularly effective vehicles for transporting RNA into cells and were responsible for delivering COVID-19 mRNA vaccines into billions of arms around the world.



We see a similar trend when we look at another enabling technology — RNA capping. The cap structure at the front of an mRNA molecule is essential for the mRNA to function within host (ie, our) cells. Adding a cap to an RNA molecule ("capping") has proven to be difficult and expensive — in some cases, the most expensive step in mRNA vaccine production. Much research — and patent filings — has therefore focussed on RNA capping technologies since the emergence of COVID-19, as illustrated in our next chart.



Conclusion

While the initial rush of patent filings relating to COVID-19 appears to be over, the pandemic has left a lasting impact on research and investment — and patent filings — relating to RNA vaccines and therapeutics more broadly. This bodes well for our preparedness to face another pandemic.

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Skinny labelling strategies: securing and enforcing medical use claims in Australia

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Overview

Patent protection for medical uses of pharmaceuticals is a topic of international interest, with a variety of approaches across the globe, underpinned by differing philosophical approaches to the patenting of medical treatment.

New active pharmaceutical ingredients are typically protected by patent claims to the pharmaceutical substance itself, without reference to any particular indication. However, inventions relating to new uses of known pharmaceutical substances may also be extremely valuable, both to patentees and patients. The novelty and inventiveness of patent claims to such inventions must often be defined by reference to the new use, raising important considerations regarding patent claim formats.

Australia takes a relatively liberal approach, allowing the patenting of patent claims directed to a method of treatment,[1] unlike Europe and New Zealand, for example. In Europe, where methods of treatment are not patentable, other patent mechanisms allow for the protection of pharmaceuticals for particular uses. The "Swiss type claim", directed to the use of a substance for the manufacture of a medicament for treatment of a particular disease is the paradigm example, but has now been superseded by the "EPC 2000 claim" to a substance for use in treating a particular disease state. Given many Australian patents start life overseas, the courts in Australia have now considered the construction of such claims and the implications for enforcement, with important differences emerging between claim types.

These issues come into particular focus in the context of the practice known as "skinny labelling", which typically involves omitting patented indications from the prescribing information (ie, label) for a generic or biosimilar product, in an attempt to avoid infringement of second medical use patents when supplying a known pharmaceutical product for an off-patent indication.

This article explores the current legal framework surrounding medical use patents in Australia and reviews relevant case law, offering practical insights for patent prosecutors and litigator.

Legal framework for second medical use claims

Medical use patents protect the use of known pharmaceutical substances for new therapeutic indications. An example considered in the Australian case law is pregabalin, previously known and used in the management of seizures, and patented by Warner Lambert for the treatment of certain types of pain.

Australian patent law does not define acceptable claim formats, provided claims meet the general requirements of the Patents Act 1990 (Cth). Several claim formats are available for medical use patents:

- Method of treatment claims: these claims typically have the form "a method of treating [disease X] comprising administering an effective amount of [substance Y]".
- Swiss type claims — these 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]". In Australia, Swiss type claims are treated as method claims directed to the act of manufacture. A prior art disclosure must disclose both a method of preparing the medicament, and the specific treatment claimed.[2]
- EPC 2000 claims — these are purpose-limited product claims typically having the form "[substance X] for use in treating [disease Y]". The status of EPC 2000 claims under Australian law is not clear. The prevailing position adopted by IP Australia in examining EPC 2000 claims has been that the term "for use" in such a claim is only limiting to the extent that the product must be suitable for the relevant use. This means that EPC 2000 claims directed to a new use of a known product have typically failed for lack of novelty during examination. However, the Federal Court has provisionally found (in the context of an interlocutory injunction application) that the specified therapeutic purpose of an EPC 2000 claim is an essential feature of the claim.[3] The IP Australia

> Patent Examiner's Manual now indicates that "the examiner will need to consider novelty or inventive step issues in the light of any use disclosed in the prior art".[4]

The claim format used significantly influences the infringement analysis. Swiss style claims and EPC 2000 claims are directed to the act of manufacture and the product manufactured, respectively, making the manufacturer the primary infringer of such a claim.

