FEDERAL COURT OF AUSTRALIA

Fidge v Pfizer Australia Pty Ltd [2024] FCA 161

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| File number: | VID 510 of 2023 |
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| Judgment of: | **ROFE J** |
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| Date of judgment: | 1 March 2024 |
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| Catchwords: | **PRACTICE AND PROCEDURE** – interlocutory applications for summary dismissal under s 31A(2) of the *Federal Court of Australia Act 1976* (Cth) and r 26.01(1)(a), (c) and (d) of the *Federal Court Rules 2011* (Cth) – applicant alleges that the respondents’ Covid-19 vaccines are, or contain, genetically modified organisms (**GMOs**) and should have been licenced under the *Gene Technology* ***Act*** *2000* (Cth) – whether the applicant has standing to seek an injunction pursuant to s 147(1) of the Act as “any other aggrieved person” – whether the intended scope and purpose of the Act is to regulate risks to the end user or recipient of a GMO product, in particular the safety and efficacy of a therapeutic GMO product — held: scope of the Act is confined to regulating specific “dealings” (as defined in the Act) with GMOs that pose a biosafety risk to people or the environment, and that the Act is intended to operate in a broader regulatory landscape with other statutes – held: standing under s 147(1) confined to persons aggrieved by the specific conduct regulated by the Act which could constitute an offence under that legislation – authorities on standing considered – whether standing can be established as a “necessary incident” of the applicant’s vocation as a medical practitioner, pursuant to *Ogle v Strickland* (1987) 13 FCR 306 – standing not established – applications for summary dismissal allowed. |
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| Legislation: | *Administrative Appeal Tribunal Act 1975* (Cth)  *Administrative Decisions (Judicial Review) Act 1977* (Cth)  *Customs Act 1901* (Cth)  *Federal Court of Australia Act 1976* (Cth)  *Gene Technology (Consequential Amendments) Act 2000* (Cth)  *Gene Technology Act 2000* (Cth)  *Judiciary Act 1903* (Cth)  *Therapeutic Goods Act 1989* (Cth)  *Trade Marks Act 1995* (Cth)  *Federal Court Rules 2011* (Cth)  *Archaeological and Aboriginal Relics Preservation Act 1972* (Vic) |
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| Cases cited: | *Alcan (NT) Alumina Pty Ltd v Commissioner of Territory Revenue* (2009) 239 CLR 27  *Antsis v Secretary, Department of Family and Community Services* (2002) 123 FCR 536  *Argos Pty Ltd v Corbell* (2014) 254 CLR 394  *Assa Abloy Australia Pty Ltd v Australian Lock Company Pty Ltd* (2005) 147 FCR 126  *Australian Conservation Foundation Inc v Commonwealth*(1980) 146 CLR 493  *Australian National Imams Council Ltd v Australian Communications and Media Authority* (2022) 404 ALR 323  *Australian Vaccination-Risks Network Inc v Secretary, Department of Health* (2022) 292 FCR 1  *Australian Vaccination-Risks Network Inc v Secretary, Department of Health* [2022] FCA 320  *Bateman’s Bay Local Council Aboriginal Land Council v Aboriginal Community Benefit Fund* (1998) 194 CLR 247  *Cameron v Human Rights and Equal Opportunity Commission* (1993) 46 FCR 509  *CIC Insurance Ltd v Bankstown Football Club Ltd* (1997) 187 CLR 384  *Dey v Victorian Railways Commissioners* (1949) 78 CLR 62  *General Steel Industries Ltd v Commissioner for Railways* (1964) 112 CLR 125  *Health World Ltd v Shin-Sun Australia Pty Ltd* (2010) 240 CLR 590  *Hobart International Airport Pty Ltd v Clarence City Council* (2022) 399 ALR 214  *Miller v Cimic Group Ltd* [2015] FCA 587  *Ogle v Strickland* (1987) 13 FCR 306  *Onus v Alcoa of Australia Ltd* (1981) 149 CLR 27  *Powell v Birmingham Vinegar Brewery Co Ltd* [1894] AC 8  *Project Blue Sky Inc v Australian Broadcasting Authority* (1998) 194 CLR 355  *Re McHattan and Collector of Customs* (1977) 18 ALR 154  *Right to Life Association (NSW) Inc v Department of Human Services and Health* (1994) 52 FCR 209  *SmithKline Beecham (Australia) Pty Ltd v Chapman* [2002] FCA 674  *Spencer v Commonwealth* (2010)241 CLR 118  *SZTAL v Minister for Immigration and Border Protection* (2017) 262 CLR 362  *Tooheys Ltd v Minister for Business and Consumer* (1981) 36 ALR 64  *Truth About Motorways Pty Ltd v Macquarie Infrastructure Investment Management Ltd* (2000) 200 CLR 591  *Unions NSW v New South Wales* (2023) 407 ALR 277  *Walton v Gardiner* (1993) 177 CLR 378 |
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| Division: | General Division |
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| Registry: | Victoria |
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| National Practice Area: | Commercial and Corporations |
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| Sub-area: | Regulator and Consumer Protection |
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| Number of paragraphs: | 137 |
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| Date of last submissions: | 26 October 2023 |
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| Date of hearing: | 23 October 2023 |
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| Counsel for the Applicant: | Mr J M Manner |
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| Solicitor for the Applicant: | PJ O’Brien & Associates |
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| Counsel for the First Respondent: | Mr B F Quinn with Ms J Lindgren |
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| Counsel for the Second Respondent: | Mr A A Segal |
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| Solicitor for the Second Respondent: | Hogan Lovells |

ORDERS

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|  | | VID 510 of 2023 |
| BETWEEN: | JULIAN FIDGE  Applicant | |
| AND: | PFIZER AUSTRALIA PTY LTD  First Respondent  MODERNA AUSTRALIA PTY LTD  Second Respondent | |

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| order made by: | ROFE J |
| DATE OF ORDER: | 1 MARCH 2024 |

THE COURT ORDERS THAT:

1. Pursuant to s 31A(2) of the *Federal Court of Australia Act 1976* (Cth) and r 26.01(1)(a), (c) and (d) of the *Federal Court Rules 2011* (Cth), the proceedings against the first respondent and second respondent be dismissed on the grounds that the applicant has no reasonable prospect of successfully prosecuting the proceedings against the respondents because the applicant is not an “aggrieved person” within the meaning of s 147(1) of the *Gene Technology Act 2001* (Cth), and otherwise has no standing to bring the proceeding.

2. The applicant pay the first respondent’s and second respondent’s costs of, and incidental to, the proceeding.

Note: Entry of orders is dealt with in Rule 39.32 of the *Federal Court Rules 2011*.

REASONS FOR JUDGMENT

ROFE J

##### 1. INTRODUCTION

1 On 6 July 2023, the applicant filed an application seeking injunctive relief against the first respondent, **Pfizer** Australia Pty Ltd, and the second respondent, **Moderna** Australia Pty Ltd, pursuant to s 147(1) of the *Gene Technology Act 2000* (Cth) (**GTA** or the **Act**). The application was amended on 14 August 2023.

2 Relief is sought on the basis that, according to the applicant, the Covid-19 vaccines sponsored by Moderna and Pfizer are, or contain, genetically modified organisms (as defined in s 10 of the Act) (**GMOs**) and therefore the respondents were required to obtain licences under the Act to supply these products for administration to patients but failed to do so. Pfizer and Moderna deny that the vaccines are, or contain, GMOs. The position of the relevant regulator under the Act, the Office of the Gene Technology Regulator (**OGTR**), is that the vaccines are not GMOs and therefore the respondents were not required to obtain licences. The applicant has not sought any relief against the OGTR.

3 The respondents contend that the applicant is not an “aggrieved person” within the meaning of s 147(1) of the Act and therefore lacks standing to bring the application. On that basis, the respondents have sought summary judgment against the applicant pursuant to s 31A(2) of the *Federal Court of Australia Act 1976* (Cth) (**FCA Act**)and r 26.01(1) of the *Federal Court* ***Rules*** *2011* (Cth).

4 The applicant, Dr Julian Fidge, asserts that he has standing under s 147(1) of the Act on a number of grounds, including his:

(a) “professional capacity” as a general practitioner (**GP**) who has overseen the administration of more than 10,000 Covid-19 vaccinations;

(b) “personal capacity” as the recipient of three Pfizer vaccines;

(c) “private capacity” due to “experiencing severe moral injury, mental harm and suffering” by reason of the reported side effects of the Pfizer and Moderna vaccines; and

(d) “public capacity” as a doctor subject to a duty to preserve human life and protect the health and safety of the public.

5 On 10 August 2023, I made orders that the respondents’ applications for summary judgment be heard on 23 October 2023, separately from the applicant’s application for interlocutory injunctive relief.

6 For the reasons that follow, I do not consider that the applicant has established that he has standing to bring the interlocutory application and therefore I will allow the respondents’ applications for summary judgment.

##### 2. BACKGROUND

7 Pfizer is the sponsor of three Covid-19 vaccines approved by the Therapeutic Goods Administration (**TGA**) under the ***Therapeutic Goods Act*** *1989* (Cth) which are registered on the Australian Therapeutic Goods Register (**ARTG**), and which are available in Australia. The ARTG registrations are:

(a) COMIRNATY (tozinameran) (Monovalent):

(i) ARTG ID 346290;

(ii) ARTG ID 377111;

(iii) ARTG ID 377110; and

(iv) ARTG ID 393433.