In contrast, method of treatment claims is directed to the act of treatment itself. Since the manufacturer is usually the target of an infringement claim, patentees rely on the indirect infringement provisions contained in s 117 of the Patents Act. Section 117 provides various bases for establishing liability on the basis of a supply of a product. The broadest circumstance arises where the supplier has reason to believe that such product will be used for an infringing purpose.[5]

Case analysis

Skinny labelling

In common with many other jurisdictions, Australia's regulatory regime for therapeutic goods requires the supplier of a prescription medicine to publish "prescribing information" (or a pharmaceutical "label") which 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, retaining only those indications that are off-patent. More elaborate versions of skinny labelling may involve an express statement that the product is not supplied for use in patent-protected indications (a "disclaimer") and/or communications with Australian prescribers and pharmacists to inform them that its product should not be prescribed or dispensed for use in patented indications. Such strategies have been the subject of several Australian cases.

The Leflunomide case

In *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd*[6] (*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. The disclaimer was considered to negate any "reason to believe" as required by s 117(2)(a) of the Patents Act, that the product would be used for psoriasis.

The Pregabalin case

The *Warner-Lambert Co LLC v Apotex Pty Ltd*[7] (*Pregabalin* case) concerned method of treatment claims covering use of pregabalin for neuropathic pain. Apotex adopted a skinny labelling strategy whereby its product label listed only the indication of treatment of seizure disorders. It also offered undertakings to notify prescribers and pharmacists that the products were only supplied for use in the treatment of seizure disorders. These measures were found 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, and that off-label use was commonplace and ethical practice.

The Fenofibrate case

Mylan Health Pty Ltd v Sun Pharma ANZ Pty Ltd[8] (*Fenofibrate* case) provided the first opportunity for consideration by the Australian Federal Court of Swiss type claims in a skinny labelling context. Mylan's patent contained both method of treatment claims and Swiss type claims directed to the use of fenofibrate for diabetic retinopathy. Sun's generic fenofibrate products were labelled for use in the off-patent hypercholesterolaemia indication.

The outcome highlighted an important distinction between Swiss type claims and method of treatment claims under Australian law. The 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, the lack of reference to the patented indication on its labelling was sufficient to establish that the generic fenofibrate products were not "for" use in the treatment of diabetic retinopathy and would not have infringed Mylan's Swiss type claims (had they not been found invalid).

By contrast, the Full Court held that Sun would have infringed Mylan's method of treatment claims for the diabetic retinopathy indication. 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.

The Melatonin case

Neurim Pharmaceuticals (1991) Ltd v Generic Partners Pty Ltd (No 5)[9] (*Melatonin* case) again concerned Swiss type and method of treatment claims. All relevant

claims related to the treatment of "a patient suffering from primary insomnia characterised by non-restorative sleep and improving the restorative quality of sleep in said patient".[10]

In this case, the generic products in question had the same indications and characteristics as the originator melatonin products. However importantly, the product label of both the originator and generic products differed from the patented indication and referred to "poor quality sleep".

Justice Nicholas took account of significant expert evidence on the distinction between "non-restorative sleep" and "poor quality sleep". Ultimately, his Honour was satisfied that a reasonable person supplying the generic product for the treatment of primary insomnia characterised by poor quality sleep would have reason to believe that the medication would be prescribed to treat primary insomnia characterised by non-restorative (or unrefreshing) sleep,[11] notwithstanding that it would also be used for other indications encompassed within the broader notion of "poor quality of sleep". Neurim was successful on its infringement case on the method of treatment claims on this basis.

However, in accordance with the principles set out by the Full Federal Court in the *Fenofibrate* case, Nicholas J confirmed that "infringement of a Swiss type claim is concerned with what the allegedly infringing manufacturer has done, not what it intended to do".[12] In this context, the physical characteristics of a product, including its packaging, dosage and product information, are the most important considerations.[13]

Justice Nicholas found that the meaning of "quality of sleep" in the approved indication was broader than the meaning of "non-restorative sleep" in the claims,[14] and that melotonin would mostly be used for other therapeutic purposes.[15] His Honour was not persuaded that the generic product was a medicament manufactured for the therapeutic purpose specified in the Swiss type claims.[16]

Future outlook

The *Fenofibrate* and *Melatonin* cases highlight the importance of adding method of treatment claims (if not already present) when an international patent application enters the national phase in Australia. These claims can strengthen patent protection against skinny labelling strategies and prove determinative in infringement proceedings. The *Melatonin* case also emphasises the desirability for an originator in ensuring that its product label matches any patented indications.