(b) COMIRNATY Original/Omicron BA.1 (tozinameran and riltozinameran) (Bivalent 1) – ARTG ID 394890; and

(c) COMIRNATY Original/Omicron BA.4-5 (tozinameran and famtozinameran) (Bivalent 2) – ARTG ID 400874.

(**Pfizer vaccines**)

8 Moderna has two Covid-19 vaccines which have been approved by the TGA and which are available in Australia. The ARTG registrations are:

(a) SPIKEVAX (elasomeran):

(i) ARTG ID 370599;

(ii) ARTG ID 388244; and

(iii) ARTG ID 388245.

(b) SPIKEVAX BIVALENT ORIGINAL/OMICRON (elasomeran and imelasomeran):

(i) ARTG ID 389513; and

(ii) ARTG ID 396452.

(c) SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 (elasomeran/davesomeran):

(i) ARTG ID 399552;

(ii) ARTG ID 399553; and

(iii) ARTG ID 406730.

(**Moderna vaccines**)

9 The Pfizer and Moderna vaccines have been endorsed by the Australian Technical Advisory Group on Immunisation and the Australian Medical Association (**AMA**).

10 As at 23 August 2023, over 65 million Covid-19 vaccine doses had been administered in Australia and a large proportion of those vaccines were either Pfizer vaccines or Moderna vaccines.

11 Dr Fidge is a practicing GP and pharmacist. He provided evidence by way of two affidavits affirmed on 6 July 2023 and 11 September 2023.

12 Dr Fidge gave evidence that he received three doses of the Pfizer vaccine and his two children also received doses of the Pfizer vaccine. Neither he nor his children received doses of the Moderna vaccine. Dr Fidge also gave evidence that he personally provided, or oversaw, the administration of more than 10,000 doses of Covid-19 vaccines to patients.

13 By way of summary, the applicant seeks interlocutory relief upon the bases that:

(a) each of the vaccines are, or contain, GMOs as defined by s 10 of the Act;

(b) in order to “deal with” the vaccines as defined in s 10 of the Act, the respondents were required by s 40 of the Act to obtain licences from the OGTR but have failed or refused to do so;

(c) the respondents knew at the relevant times that:

(i) the vaccines are, or contain, GMOs; and

(ii) the vaccines were not licensed pursuant to s 40 of the Act.

(d) the respondents dealt with and continue to deal with the vaccines in Australia by, among other things, importing, distributing and transporting the vaccines (**Vaccine Dealings**);

(e) these Vaccine Dealings in the absence of a licence are unlawful pursuant to s 32 and s 33 of the Act (the **Breaches**);

(f) Dr Fidge is an “aggrieved person” within the meaning of s 147(1) of the Act in respect of the Breaches because, as stated in his first affidavit, he “recommended to patients, and received these Products [himself], without being fully informed that this new class of drugs is capable of transferring genetic material” (which he considers poses significant adverse health risks).

14 The respondents deny that the vaccines are GMOs or that they have committed any wrongdoing under the Act. In summary, Pfizer’s position is that:

(a) the vaccines are not GMOs because they do not satisfy the definition of “organism” under the GTA; and

(b) the position of the OGTR is that the vaccines are not GMOs.

15 The parties agreed that the question of whether Dr Fidge has standing is premised on the assumption (for the purposes of the respondents’ applications) that the vaccines are GMOs and the respondents therefore breached the Act by dealing with the vaccines. Thus, for the purposes of this summary judgment application, I do not need to determine whether the vaccines are GMOs or the resulting question of whether Pfizer and Moderna breached the Act by failing to obtain licences for the Vaccine Dealings. I have therefore disregarded any evidence filed by the parties that address whether the vaccines are GMOs.

##### 3. SUMMARY JUDGMENT

16 The respondents seek summary judgment under s 31A(2) of the FCA Act and r 26.01(1) of the Rules on the basis that the applicant lacks standing to seek relief under s 147(1) of the Act.

17 Section 31A of the FCA Act provides:

**31A Summary judgment**

(1) The Court may give judgment for one party against another in relation to the whole or any part of a proceeding if:

(a) the first party is prosecuting the proceeding or that part of the proceeding; and

(b) the Court is satisfied that the other party has no reasonable prospect of successfully defending the proceeding or that part of the proceeding.

(2) The Court may give judgment for one party against another in relation to the whole or any part of a proceeding if:

(a) the first party is defending the proceeding or that part of the proceeding; and

(b) the Court is satisfied that the other party has no reasonable prospect of successfully prosecuting the proceeding or that part of the proceeding.

(3) For the purposes of this section, a defence or a proceeding or part of a proceeding need not be:

(a) hopeless; or

(b) bound to fail;

for it to have no reasonable prospect of success.

(4) This section does not limit any powers that the Court has apart from this section.

(5) This section does not apply to criminal proceedings.

18 Rule 26.01(1) of the Rules provides:

**26.01 Summary judgment**

(1) A party may apply to the Court for an order that judgment be given against another party because:

(a) the applicant has no reasonable prospect of successfully prosecuting the proceeding or part of the proceeding; or

(b) the proceeding is frivolous or vexatious; or

(c) no reasonable cause of action is disclosed; or

(d) the proceeding is an abuse of the process of the Court; or

(e) the respondent has no reasonable prospect of successfully defending the proceeding or part of the proceeding.

19 In ***Unions NSW*** *v New South Wales* (2023) 407 ALR 277, Kiefel CJ, Gageler, Gordon, Gleeson and Jagot JJ stated at [15]:

Exceptional categories aside, there can be no “matter” within the meaning of Ch III of the Constitution unless “there is some immediate right, duty or liability to be established by the determination of the Court” in the administration of a law and unless the determination can result in the Court granting relief which both quells a controversy between parties and is available at the suit of the party seeking that relief. Standing to seek relief is in that way “subsumed within the constitutional requirement of a ‘matter’”.

(Citations omitted.)

20 In expressing the same principle, Gageler and Gleeson JJ in ***Hobart International*** *Airport Pty Ltd v Clarence City Council* (2022) 399 ALR 214at [49] explained the concept of standing:

Standing, in the sense of a right to seek from a court an order that would operate to resolve the controversy, is in that way inseparable from justiciability and, therefore, is intrinsic to the existence of the matter without which the federal jurisdiction of the court to make the order cannot exist. That is what has been meant when it has often been said that standing is “subsumed within the constitutional requirement of a matter”.

21 If an applicant lacks standing to bring the proceeding, then there can be no matter before the Court and therefore there can be no prospects of succeeding in that application. Relatedly, an abuse of process arises where the applicant’s case is “foredoomed to fail” which will always be the case where the applicant lacks standing: see *Miller v Cimic Group Ltd* [2015] FCA 587 at [14] (per Reeves J) referring to the High Court decision of *Walton v Gardiner* (1993) 177 CLR 378 at 393 (per Mason CJ, Deane and Dawson JJ).

22 It is clear that without standing an applicant has no prospect of success, no reasonable cause of action and the proceeding is an abuse of process. The question of standing therefore entirely resolves the question of whether summary judgment is available, irrespective of where the bar is set for assessing the prospects of the applicant’s success on the substantive matter. As such, it is unnecessary to address the dispute that arose between the respondents and the applicant regarding the construction of s 31A of the FCA Act and whether the cases relied upon by the applicant that pre-dated the insertion of s 31A, such as *Dey v Victorian Railways Commissioners* (1949) 78 CLR 62 and *General Steel Industries Ltd v Commissioner for Railways* (1964) 112 CLR 125, remained good law after *Spencer v Commonwealth* (2010)241 CLR 118.

##### 4. STANDING

23 What is required to establish standing varies depending upon the relief sought. Where the source of relief is a statute, the requirements for standing will be expressly or implicitly provided by the statute: *Hobart International* at [56] (per Gageler and Gleeson JJ).

24 Although the requirements for standing for relief under a statute are provided for by that act, the authorities on standing more broadly are nonetheless relevant to provide guidance on those requirements.

25 In *Hobart International*, Gageler and Gleeson JJat [65] explained the basic concept of standing and clarified that the different expressions of standing reflected in the case law are, in fact, one consistent test:

Though the expression of standing has been [described] variously in terms of a “sufficient interest”, a “sufficient material interest”, a “special interest” or a “real interest”, the conception of standing developed through that body of case law has been consistent. That conception of standing has involved recognition that a person who does not claim to have a legal right or equitable interest to be vindicated by a declaration or other order that would resolve a controversy about a right or obligation may yet have a material interest in seeking the order. In this context, an interest will be “material” if the person “is likely to gain some advantage, other than the satisfaction of righting a wrong, upholding a principle or winning a contest, if [the order is made] or to suffer some disadvantage, other than a sense of grievance or a debt for costs, if [the order is not made]”. Depending on the totality of the circumstances, the material interest that the person has in seeking the order may be sufficient to justify a court entertaining the proceeding in which the order is sought.

26 In ***Onus v Alcoa*** *of Australia Ltd* (1981) 149 CLR 27 at 35, Gibbs CJ identified the conflicting considerations when considering questions of standing:

On the one hand it may be thought that in a community which professes to live by the rule of law the courts should be open to anyone who genuinely seeks to prevent the law from being ignored or violated. On the other hand, if standing is accorded to any citizen to sue to prevent breaches of the law by another, there exists the possibility, not only that the processes of the law will be abused by busybodies and cranks and persons actuated by malice, but also that persons or groups who feel strongly enough about an issue will be prepared to put some other citizen, with whom they have had no relationship, and whose actions have not affected them except by causing them intellectual or emotional concern, to very great cost and inconvenience in defending the legality of his actions.

27 Most recently in *Australian Vaccination-Risks Network Inc v Secretary, Department of Health* (2022) 292 FCR 1 (***AVN FC***), Rares J at [30]-[32] (Katzmann J and Wigney J agreeing) summarised the requirements of the special interest test:

[30] While there are many cases dealing with what is a sufficient basis to sue, a leading authority is *Australian Conservation Foundation Incorporated v The Commonwealth* (1980) 146 CLR 493. Gibbs J, with whom Mason J substantially agreed in concurring reasons (at 547) and Stephen J formed the majority. Gibbs J noted (at 519) that there the plaintiff, the **Foundation**, had about 6,500 members drawn from around the Commonwealth, received annual grants from the Commonwealth as a contribution to its administrative expenses that formed a not insubstantial proportion of its income, and endeavoured to influence national policy on matters affecting the environment, for which purpose it had made submissions to governments and public authorities in respect of environmental matters, including under the statute the subject of the proceeding in the High Court.

[31] The majority affirmed the decision of Aickin J at trial that the Foundation lacked standing to bring the proceeding, *first*, because nothing in the statutory scheme envisaged that a person other than those whom the statute recognised as having an interest should be able to challenge decisions made under it (at 524–525 per Gibbs J, 547 per Mason J and see at 546 per Stephen J) and, *secondly*, on the basis that, as Gibbs J held at 526 (and see too 547 per Mason J and at 539 per Stephen J):

It is quite clear that **an ordinary member of the public, who has no interest other than that which any member of the public has in upholding the law, has no standing to sue to prevent the violation of the public right, or to enforce the performance of a public duty**. There is no difference, in this respect, between the making of the declaration and the grant of an injunction. The assertion of public rights and the prevention of public wrongs by means of those remedies is the responsibility of the Attorney-General who may proceed either ex officio or on the relation of a private individual. **A private citizen who has no special interest is incapable of bringing proceedings for that purpose, unless of course, he is permitted by statute to do so.**

(Emphasis added.)

[32] In addition, Gibbs J said (at 530) and Mason J expressly agreed (at 548) that:

A belief, however strongly felt, that the law generally or a particular law, should be observed, or that the conduct of a particular kind should be prevented does not suffice to give its possessor locus standi.

28 In *Australian Vaccination-Risks Network Inc v Secretary, Department of Health* [2022] FCA 320 (***AVN***), the applicant commenced proceedings seeking mandamus to require the Secretary of the Department of Health to consider whether to exercise his powers under ss 29D, 30(1)(a) and (2)(a) of the Therapeutic Goods Act to cancel or suspend the provisional registration of three Covid-19 vaccines, including the Pfizer and Moderna vaccines. Mr Neugebauer, who was not a member of AVN, sought to be joined to the proceeding. The primary judge and the Full Court held that neither AVN nor Mr Neugebauer had standing to bring the proceeding either under s 39B of the *Judiciary Act 1903* (Cth) or as a “person aggrieved” under the *Administrative Decisions (Judicial Review) Act 1977* (Cth) (**ADJR Act**).

29 The AVN asserted standing on the basis that, among other things, its objectives are to facilitate discussion, represent members and lobby governments with respect to concerns about the safety and efficacy of vaccines. Mr Neugebauer asserted standing on the basis that his employment had been terminated for failing to comply with a vaccine mandate and that he held strong views about the risks posed by vaccines.

30 In *AVN FC*, Rares J held at [41]:

As happened in *Australian Conservation Foundation* 146 CLR 493, AVN was seeking to enforce public law remedies, to prevent or correct what it asserted was a public wrong, in respect of the duties which the Secretary had under the *Therapeutic Goods Act*, as a matter of principle and as part of an endeavour to achieve its objects and uphold the values which it was formed to promote: cf 146 CLR at 530. It follows that, as her Honour correctly found, AVN had no special interest, other than that of any member of the public, and, therefore, did not have standing to challenge the decisions the subject of its application below.

31 Further, the primary judge concluded that Mr Neugebauer lacked standing because his interest was “properly characterised as emotional in nature and its connection with the subject matter of the Judicial Review Case is too remote”: *AVN* at [144] (per Perry J).

32 Although *AVN* has some parallels to the present case, it did not concern standing under the GTA and the applicant’s primary asserted basis for standing in this case, his vocation as a medical practitioner, is different to that of both the applicants in *AVN*.

33 There are two principles that emerge from the case law that are highly relevant to whether the applicant has standing under the GTA to bring this proceeding:

(a) An aggrieved person must be able to “show a grievance which will be suffered as a result of the decision complained of beyond that which he or she has as an ordinary member of the public”: *AVN* at [106] (per Perry J), quoting *Tooheys Ltd v Minister for Business and Consumer* (1981) 36 ALR 64 at 79 (per Ellicott J) (cited with approval in *Argos Pty Ltd v Corbell* (2014) 254 CLR 394 at [28] (per French CJ and Keane J), [61] (per Hayne and Bell JJ)).

(b) An emotional, moral or intellectual interest in the decision, however strong, is not sufficient to constitute a special interest: *Onus v Alcoa* at 35 (per Gibbs CJ); *Australian Conservation Foundation Inc v Commonwealth*(1980) 146 CLR 493 at 530 (per Gibbs J), 548 (per Mason J) (***ACF***).

34 Accordingly, the applicant must establish that the grievance he will suffer as a result of the Breaches is beyond that of an ordinary member of the public and is more than a mere emotional or intellectual concern. What is required to demonstrate that Dr Fidge has a sufficient interest beyond that of an ordinary member of the public will depend on what the GTA expressly or implicitly requires to be established: *Hobart* *International* at [56] (per Gageler and Gleeson JJ). This requires an examination of the text, scope and purpose of the GTA.

##### 5. THE GTA

35 The applicant relies on s 147(1) of the Act, which states:

If a person has engaged, is engaging, or is about to engage in any conduct that is or would be an offence against this Act or the regulations, the Federal Court of Australia (the ***Court***) may, on the application of the Regulator or *any other aggrieved person*, grant an injunction restraining the person from engaging in the conduct.

(Emphasis added.)

36 There are no decided cases on s 147(1) and the phrase “any other aggrieved person” is not defined in the Act. The High Court said in ***Health World*** *Ltd v Shin-Sun Australia Pty Ltd* (2010) 240 CLR 590 at [21] (per French CJ, Gummow, Heydon and Bell JJ) that the “meaning of a general expression like ‘aggrieved’ will depend on an examination of the language of the particular statute in which it appears”. Therefore, whether the applicant is an “any other aggrieved person” turns on the proper construction of the Act according to ordinary principles of statutory construction.

###### 5.1 Principles of statutory construction

37 The applicable principles of statutory construction were not in dispute.

38 The correct approach was set out by Kiefel CJ, Nettle and Gordon JJ in ***SZTAL****v Minister for Immigration and Border Protection* (2017) 262 CLR 362 at [14]:

The starting point for the ascertainment of the meaning of a statutory provision is the text of the statute whilst, at the same time, regard is had to its context and purpose. Context should be regarded at this first stage and not at some later stage and it should be regarded in its widest sense. This is not to deny the importance of the natural and ordinary meaning of a word, namely how it is ordinarily understood in discourse, to the process of construction. Considerations of context and purpose simply recognise that, understood in its statutory, historical or other context, some other meaning of a word may be suggested, and so too, if its ordinary meaning is not consistent with the statutory purpose, that meaning must be rejected.

39 Their Honours cited *CIC Insurance Ltd v* ***Bankstown*** *Football Club Ltd* (1997) 187 CLR 384 at 408 (per Brennan CJ, Dawson, Toohey and Gummow JJ), *Project Blue Sky Inc v Australian Broadcasting Authority* (1998) 194 CLR 355 at [69]-[71] (per McHugh, Gummow, Kirby and Hayne JJ) and *Alcan (NT) Alumina Pty Ltd v Commissioner of Territory Revenue* (2009) 239 CLR 27 at [47] (per Hayne, Heydon, Crennan and Kiefel JJ). Pfizer put particular emphasis on the following observations in *Bankstown* at 408:

the modern approach to statutory interpretation (a) insists that the context be considered in the first instance, not merely at some later stage when ambiguity might be thought to arise, and (b) uses "context" in its widest sense to include such things as the existing state of the law and the mischief which, by legitimate means such as those just mentioned, one may discern the statute was intended to remedy. Instances of general words in a statute being so constrained by their context are numerous. In particular, as McHugh JA pointed out in *Isherwood v Butler Pollnow* *Pty Ltd*,*if the apparently plain words of a provision are read in the light of the mischief which the statute was designed to overcome and of the objects of the legislation, they may wear a very different appearance.* Further, inconvenience or improbability of result may assist the court in preferring to the literal meaning an alternative construction which, by the steps identified above, is reasonably open and more closely conforms to the legislative intent.