A key unresolved issue is whether the same approach will be taken to biosimilar products. Biosimilar products are highly similar versions of approved biological medicines, derived from living organisms rather than chemical synthesis. Because of their different nature, Australia's regulatory approval process for biosimilars is different to that for small molecule products (the subject of all of the cases above). One of the effects of this is that government reimbursement for biological medicines is more likely to limited to use for particular indications, with stricter controls put in place around prescription/reimbursement. It remains to be seen whether these more complex factors may provide additional strategies to avoid a finding that there is reason to believe the product will be used off-label.

Additionally in several previous cases, the courts have noted that a blanket injunction on supply of generic products may not be an appropriate remedy in circumstances where infringement is found due to a reason to believe the product will be used for infringing purposes, but where there is also substantial non-infringing use of those products. In each case to date, the relevant patents have been found invalid, meaning no determination was made on injunctive relief. However, in *AstraZeneca AB v Apotex Pty Ltd*,[17] the Full Federal Court stated that:

> It may be undesirable to impose a blanket restraint upon a supplier who has reason to believe that only some consumers, perhaps a very small minority, may put the product that is or may be supplied to them to an infringing use. This is because the effect of such an injunction may be to deny a supplier access to a market, and consumers' access to a product, in circumstances where the supplier could have no reason to believe that the majority of consumers would put the product to an infringing use.[18]

Justice Nicholas made similar comments in the *Melatonin* case,[19] although the patent had expired. This is an important issue, and the courts may look to practitioners to propose creative and tailored solutions.

Conclusion and takeaway tips

While skinny labelling strategies can avoid infringement, they are subject to a number of legal and regulatory considerations. As demonstrated in recent case law, the format of the patent claims, the specific labelling practices, and the broader market context all influence the outcome of infringement cases. Future litigation may further refine the relevant principles.

For originators, practical steps that can be taken to strengthen the case against skinny labelling strategies include:

- ensuring that product labels align with patented indications
- including method of treatment claims when applications enter Australian national phase, if they are not present already

For patent prosecutors and litigators, the recent case law highlights critical considerations in the protection and enforcement of medical use patents, underscoring

the importance of carefully considering claim formats and interrelated regulatory issues in the protection and enforcement of medical use patents. The choice between method of treatment claims, Swiss type claims and EPC 2000 claims can significantly impact the outcome of infringement cases. In addition, recent judgments suggest that courts may expect creative, proportionate injunctions instead of blanket bans where non-infringing use exists. This requires innovative legal strategies to balance market access with patent enforcement.

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Footnotes

1. *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* (2013) 253 CLR 284; 304 ALR 1; [2013] HCA 50; BC201315312.
2. *Otsuka Pharmaceutical Co Ltd v Generic Health Pty Ltd (No 4)* (2015) 113 IPR 191; [2015] FCA 634; BC201505898.
3. *Biogen International GmbH v Pharmacor Pty Ltd* (2021) 399 ALR 255; 165 IPR 64; [2021] FCA 1591; BC202113898.
4. IP Australia, "5.5.4.7 'For use in', 'when used', and similar wording in claims", October 2023, accessed 3 February 2025 https://manuals.ipaustralia.gov.au/patent/5.5.4.7-for-use-in-when-used-and-similar-wording-in-claims.
5. Patents Act 1990 (Cth), s 117(2)(b).
6. Above n 1.
7. *Warner-Lambert Co LLC v Apotex Pty Ltd* (2014) 311 ALR 632; 106 IPR 218; [2014] FCAFC 59; BC201403651.
8. *Mylan Health Pty Ltd v Sun Pharma ANZ Pty Ltd* (2020) 279 FCR 354; 380 ALR 582; [2020] FCAFC 116; BC202006167.
9. *Neurim Pharmaceuticals (1991) Ltd v Generic Partners Pty Ltd (No 5)* [2024] FCA 360; BC202404360.
10. Above, at [30].
11. Above n 9, at [258].
12. Above n 8, at [222].
13. Above n 9, at [291].
14. Above n 9, at [293].
15. Above n 9, at [296].
16. Above n 9, at [297].
17. *AstraZeneca AB v Apotex Pty Ltd* (2014) 226 FCR 324; 107 IPR 177; [2014] FCAFC 99; BC201407020.
18. Above, at [444].
19. Above n 9, at [247].

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The Nobel Prize Winners 2024: a snapshot of their patent footprints

Yuchen Yao *and* ***David Hvasanov*** *SPRUSON & FERGUSON PTY LTD*

The much-anticipated Nobel Prize winners of 2024 were announced in October 2024, honouring the contributions that, as per Alfred Nobel's will of 1895, "have conferred the greatest benefit to humankind". In this article, we present selected patents of these winners, that at least to some extent, result from or lead to their celebrated works.

Chemistry

On 9 October 2024, the Royal Swedish Academy of Sciences announced that the 2024 Nobel Prize in chemistry was rewarded to David Baker for "for computational protein design", jointly with Demis Hassabis and John M Jumper "for protein structure prediction".

The Committee commented that:

> Proteins generally consist of 20 different amino acids, which can be described as life's building blocks. In 2003, **David Baker** succeeded in using these blocks to design a new protein that was unlike any other protein. Since then, his research group has produced one imaginative protein creation after another, including proteins that can be used as pharmaceuticals, vaccines, nanomaterials and tiny sensors.
> . . .
> In 2020, **Demis Hassabis** and **John Jumper** presented an AI model called AlphaFold2. With its help, they have been able to predict the structure of virtually all the 200 million proteins that researchers have identified. Since their breakthrough, AlphaFold2 has been used by more than two million people from 190 countries. Among a myriad of scientific applications, researchers can now better understand antibiotic resistance and create images of enzymes that can decompose plastic.[1]

These discoveries have enabled protein structures prediction and design, which significantly benefits humankind.

Below, we highlight two patent families with Baker and Jumper listed as co-inventors.

David Baker — self-assembling protein nanostructures displaying paramyxovirus and/or pneumovirus F proteins and their use

This patent family claims priority to US Provisional Application No 62/481,331 and has an earliest priority date of 4 April 2017. PCT Application No PCT/US2018/025880 includes nine independent claims. Claim 1 defines:

> 1. A nanostructure, comprising:
> (a) a plurality of first assemblies, each first assembly comprising a plurality of identical first poly peptides;
> (b) a plurality of second assemblies, each second assembly comprising a plurality of identical second polypeptides, wherein the second polypeptide differs from the first polypeptide;
> wherein the plurality of first assemblies non-covalently interact with the plurality of second assemblies to form a nanostructure; and
> wherein the nanostructure displays multiple copies of one or more paramyxovirus and/or pneumovirus F proteins, or antigenic fragments thereof, on an exterior of the nanostructure.

Claim 36 defines:

> 36. A method for generating an immune response to paramyxovirus and/or pneumovirus F protein in a subject, comprising administering to the subject in need thereof an effective amount of the nanostructure or immunogenic composition of any one of claims 1–29 and 34–35 to generate the immune response.

Claim 37 defines:

> 37. A method for treating or limiting a paramyxovirus and/or pneumovirus infection in a subject, comprising administering to the subject in need thereof an effective amount of the nanostructure or immunogenic composition of any one of claims 1–29 and 34–35 to, thereby treating or preventing paramyxovirus and/or pneumovirus infection in the subject.

The other independent claims include those directed to a recombinant nucleic acid, a recombinant expression vector, a recombinant host cell, an immunogenic composition and a process for assembling the nanostructures.

The invention relates to synthetic nanostructures and methods of designing such nanostructures. The first polypeptides and the second polypeptides are non-naturally occurring proteins that can be produced by any suitable means, including recombinant production or chemical synthesis.

There are no specific primary amino acid sequence requirements for the first and second polypeptides. The nanostructures can be used for generating an immune response to paramyxovirus and/or pneumovirus F protein in a subject, and/or treating or limiting a paramyxovirus and/or pneumovirus infection.

John M Jumper — machine learning for determining protein structures

This patent family claims priority from US Provisional Applications No 62/734,757, 62/734,773 and 62/770, 490 and has an earliest priority date of 21 September 2018. PCT Application No PCT/EP2019/074670 has seven independent claims.