(Citations omitted.) (Emphasis added by Pfizer.)

40 In an already cited passaged, the High Court in *Health World* said at [21]:

the meaning of a general expression like “aggrieved” will depend on an examination of the language of the particular statute in which it appears. That examination will reveal the subject, scope and purpose of the statute, and the meaning of “aggrieved” may vary as the subject, scope and purpose varies.

(Citations omitted.)

41 The Court went on to examine at [22]-[27] the “concern” or purpose revealed by the ***Trade Marks Act*** *1995* (Cth), and how the legislative scheme sought to achieve that purpose. That is the enquiry that must now be undertaken for the GTA: assessing the subject, scope and purpose of the GTA and how the legislative scheme seeks to achieve that purpose.

###### 5.2 Submissions as to purpose and scope of the Act

42 Pfizer contends that the purpose of the Act is to confine standing to persons aggrieved by the specific conduct regulated by the GTA which could constitute an offence against that legislation. Pfizer says that s 147(1) is not intended to afford a broad remedy for any person with either general or specific grievances with GMOs arising from activities, uses or conduct not regulated by the GTA. This includes health and safety risks to consumers that may only be indirectly related to dealings under the Act, especially where such risks are specifically regulated by other statutory regimes or bodies. Moderna did not make submissions on the construction of the Act.

43 The applicant contends that the Act has a far broader purpose which includes the general protection of the health and safety of the public. The applicant’s asserted bases for standing all depend on a concern that by being or containing GMOs, the vaccines have the potential to harm patients who are administered a dose of the vaccine. This is a concern with the health of the consumer of a vaccine. Thus, the critical question to determine with respect to the Act is the extent to which, if any, it regulates risks to the end user or recipient of a GMO product, in particular the safety and efficacy of a therapeutic GMO product. The answer to that question will largely resolve whether the applicant is an “aggrieved person” within the meaning of s 147(1) of the Act or, put differently, has a special interest in the subject matter of the proceeding such as to have standing.

###### 5.3 Scheme and operation of the Act

44 The object of the Act is set out in s 3:

The object of this Act is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

45 Section 4 provides that the object of the Act is to be achieved through a regulatory framework which:

(aa) provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation; and

(a) provides an efficient and effective system for the application of gene technologies; and

(b) operates in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GM products.

Note: Examples of the schemes mentioned in paragraph (b) are those that regulate food, agricultural and veterinary chemicals, industrial chemicals and therapeutic goods.

46 A number of definitions of terms used in the Act are set out in s 10. Section 10 defines the phrase “deal with” exhaustively:

***deal with***, in relation to a GMO, means the following:

(a) conduct experiments with the GMO;

(b) make, develop, produce or manufacture the GMO;

(c) breed the GMO;

(d) propagate the GMO;

(e) use the GMO in the course of manufacture of a thing that is not the GMO;

(f) grow, raise or culture the GMO;

(g) import the GMO;

(h) transport the GMO;

(i) dispose of the GMO;

and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (i).

47 Part 3 of the Act establishes the OGTR and sets out its functions and powers in s 27 and s 28.

48 “Dealings with GMOs” are regulated in Pt 4 of the Act. In relation to the “dealings” with GMOs that the GTA seeks to regulate for the purposes of managing risks posed by gene technology, the word “dealing” is not defined.

49 However, the definition of “deal with” covers various categories of conduct or activities involving the handling of GMOs in research, agricultural and commercial settings. It is directed to conduct or activities which could give rise to occupational health and safety risks for individuals who are handling a GMO, or conduct or activities which could lead to the release of a GMO into the environment. Those matters fall within the general category of biosafety risks.

50 The GTA regulates the dealings defined in s 10 in four main ways:

(a) by a licensing system established in Pt 5;

(b) by inclusion of dealings on the GMO register, together with any applicable licence conditions (Pt 6, Div 3);

(c) by designation of a dealing as a notifiable low risk dealing which might have certain requirements set out in the *Gene Technology Regulations 2001* (Cth) (Pt 6, Div 2); and

(d) by an emergency dealing determination issued by the Minister for the Department of Health and Aged Care (Pt 5A).

51 Part 4 of the GTA sets out the offence provisions, the titles of which are set out below:

32. Person not to deal with a GMO without a licence

33. Person not to deal with a GMO without a licence – strict liability offence

34. Person must not breach conditions of a GMO licence

35. Person must not breach conditions of a GMO licence – strict liability offence

35A. Person must not breach conditions of emergency dealing determination

35B. Person must not breach conditions of emergency dealing determination – strict liability offence.

36. Person must not breach conditions on GMO Register

37. Offence relating to notifiable low risk dealings

38. Aggravated offences – significant damage to health or safety of people or to the environment

52 As noted above, the applicant alleges that the respondents have contravened s 32 and s 33 by dealing with the vaccines without a licence.

53 Section 32(1) relevantly provides that a person commits an offence if (a) “the person deals with a GMO, knowing that it is a GMO” and (b) “the dealing with the GMO by the person is not authorised by a GMO licence, and the person knows or is reckless as to that fact” and then specifies a number of further requirements. Section 33 is worded in similar terms but is a strict liability offence.

54 Sections 32 and 33 only make it an offence for specified dealings to be undertaken without a licence. That is, s 32 and s 33, like all the other offences provided by the Act, are confined to the specified dealings defined in s 10. Part 5, which sets out the licensing system under the Act, and Div 3 of Pt 6, which sets out the GMO register, is similarly confined to “dealings” as defined by s 10.

55 It is not an offence against the GTA for anyone to administer, supply for administration, or facilitate the administration of a GMO without a licence. That is because the definition of “deal with” in s 10 makes no reference to the use or administration of a GMO for its ultimate intended purpose, such as consumption or ingestion in the case of GMO food, or administration of GMO products to patients in the case of medication. That observation is critical because, as will be discussed below, the applicant’s various bases for standing all depend on concerns regarding the safety of administering GMO vaccines to patients and not, for example, the risks posed by the transportation and disposal of GMO vaccines. The applicant nonetheless contends that the Act is concerned with the ultimate intended purpose of the GMO and the risks posed to consumers.

###### 5.4 Purpose of the Act

56 The object of the Act in s 3 makes clear that the Act is intended to protect the health and safety of people and the environment. Many acts seek to protect the health and safety of the public or the environment in a general sense, such as various state road safety acts, environmental legislation and occupational health and safety legislation. However, that general objective of protecting health and safety or the environment is typically qualified in these acts by some particular risk and specific means of managing that risk — they are not concerned with protecting health and safety at large.

57 I consider that the GTA seeks to protect the health and safety of people in a limited sense only, by identifying certain risks posed by gene technology (not all risks) and managing those risks through regulating certain dealings with GMOs. The mischief which the statute was designed to overcome was, as explained below, to fill gaps with respect to the regulation of GMOs as part of a broader regulatory scheme. The Act was not, and is not, intended to operate as the sole statute that regulates each and every issue with respect to GMOs.

58 The applicant contends that the object in s 3 to “protect the health and safety of people” is unlimited and not qualified by the means sought to achieve that purpose. The thrust of much of the applicant’s submissions proceeded on the basis that his standing could be established merely because Dr Fidge’s purpose as a doctor aligns with the purpose of the Act. As the applicant’s counsel, Mr Manner, put it: “The Act is directed towards the health and safety of Australians, and so is Dr Fidge”.

59 However, even if I were to accept that the purpose of the Act was simply to “protect the health and safety of people” in an unqualified sense, that does not take the applicant very far. Standing under the Act is not derived from a person being able to identify that their interests align with the general purpose of the Act. Standing is conferred by s 147(1) which requires that a person show they are aggrieved by “conduct that is or would be an offence against this Act”.

60 The fact that there are activities or conduct relating to GMOs that do not fall within the scope of the “dealings” regulated by the GTA is no legislative oversight. Section 4(b) and its accompanying note (set out above) explains that the GTA is not the exclusive regulatory regime applicable to GMOs but is intended to operate in conjunction with other statutory schemes, including the scheme to regulate therapeutic goods, such as vaccines, established under the Therapeutic Goods Act.

61 Section 4(b) is a clear recognition that the Act does not cover the field in respect of GMOs. The legislative history and mischief that the Act was intended to address, as identified in the Explanatory Memorandum, strongly supports this conception of the Act as one piece in a broader regulatory approach to GMOs, not a one stop shop for all issues related to GMOs.

###### 5.5 Context

62 Thecontext in which the GTA was introduced confirms the confined scope of dealings intended to give rise to an offence under the legislation, which may in turn provide an aggrieved person with standing under s 147(1).

63 Gene technology has been utilised in research and commercial applications in Australia for several decades. When the Gene Technology **Bill** 2000 (Cth) was introduced, gene technology was already regulated by the following statutory regulators:

|  |  |
| --- | --- |
| **Application** | **Statutory regulator** |
| Foods | Australia New Zealand Food Authority (**ANZFA**) |
| Therapeutic goods and human gene therapy | Therapeutic Goods Administration |
| Agricultural and veterinary chemicals | National Registration Authority |
| Industrial chemicals | National Industrial Chemicals Notification and Assessment Scheme |
| Imports/exports | Australian Quarantine and Inspection Service and the Australian Customs Service |

64 A non-statutory advisory body, the Genetic Manipulation Advisory Committee (**GMAC**), also provided support to the statutory regulators. Section 2 of the Explanatory Memorandum is titled “Problem” and explains that there were concerns GMAC was not adequately empowered to regulate the growth in gene technology. The Explanatory Memorandum explained the choice of regulatory model:

When established, the GMAC administrative system was designed to deal with research into GMOs, or utilisation of GMOs, conducted within contained facilities.

Currently in Australia, the application of gene technology is quite different, as there has been an emergence of GMOs which do not fall within the legislative mandate of existing regulators. Also, there is an increasing shift from work being conducted in laboratories to GMOs being released into the environment either for the purposes of field trials or for commercial release.

…

Activities with GMOs and GM products that are currently unregulated

Examples of ‘gap’ GMOs which are currently overseen by GMAC under administrative arrangements but which are not regulated under any existing legislation include:

* the growing of GM agricultural crops;
* the growing or breeding of GM animals or fish;
* the use of GM micro-organisms designed to decompose toxic substances (bioremediation);
* *the use of GM viruses and GM vaccines.3*

(Emphasis added.)

65 Footnote 3 states:

While the TGA regulates the safety, quality and efficacy of vaccines (and GTRAP also oversees clinical trials utilising viruses), *they do not regulate occupational health and safety risks to the producer of the vaccine or virus. Nor do they examine any environmental risk which may be associated with the use of the GM vaccine.* At present advice on these issues is provided by GMAC.

(Emphasis added.)

66 To address the problem identified, the Commonwealth Parliament adopted a legislative model which expressly preserved the functions of the existing statutory regulators and created a further statutory regulator, the OGTR, to regulate the gaps, referred to as “dealings”. The Explanatory Memorandum explained the policy choice of regulatory model, which is a clear expression of the mischief which the statute was designed to overcome and of the objects of the legislation:

**Option 1 -** the Bill operates as a ‘gap filler’ regulating all dealings with live, viable GMOs and also GM products not regulated by existing regulators.

The proposed Bill regulates all “dealings” (including research, manufacture, production, propagation, commercial release and import) with live viable GMOs that have been modified by techniques of gene technology, including the progeny (or descendants) of such GMOs which also share a genetically modified trait. This recognises that at present most of the “gaps” in legislative oversight exist in relation to dealings with live viable organisms. Examples include laboratory research involving the genetic modification of animals, plants, bacteria and viruses and the growing of crops, animals and fish.

The legislation will also regulate GM products (non-live or non-viable products) where they are not regulated by an existing regulatory scheme. This recognises that most GM products are regulated by existing regulatory agencies (for example, GM medicines, foods and chemicals) but that there may be some products that are not currently regulated (for example, stock feed).

**Option 2 -** The Bill creating a ‘super-regulator’ or ‘one stop shop’

Under this approach, the legislation would establish a ‘one stop shop’ for the regulation of GMOs and GM products. All GMOs and GM products would be comprehensively regulated by a single agency regardless of whether the GMOs or GM products were also therapeutic goods, foods, agricultural and veterinary chemicals or industrial chemicals.

…

**Conclusion and recommended option:**

The Bill reflects a preference for Option 1.

67 After the Bill was passed, a further Act was introduced, being the *Gene Technology (Consequential Amendments) Act 2000* (Cth). That Act amended the statutes governing the existing regulators to ensure cooperation with the OGTR with respect to gene technology. Amendments were made to the Therapeutic Goods Act, including the insertion of ss 30C, 30D and 30E regarding consultation with the OGTR.

68 The applicant points out that ss 30C, 30D and 30E of the Therapeutic Goods Act “require” that the TGA refer a GMO vaccine to the OGTR for advice before approving it. According to the applicant, this shows that the OGTR has absolute control over the regulation of GMOs in Australia, including as to the safety and efficacy of GMO vaccines. I reject that construction.

69 The insertion of ss 30C, 30D and 30E in the Therapeutic Goods Act did not expand the powers of the OGTR and broaden the reach of the GTA beyond that provided by the text of the GTA. It is entirely reasonable that the TGA should obtain advice and information about the safety and efficacy of vaccines from every possible source. However, the OGTR’s expertise about GMOs and its role in providing advice to the TGA under the Therapeutic Goods Act does not mean that it is ultimately responsible for determining the safety and efficacy of therapeutic goods. To suggest otherwise is directly contrary to the clear legislative intention arising from the texts of both the Therapeutic Goods Act and the GTA: namely, that the TGA is the entity responsible for regulating therapeutic goods. Sections 30C, 30D and 30E of the Therapeutic Goods Act simply reflect a sensible collaboration between two regulators in the context of two broader regulatory regimes.

70 Perry J summarised the key features of the Therapeutic Goods Act in *AVN* at [49]-[63]. The objects of the Therapeutic Goods Act are set out in s 4 and include “the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods” that are used in Australia or exported from Australia.

71 In the specific context of Covid-19 vaccines, the OGTR recently described the different spheres of regulation by the GTA and the Therapeutic Goods Act at [9], [10] and [13] of the “Summary of the Risk Assessment and Risk Management Plan” for AstraZeneca’s (modified chimpanzee adenovirus Y25) vaccine licence application as follows:

The TGA provides a national system of controls for therapeutic goods. It administers the provisions of the *Therapeutic Goods Act* *1989* which specifies the standards that must be met before a vaccine can be registered on the Australian Register of Therapeutic Goods (ARTG). Inclusion in ARTG is required before a vaccine can be lawfully supplied in Australia. As part of this process, the TGA would assess the quality, safety and efficacy of the vaccine. Quality aspects could include batch-to-batch consistency in vaccine composition, purity and potency. Safety aspects could include toxicological and allergenicity profile of the vaccine, including any excipients, by-products and impurities from manufacture.

The administration or use of GMOs as therapeutics is not regulated under gene technology legislation. The Regulator does not assess vaccine excipients and does not assess manufacturing by-products and impurities unless they are themselves GM products.

…

For the commercial supply of a GM COVID-19 vaccine, dealings regulated under the Act include the import, transport, storage and disposal of GMO’s. The regulator has assessed risks to people as a consequence of conducting these activities and risks from persistence of the GMO’s in the environment.

72 The process for consideration of the approvals AstraZeneca sought for its Covid-19 vaccine (which is a GMO, based on different vaccine technology to the Pfizer and Moderna vaccines) illustrate the different conduct regulated by the GTA and the Therapeutic Goods Act and the corresponding division of regulatory responsibility between the OGTR and the TGA. AstraZeneca has sought and obtained three licences from the OGTR:

(a) two licences “to manufacture, supply frozen bulk drug substance, formulate and fill/finish the GM vaccine”. Those licences are for dealings not involving intentional release of a GMO into the environment; and

(b) a further licence for the commercial supply of its Covid-19 vaccine including the import, transport, storage and disposal of GMOs. That licence is for dealings involving intentional release of a GMO into the environment. In response to that application, the OGTR prepared a Risk Assessment and Risk Management Plan (**RARMP**) pursuant to s 50 of the GTA.

73 The RARMP explains the scope of the OGTR’s assessment as follows:

The current assessment focused on risks posed to people other than the intended vaccine recipient and to the environment, including long term persistence of the GMOs, which may arise from the import, transport, storage or disposal of the GMO.

74 The RARMP concluded that:

Before the GM vaccine can be used, [AstraZeneca] must also obtain regulatory approval from the Therapeutic Goods Administration (TGA). Therapeutic goods for sale in Australia must be included in the Australian Register of Therapeutic Goods (ARTG) under the Therapeutic Goods Act 1989.

…

The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application, which concludes that the proposed supply of the GM vaccine poses negligible risks to human health and safety and the environment and no specific risk treatment measures are imposed. However, general licence conditions have been imposed to ensure that there is ongoing oversight of the proposed supply.

75 The approach of a regulator in interpreting and implementing a statute carries little weight as a means of construing that statute. However, in this case, the approach of the OGTR in explaining and executing its functions under the GTA reflects the conclusions I have independently drawn from the text and context of the statute that the GTA’s purpose is to regulate GMOs through a “gap-filling” model, leaving some areas of GMO regulation to other regulators, including the TGA.

5.5.1 Applicant’s submissions on context

76 The applicant primarily relied on the Explanatory Memorandum to the Act, not the text of the Act, to support his construction of the purported purpose of the Act.

77 According to the applicant, the Explanatory Memorandum indicates that the intended scope of the Act extends to regulating risks to consumers from GMOs.

78 First, the applicant contends that the reference in the Explanatory Memorandum to “the use of GM viruses and GM vaccines” not being “regulated under any existing legislation” confirms that the Act is intended to regulate the safety of GMO vaccines which he submits are outside the purview of the TGA. The applicant says that footnote 3 (extracted above) only refers to the TGA’s role in regulating “the safety, quality and efficacy of vaccines” simpliciter, not GMO vaccines, which supports his construction that the GTA is designed to fill this gap and regulate GMO vaccines.