Claim 1 defines:

> 1. A method performed by one or more data processing apparatus for determining a final predicted structure of a given protein, wherein the given protein includes a sequence of amino acids, wherein a predicted structure of the given protein is defined by values of a plurality of structure parameters, the method comprising:
> generating a plurality of predicted structures of the given protein, wherein generating a predicted structure of the given protein comprises:
> obtaining initial values of the plurality of structure parameters defining the predicted structure;
> updating the initial values of the plurality of structure parameters, comprising, at each of a plurality of update iterations:
> determining a quality score characterizing a quality of the predicted structure defined by current values of the structure parameters, wherein the quality score is based on respective outputs of one or more scoring neural networks which are each configured to process: (i) the current values of the structure parameters, (ii) a representation of the sequence of amino acids of the given protein, or (iii) both; and
> for one or more of the plurality of structure parameters:
> determining a gradient of the quality score with respect to the current value of the structure parameter; and
> updating the current value of the structure parameter using the gradient of the quality score with respect to the current value of the structure parameter; and determining the predicted structure of the given protein to be defined by the current values of the plurality of structure parameters after a final update iteration of the plurality of update iterations; and
> selecting a particular predicted structure of the given protein as the final predicted structure of the given protein.

Claim 16 defines:

> 16. A method performed by one or more data processing apparatus for determining a predicted structure of a given protein, wherein the given protein includes a sequence of amino acids, wherein the predicted structure of the given protein is defined by values of a plurality of structure parameters, the method comprising:
> obtaining initial values of the plurality of structure parameters defining the predicted structure;
> updating the initial values of the plurality of structure parameters, comprising, at each of a plurality of update iterations:
> determining a quality score characterizing a quality of the predicted structure defined by current values of the structure parameters, wherein the quality score is based on respective outputs of one or more scoring neural networks which are each configured to process: (i) the current values of the structure parameters, (ii) a representation of the sequence of amino acids of the given protein, or (iii) both; and
> for one or more of the plurality of structure parameters:
> determining a gradient of the quality score with respect to the current value of the structure parameter; and
> updating the current value of the structure parameter using the gradient of the quality score with respect to the current value of the structure parameter;
> determining the predicted structure of the given protein to be defined by the current values of the plurality of structure parameters after a final update iteration of the plurality of update iterations.

The other independent claims include those directed to a method of obtaining a ligand, a method of obtaining a polypeptide ligand, a method of identifying the presence of a protein mis-folding disease and relevant computer storage media storage devices and storing instructions.

Recognising that the biological function of a protein is determined by its structure and determining protein structures, may facilitate understanding life processes and the design of proteins. This invention relates to a system and a method of predicting protein structures.

For example, the method and system involve processing data to define an amino acid sequence of a certain protein, using machine learning algorithms to generate a final predicted structure of the protein. The final predicted structure defines an estimate of a three-dimensional configuration of the atoms in the amino acid sequence of the protein after the protein undergoes protein folding.

The invention vastly improves on previous methods of determining protein structures using physical experiments, which can be time-consuming and expensive. The invention may be used in drug development, as the protein structure can be used to determine how drugs bind to a protein.

Hassabis does not appear to be a co-inventor of any patent applications directly in relation to protein structure prediction.

Physiology or Medicine

On 7 October 2024, the Nobel Assembly at Karolinska Institutet announced that the 2024 Nobel Prize in Physiology or Medicine was rewarded to Victor Ambros and Gary Ruvkun "for the discovery of microRNA and its role in post-transcriptional gene regulation".

The Committee commented that:

> Victor Ambros and Gary Ruvkun were interested in how different cell types develop. They discovered microRNA, a new class of tiny RNA molecules that play a crucial role in gene regulation. Their groundbreaking discovery revealed a completely new principle of gene regulation that turned out to be essential for multicellular organisms, including humans. It is now known that the human genome codes for over one thousand microRNAs. Their surprising discovery revealed an entirely new dimension to gene regulation. MicroRNAs are proving to be fundamentally important for how organisms develop and function.[2]

We present two patent families having Ambros or Ruvkun listed as co-inventors. These two patent families relate to applications of microRNAs for potential treatment or diagnosis of human diseases and/or conditions.