79 The applicant’s interpretation of footnote 3 cannot be sustained. His broader contention is inconsistent with how the Act regulates GMOs through defined dealings, and the complete absence of any intention to regulate the administration of GMOs to consumers. The suggestion that the legislature intended for the GTA, not the Therapeutic Goods Act, to regulate the safety, efficacy and administration of GMO vaccines is simply inconsistent with the text and purpose of both acts.

80 Second, the applicant relies upon the following parts of the Explanatory Memorandum to support his argument that the Act is ultimately concerned with the end use of GMOs for consumers:

**2. Problem**

*GMOs and GM products present a range of possible health and environmental risks to the community*. These risks vary depending on the particular activity proposed to be undertaken and the particular GMO or GM product.

*While the level of knowledge about possible risks is growing in the community, there remains inadequate information available to the community and consumers. Individuals may also have difficulty in assessing and processing available information to help them make informed choices about what levels of possible risk they consider to be acceptable to their health and safety.*

*In addition, there are possible risks to public health*and the environment that may not be properly taken into account by either the industry involved with GMOs or GM products, or *the consumers, or users of GMOs or GM products*.

There are difficulties in relying upon industry to provide the necessary information and make appropriate risk assessment and management decisions. This is because, in an objective aggregate sense, *it may not be in their best interests to draw the possibility of risk to the attention of prospective consumers and the community generally. Equally, consumers might discount the usefulness of industry provided information on that basis.*

*There is, therefore, a case for government intervention to assess and manage the risks and to provide information to consumers and the community*.

Given the growth in gene technology, *the current government intervention is, however, inadequate.*

(Emphasis added by the applicant.)

81 The Explanatory Memorandum assesses the impact on consumers (in addition to government, business and the community) of various options considered by the Bill, such as the preferred regulatory model to be adopted by the Act, the provision of expert advice to the regulator and the regulation of dealings of GMOs. The applicant is therefore correct that the Explanatory Memorandum is concerned with the consumer, or end user, of GMO products to some extent. But that can be explained this way: the health and safety of those who consume or use GMO food, medicines or agricultural products is potentially impacted by the dealings regulated by the Act. For example, GMO food or medicine, which might be approved for consumption by ANZFA or the TGA, respectively, may impact consumers’ health and safety if those products are contaminated or mishandled during importation, storage or transportation. Those potential risks to the consumer are distinct from the risks directly arising from the safety of GMO foods or medicines.

82 The applicant contends that the Act’s focus on consumers is also evident from the fact that the Explanatory Memorandum refers to the OGTR having the function of providing advice to members of the public in relation to the genetic safety of end users of GMO products. That function and purpose is evidenced by the emphasised text above discussing the limited level of knowledge about GMOs in the community and the lack of reliability or utility of industry provided information.

83 I accept that the OGTR has advisory functions, but the nature of the advice it is required to provide to the general public is confined. The OGTR’s advisory functions are defined in s 27(e), (f) and (g) of the GTA as follows:

**27 Functions of the Regulator**

The Regulator has the following functions:

…

(e) to provide information and advice to other regulatory agencies about GMOs and GM products;

(f) to provide information and advice to the public about the regulation of GMOs;

(g) to provide advice to the Ministerial Council about:

(i) the operations of the Regulator and the Gene Technology Technical Advisory Committee; and

(ii) (ii) the effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation;

84 As s 27(e) makes clear, the advice to be provided to the public is “about the regulation of GMOs”, whereas the OGTR is required to provide advice to other regulatory agencies “about GMOs and GM products” (s 27(f)). Consequently, the OGTR’s defined advisory function does not extend to providing information and advice about the efficacy of GMO vaccines to the general public. That is a matter expressly dealt with by s 61(5A) and (5C) of the Therapeutic Goods Act.

85 Further, while the OGTR has an advisory function, that function is separate from the dealings which give rise to the offences under the Act that may be restrained by an injunction under s 147. That is, the advisory function in s 27 is not caught by the offence provisions in Pt 4 to which s 147 is tethered. Therefore, the references in the Explanatory Memorandum to the OGTR’s role in advising consumers about the risks of GMOs does not assist the applicant’s construction of the Act with respect to standing.

###### 5.6 Meaning of “any other aggrieved person” in s 147(1)

86 Section 147 sits within Pt 10 which is entitled “Enforcement”. Section 147, together with the other provisions which make up Pt 10, are directed to the entirety of Pt 4. The words of s 147(1) expressly adopt the scope of dealings regulated by the GTA reflected in the offence provisions:

If a person has engaged, is engaging, or is about to engage in any conduct *that is or would be an offence against this Act* or the regulations, the Federal Court of Australia (the ***Court***) may, on the application of the Regulator or any other aggrieved person, grant an injunction restraining the person from engaging in the conduct.

(Emphasis added.)

87 An injunction may be granted “on the application of the Regulator or any other aggrieved person” but only to restrain “the conduct”, being “conduct that is or would be an offence under this Act”. I have set out all the offence provisions above. The applicant has only alleged that the respondents contravened the offences in s 32 and s 33 of the Act by dealing with a GMO product in one of the ways set out in s 10 without a licence. The other offence provisions dealing with the GMO register, notifiable low risk dealings and emergency dealings are not relevant.

88 The applicant contends that the specific dealings regulated by the Act are essential to the administration of GMO products to consumers — specifically, the importation, transportation and disposal of GMO products. The applicant says that “but for” these types of dealings, there could be no lawful consumption of GMO products by any person in Australia. As such, the GTA, and by extension the OGTR, has “absolute control” over the regulation of GMO products in Australia. The applicant submits that but for the respondents’ alleged Breaches, the vaccines could never have been imported, transported and ultimately distributed to Dr Fidge and therefore he could not have administered the vaccines to patients or received the vaccine himself. On this basis, the applicant concludes that he is an “aggrieved person” within the meaning of s 147(1).

89 I accept that the purpose of Act is slightly broader than that posited by Pfizer. The Act indirectly regulates the administration of GMO vaccines to patients by regulating the process of importation, distribution and supply of a GMO product. However, I do not consider that that conclusion assists the applicant.

90 The GTA should not be viewed in isolation. As s 4(b) of the Act and the Explanatory Memorandum make clear, the GTA is one statute in a broader regulatory framework that regulates GMOs. The legislature is clearly concerned with the risks posed to consumers from the consumption or use of GMOs (in whatever form). However, the legislature has made a clear choice that regulators other than the OGTR are responsible for managing those risks even if, as the applicant contends, GMO products could not lawfully reach the point of administration or consumption in Australia without a licence under the GTA.

91 The applicant’s submission that the OGTR has “absolute control over the distribution of GMO vaccines in Australia” is based on an expansive view of the types of activities within the definition of “deal with” in s 10. The applicant’s construction fails to read those activities together with the other parts of the Act that explain how the OGTR is actually empowered to regulate those particular activities. The OGTR regulates only particular aspects of importation and transportation, being those presenting biosafety risks. For example, s 62(2) sets out licence conditions that may be imposed on dealings, including those relating to the required level of containment in facilities (subs (e)), waste disposal requirements (f), “actions to be taken in case of the release of a GMO from a contained environment” (j), “supervision by, and monitoring by, Institutional Biosafety Committees” (m) and “limiting the dissemination or persistence of the GMO or its genetic material in the environment” (o).

92 By contrast, the TGA regulates the safety, efficacy and quality of therapeutic goods, and controls which therapeutic goods can be imported and supplied in Australia. The applicant’s submission, in effect, assumes the “super-regulator” model which the legislature expressly disavowed when it adopted the gap-filler model proposed in the Bill.

93 Further, the use of the words “or any other” in s 147(1) suggest that standing of the “other aggrieved person” could be no wider than that of “the Regulator”. The standing of the Regulator must necessarily be confined to preventing “dealings” prohibited by the Act. The Regulator cannot seek injunctions under the GTA to prevent conduct that is regulated by another act for which another regulator is responsible. The legislature therefore cannot have intended that a person aggrieved by conduct regulated by otherstatutory regulators (here, the approval of vaccines by the TGA) would be able to seek an injunction under the GTA to restrain that conduct. Accordingly, an injunction under s 147(1) cannot be sought by a person who is aggrieved by the use of a GMO where that use is not one of the exhaustively defined dealings regulated by the Act.

94 The applicant further submits that he does not need to be directly aggrieved by the conduct that may be an offence against the Act but may establish standing if he is indirectly aggrieved, in the sense that but for the respondents’ Vaccine Dealings and Breaches he would never have administered the vaccines or received them himself. The applicant cites Brennan J’s comments in *Re* ***McHattan*** *and Collector of Customs* (1977) 18 ALR 154 at 157, an Administrative Appeals Tribunal decision, for that proposition:

a decision which affects the interests of one person directly may affect the interest of others indirectly. Across the pool of sundry interests, the ripples of affectation may widely extend.

95 The applicant did not refer to any other authority that established that standing may derive from an indirect “aggrievement” or “special interest”. The applicant’s reliance on *McHattan* is ill-conceived for two reasons. First, *McHattan* has limited precedential authority as Brennan J explicitly stated at 156 that “I should wish to restrict the ambit of this decision so far as it may be restricted to the precise circumstances of the present case”. The case concerned judicial review under the *Administrative Appeal Tribunal Act 1975* (Cth) of a decision of the Collector of Customs under the *Customs Act 1901* (Cth).