Victor Ambros — isolating circulating microRNA (miRNA)

This patent family claims priority from US Provisional Application No 62/030,773 and has an earliest priority date of 30 July 2014. Granted US Patent No 9,896,683 has two independent claims:

> 1. A method for isolating RNA from a sample, the method comprising:
> digesting the sample with Proteinase K in the presence of chaotropic salts and detergent;
> extracting RNA from the sample using an alkaline phenol:chloroform extraction; and
> isolating the extracted RNA from the sample.
> 16. A method of detecting a level of a circulating miRNA in a subject, the method comprising:
> providing a sample comprising plasma or serum from a subject;
> lysing the sample;
> extracting RNA from the sample using ph 8.0 phenol:chloroform extraction;
> isolating the extracted RNA from the sample;
> and determining a level of the miRNA in the extracted RNA.

Recognising that the levels of specific microRNAs in normal and diseased tissue or in body fluids can provide information about the disease status of a patient, this patent family discloses methods of isolating RNAs from a sample, for example, blood from a human subject and methods of detecting a level of a circulating miRNA from plasma or serum sample of a human subject, using alkaline phenol:chloroform extraction. These methods may be able to significantly increase the yield of many assayable small RNAs such as miRNA, some by tenfold or more over standard methods at that time.

The cycle threshold values obtained using the invention were compared with those obtained by standard commercial methods at the time (miRNeasy and acid phenol) and was found that most of the cycle threshold values are lower, meaning that the invention provided better detection outcomes than existing standard methods.

The invention can provide a convenient, inexpensive, and non-invasive way to diagnose and/or track the progress of treatment of diseases that would be otherwise difficult to diagnose or treat.

Gary Ruvkun — methods and compositions for inhibiting detoxification response

This patent family claims priority from US Provisional Application No 62/210,685 and has an earliest priority date of 27 August 2015. Granted US Patent No 10 ,988,765 has three independent claims:

> 1. A method of attenuating a detoxification response and/or treating related symptoms in a subject in need of such treatment, the method comprising administering an inhibitor of expression of a daf-22 gene or its human homolog, SCPx.
> 12. A method of reducing toxicity of a pharmaceutical compound in a subject, the method comprising:
> co-administering to the subject, (1) said pharmaceutical compound, and (2) an effective amount of an inhibitor of expression of a daf-22 gene or its human homolog, SCPx, wherein the toxicity of the pharmaceutical compound is reduced in the presence of the inhibitor compared to the toxicity of the pharmaceutical compound administered in the absence of the inhibitor.
> 14. A method of increasing efficacy of a pharmaceutical compound in a subject, the method comprising:
> co-administering to the subject, (1) said pharmaceutical compound, and (2) an effective amount of an inhibitor of expression of a daf-22 gene or its homolog SCPx thereof, wherein the efficacy of said pharmaceutical compound is increased in the presence of the inhibitor compared to the efficacy of said pharmaceutical compound in the absence of said inhibitor.

This invention relates to the induction detoxification response and immune response in distinct somatic cells by germline mutations in translation components. The inventors identified genes of the activation pathways that are responsible for the induction of these responses, making the identified genes targets for attenuating translation defect induced detoxification and immune response. The invention discloses methods and compositions for attenuating detoxification response and immune response and/or treat related symptoms thereof by inhibiting expression of identified genes using inhibitors, particularly microRNA inhibitors. These methods may be used to treat subjects with translation defect to reduce toxicity or side effects of a pharmaceutical compound by inhibiting expression of identified genes or activation of identified pathways. They may also be used to increase efficacy of a pharmaceutical compound, which may induce translation defects and exhibit poor pharmacokinetics.

Conclusion

The patent system encourages innovation by providing incentives to innovators. For those with an interest in the most commemorated scientific and technological innovation in 2024 and intellectual property, this article makes for interesting reading.

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Footnotes

1. The Nobel Prize "Nobel Prize in Chemistry 2024" press release (9 October 2024) www.nobelprize.org/prizes/chemistry/2024/press-release/.
2. The Nobel Prize "Nobel Prize in Physiology or Medicine 2024" press release (7 October 2024) www.nobelprize.org/prizes/medicine/2024/press-release/.

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