96 Second, the applicant has quoted Brennan J out of context. Immediately following the passage quoted by the applicant, Brennan J states (at 157):

The problem which is inherent in the language of the statute is the determination of the point beyond which the affection of interests by a decision should be regarded as too remote for the purposes of s 27(1). The character of the decision is relevant, for if the interests relied on are of such a kind that a decision of the given character could not affect them directly, there must be some evidence to show that the interests are in truth affected.

97 Brennan J concluded that the applicant, who was a customs agent, did not have standing to challenge a decision of the Customs Collector to demand payment from one of his clients because the applicant’s commercial and reputational interests in his advice being shown to be erroneous by the decision was too tenuous or remote to be affected “in truth”.

98 As such, the applicant has not pointed me to any relevant authority that supports his submission that he need not be directly aggrieved by the “conduct that is an offence against the Act” but may be indirectly impacted in some remote way.

99 Finally, the applicant criticised Pfizer’s narrow construction of the Act. He essentially asked: if I do not have standing, then who could possibly qualify as an aggrieved person under the Act? In response, Pfizer gave two general categories of persons who may qualify as an aggrieved person for the purpose of s 147(1).

100 First, a person may be aggrieved by conduct which is in breach of a condition, whether that be a breach of a licence condition, an emergency dealing determination condition, a condition included on the GMO Register or one of the conditions set out in the regulations in relation to notifiable low risk dealings. By way of example, ss 62 to 65 set out the various conditions which may be included in a licence. Section 62(2) states:

(2) Licence conditions may relate to, but are not limited to, the following:

(a) the scope of the dealings authorised by the licence;

(b) the purposes for which the dealings may be undertaken;

(c) variations to the scope or purposes of the dealings;

(d) documentation and record‑keeping requirements;(e) the required level of containment in respect of the dealings, including requirements relating to the certification of facilities to specified containment levels;

(f) waste disposal requirements;

(g) measures to manage risks posed to the health and safety of people, or to the environment;

(h) data collection, including studies to be conducted;

(i) auditing and reporting;

(j) actions to be taken in case of the release of a GMO from a contained environment;

(k) the geographic area in which the dealings authorised by the licence may occur;

(l) requiring compliance with a code of practice issued under section 24, or a technical or procedural guideline issued under section 27;

(m) supervision by, and monitoring by, Institutional Biosafety Committees;

(n) contingency planning in respect of unintended effects of the dealings authorised by the licence;

(o) limiting the dissemination or persistence of the GMO or its genetic material in the environment.

101 These are examples of conditions the breach of which may cause grievance to either individuals directly interacting with a GMO, or people at locations which are adjacent to the location where the GMO is used or released. Individuals directly interacting with a GMO could include laboratory technicians, individuals involved in manufacturing GMOs or individuals responsible for transporting GMOs.

102 The second category encompasses persons who may be aggrieved by the biosafety risks arising from conduct that constitutes a dealing but for which no licence was sought and for which no conditions have been imposed to mitigate biosafety risks. Such a person may include a transport worker who was handling vials of GMO products that were unlicenced and therefore did not know of, and did not take relevant precautions to deal with, the relevant risks. A further example might be someone who owned land upon which GMO products were being disposed of and where there were occupational risks and environmental risks associated with the disposal and storage of those materials.

103 I accept that these are plausible examples of persons who may constitute “any other aggrieved person” under the Act. I therefore reject the applicant’s assertion that Pfizer’s construction of the Act is so “narrow, myopic and restrictive” that it prevents basically anyone, or at least those with a real interest, from having standing to challenge breaches of the Act.

###### 5.7 Conclusion

104 The scope of GTA is confined and intended to operate in a broader regulatory landscape with other statutes, including the Therapeutic Goods Act. The GTA regulates specific dealings with GMOs that pose a biosafety risk to people or the environment. The Act does not regulate the quality, efficacy and safety of GMO vaccines for administration to humans; that is the role of the Therapeutic Goods Act. The applicant’s construction of the Act as a “one stop shop” for GMOs that provides a recourse for individuals to raise concerns about any risks associated with GMOs is simply not supported by the text or context of the Act. I consider that standing for the purposes of s 147(1) is confined to persons aggrieved by the specific conduct regulated by the GTA which could constitute an offence against that legislation. This includes “deal[ing] with” a GMO (as defined in s 10) without a licence.

105 In any event, even if I were to accept the applicant’s construction of the Act, namely that the Act seeks to capture the ultimate intended end use of GMOs, I do not consider that the applicant is an aggrieved person for the purposes of s 147(1). This is addressed below.

##### 6. IS THE APPLICANT “ANY OTHER AGGRIEVED PERSON”?

106 The applicant asserts that he has standing to seek relief under s 147(1) because he is affected by the Vaccine Dealings and Breaches in various capacities, which are summarised below:

(a) “professional capacity”: the applicant refers to having overseen the administration of more than 10,000 Covid-19 doses. He says that he is personally exposed to legal claims from his patients and future patients in relation to the vaccines because, by being unable to advise them that the vaccines are, or contain, GMOs, he is depriving them of fully informed consent of the associated risks. He also says that he abrogated his duty as a doctor to do no harm by administering vaccines which he now believes to be unsafe because they are, or contain, GMOs;

(b) “personal capacity”: the applicant refers to having received three Pfizer vaccines and having administered the Pfizer vaccines to his children;

(c) “private capacity”: the applicant states that he is experiencing “a severe moral injury, mental harm and suffering” by reason of the large number of “deaths, illnesses and injuries reported to the TGA to date”; and

(d) “public capacity”: This capacity is based on the applicant’s alleged duty as a doctor to preserve human life and protect the health and safety of the public. It is evidently derived from his vocation as a doctor and therefore closely tied to the “professional capacity”. The applicant states that he is “compelled to speak for all members of the Australian community” who, for various reasons, are not in his position regarding education, training, experience, skills and resources. The applicant also refers to the Australian Health Practitioner Regulation Agency’s (**AHPRA**) Code of Conduct and the duties set out in that document regarding the provision of information to patients, the Hippocratic Oath and the AMA Code of Ethics. He says that these codes of conduct impose an obligation on him to provide patients fully informed consent about any issues that may impact their health and safety which would include whether vaccines contain GMOs (which he believes renders the vaccines unsafe).

107 At the outset, the applicant’s “private capacity” can be dismissed as a basis for standing as it evidently relates to an emotional or moral concern about deaths or injuries caused by the vaccine suffered by members of the community. An emotional, moral or intellectual interest, however strong, is not sufficient to constitute a special interest: *Onus v Alcoa* at 35 (per Gibbs CJ); *ACF* at 530 (per Gibbs J), 548 (per Mason J).

108 The applicant’s “professional” and “personal” capacities can also be readily dismissed for at least two reasons.

109 First, the applicant’s standing based on these capacities, if it did exist, has now dissolved. I infer from Dr Fidge’s affidavits that he is no longer administering Covid-19 vaccines to patients, his children or receiving them himself, and has no intention to do so in the future. Consequently, there is no utility in the relief he now seeks, being an injunction. That is, even if we assume Dr Fidge, his children or his patients suffered harm as a result of receiving the vaccines, there is nothing an injunction can do to remedy that harm. With respect to his “professional capacity”, even if the applicant had legal exposure to claims from patients for administering the vaccines (which is denied by the respondents), an injunction against the respondents now would not diminish his legal liability.

110 Kiefel CJ, Gageler, Gordon, Gleeson and Jagot JJ in *Unions NSW* held at [18] that “[a]s the standing of a party to seek declaratory relief depends on the sufficiency of the interest of that party in obtaining that relief, a sufficient interest must continue to subsist up until the time at which relief is granted or refused”. Further, as Gaudron J observed in *Truth About Motorways Pty Ltd v Macquarie Infrastructure Investment Management Ltd* (2000) 200 CLR 591 at [52]:

a declaration cannot be made if it “will produce no foreseeable consequences for the parties”. That is not simply a matter of discretion. Rather, a declaration that produces no foreseeable consequences is so divorced from the administration of the law as not to involve a matter for the purposes of Ch III of the Constitution. And as it is not a matter for those purposes, it cannot engage the judicial power of the Commonwealth.

(Citations omitted.)

111 As such, Dr Fidge cannot assert standing on the basis of his “professional” or “personal” capacities as the injunction sought would have no “foreseeable consequences” for him with respect to those capacities. Given this conclusion, it is unnecessary to resolve the dispute that arose between Moderna and the applicant regarding whether the evidence established that the applicant had administered the Moderna vaccine to patients.

112 The second reason why the “professional” and “personal” capacities are not bases for standing is because they both relate to interests or concerns held by the applicant about the safety of the vaccines. The applicant has not identified any dealing or offence under the Act for which he is aggrieved. He has not said, for example, that the risks posed to his, his children’s or his patients’ safety from the vaccines arise from the importation, distribution or transportation of the vaccines. Therefore, the applicant is not “any other aggrieved person” within the meaning of s 147(1) of the Act in either his “professional” or “personal” capacity.

113 The respondents raised as a third reason why the applicant’s “professional” capacity was not a basis for standing: that he was just one of many hundreds of thousands of medical practitioners who administered the vaccine or who had a professional obligation to protect the health and safety of the public. There is nothing in the GTA or in any of the authorities on standing discussed above that precludes a person from having standing merely because the class of people who may have a special interest is very large. As the applicant’s counsel noted, the Court in ***Ogle*** *v Strickland* (1987) 13 FCR 306 (discussed below) did not consider the number of priests in the country. The focus is on whether a person has a special interest in the proceeding beyond that of an ordinary member of the public. That is not a mathematical enquiry.

114 The applicant primarily relied upon his “public” capacity to establish standing and relied upon several cases in doing so. Most of the cases relied upon by the applicant were not applicable to his circumstances, save for a few exceptions discussed below.

115 Contrary to Pfizer’s submissions, I do not consider that the applicant’s standing based on his “public” capacity fails alongside his standing based on his “professional” and “personal” capacities. His “public” capacity relates to his ongoing obligation as a doctor to protect the health and safety of the public. As these vaccines continue to be administered, an injunction would have utility in preventing patients from receiving what Dr Fidge considers to be an unsafe vaccine.

116 The applicant relied upon numerous authorities where the question of standing depended on the existence of a relevant commercial interest, either in the form of a competitor or a related business, such that there was a close and direction connection with the potential to cause serious financial detriment. These cases included *Bateman’s Bay Local Council Aboriginal Land Council v Aboriginal Community Benefit Fund* (1998) 194 CLR 247; *SmithKline Beecham (Australia) Pty Ltd v Chapman* [2002] FCA 674; *Assa Abloy Australia Pty Ltd v Australian Lock Company Pty Ltd* (2005) 147 FCR 126; *Health World.*

117 The applicant placed great emphasis on *Health World* in particular. In that case, French CJ, Gummow, Heydon and Bell JJ held at [45] that Health World was an aggrieved person under the Trade Marks Act on the basis that “Health World and Shin-Sun are rivals in selling the health products in question. They are in the same trade, and they each trade in the class of goods in respect of which the challenged mark is registered”. The High Court’s analysis was based on the unique attributes of the Trade Marks Act.

118 The applicant also cited *Health World* at [26] and [30] for the proposition that the meaning of “aggrieved person” should be construed liberally. However, when those paragraphs are read in full, and understood in the context of the Court’s detailed discussion of the construction of the Trade Marks Act, it is evident that the Court’s statement of principle (at [30]) was merely that “the word ‘aggrieved’ in the trade mark legislation is to be ‘liberally construed’”, not that the word should be, as a general proposition, construed liberally in all statutes.

119 The applicant contends that because the High Court in *Health World* considered that the mere possibility of matters constituting aggrievement were sufficient, the applicant must be aggrieved because his “matters of aggrievement … are real and made manifest”. This analogy fails for two reasons. First, the meaning of the phrase “aggrieved” depends on the subject, scope and purpose of the relevant statute and, as I have said, the subject, scope and purpose of the GTA and the Trade Marks Act are not comparable. Second, the Court’s discussion at [35]-[38] in *Health World*, referencing *Powell v Birmingham Vinegar Brewery Co Ltd* [1894] AC 8, concerned a commercial interest and the mere possibility that a competitor may intend to trade in the article in question, even where there is no evidence of actual desire or intention to use that mark. The applicant does not assert any commercial interest in relation to the alleged Breaches of the GTA or assert that, if not restrained, the respondents would cause financial detriment to his business. Therefore, the analogy based on *Health World* fails.

120 The applicant primarily relied upon *Onus v Alcoa* and *Ogle* to support his claim for standing by drawing an analogy between himself and the parties who were held to have standing in those cases.

121 In *Onus v Alcoa*, s 21 of the *Archaeological and Aboriginal* ***Relics Preservation Act*** *1972* (Vic) provided that a person “who wilfully or negligently defaces or damages or otherwise interferes with a relic or carries out an act likely toendanger a relic shall be guilty of an offence against this Act”.

122 The appellants were members of the Gournditch-jmara people who, according to their laws and customs, were the custodians of the relics on the respondent’s property. The Court unanimously held that they had a special interest in restraining persons from contravening s 21 of the Relics Preservation Act that was “greater than that of other members of the public and indeed greater than that of other persons of aboriginal descent who are not members of the Gournditch-jmara people”: Gibbs CJ at 36. Gibbs CJ observed at 36-37:

They claim that the relics are of cultural and spiritual importance to them, and that they have used the relics to teach their children the culture of their people.

…

The present is not a case in which a plaintiff sues in an attempt to give effect to his beliefs or opinions on a matter which does not affect him personally except in so far as he holds beliefs or opinions about it. The appellants claim not only that their relics have a cultural and spiritual significance, but that they are custodians of them according to the laws and customs of their people, and that they actually use them. The position of a small community of aboriginal people of a particular group living in a particular area which that group has traditionally occupied, and which claims an interest in relics of their ancestors found in that area, is very different indeed from that of a diverse group of white Australians associated by some common opinion on a matter of social policy which might equally concern any other Australian.

123 The applicant contends that the traditional laws and customs of the Gournditch-jmara people are analogous to the special regulations and rules of conduct applicable to Dr Fidge as a practicing medical doctor (referred to above at [106](d)).

124 That analogy cannot be sustained. The Gournditch-jmara people were the custodians of the relics and therefore directly impacted by the destruction of the relics. This meant they were more particularly affected than other members of the Australian community, including other indigenous Australians. Dr Fidge (or any other medical practitioner for that matter) is not directly impacted by whether the respondents may have imported, distributed or transported GMO vaccines without a licence. Dr Fidge is not, for example, a factory or transport worker who may have been exposed to biosafety risks associated with GMOs that have not been properly managed due to an unlicenced dealing.

125 In my view, the case most analogous to the applicant’s assertion of standing is *Ogle.*

126 In *Ogle,* the Full Court of this Court unanimously found that two Christian ministers were both a"person who is aggrieved” within the meaning of s 5(1) of the ADJR Act by a decision of the Censorship Board allowing the importation of what the ministers considered to be a blasphemous film into Australia. Lockhart J and Fisher J, in separate decisions, found that the appellants had standing on the basis of their vocation. Lockhart J said at 318:

As ministers of religion they are in a special position compared with ordinary members of the public in that it is their duty and vocation to maintain the sanctity of the Scriptures, to spread the Gospel, to teach and foster Christian beliefs and to repel or oppose blasphemy.

…

It is true that the appellants have no special interests in the subject matter of the decision in the sense of legal or equitable rights or proprietary or pecuniary interests; but they are persons aggrieved becauseto repel blasphemy is *a necessary incident of their vocation*. To deny them standing would deny an important class in the community an effective means and procedure for challenging decisions of the kind involved in this case.

(Emphasis added.)

127 Wilcox J found standing on the much broader basis that the appellants were persons aggrieved by reason of the outrage to their feelings as committed Christians. Fisher J disagreed with this broader formulation, noting at 308 that the appellants’ interest “extends beyond that of other members of the Christian community whose limited concern could be fairly described as only ‘intellectual or emotional’”. Lockhart J did not express a view on this point.

128 Lockhart J and Fisher J’s reasoning has been applied in subsequent decisions whereas Wilcox J’s has not: see, eg, *Cameron v Human Rights and Equal Opportunity Commission* (1993) 46 FCR 509 at 519 (per Beaumont and Foster JJ, French J agreeing); *Right to Life Association (NSW) Inc v Department of Human Services and Health* (1994) 52 FCR 209 at 222-225 (per Lindgren J); ***Antsis*** *v Secretary, Department of Family and Community Services* (2002) 123 FCR 536 at [27]-[29] (per Kenny J).

129 However, the correctness of *Ogle* is not beyond doubt. As Jagot J summarised in *Australian National Imams Council Ltd v Australian Communications and Media Authority* (2022) 404 ALR 323 at [91]:

Doubts have been expressed about the correctness of the decision in *Ogle v Strickland* (1987) 13 FCR 306; 71 ALR 41; 12 ALD 435 (*Ogle v Strickland*)that a Christian minister of religion was a person aggrieved by a decision to allowthe importation of an allegedly blasphemous film into Australia: see, for example, *North Coast Environment Council Inc v Minister for Resources* (1994) 55 FCR492; 127 ALR 617; 36 ALD 533 in which Sackville J at FCR 510; ALR 634;ALD 549 questioned the validity of a distinction between a “vocational interestin a set of values and an interest based on a deeply held but non-vocationalcommitment to those same values” on which the reasoning in *Ogle v Strickland* appears to have been based. In *Right to Life Assoc (NSW) Inc v Secretary, Department of Human Services and Health* (1995) 56 FCR 50; 37 ALD 357 (*Right to Life*) an organisation the objects of which related directly to the challenged decision (importation and trial of a drug to terminate early pregnancy) did not have standing based on its genuine and deeply held belief in the illegality and immorality of the drug, as no “intellectual, philosophical and emotional concern” would suffice to change the legal character of a person’s interest in a decision: at FCR 69; ALD 375. See also *Re McBain; Ex parte Australian* *Catholic Bishops Conference* (2002) 209 CLR 372; 188 ALR 1; [2002] HCA 16 at [115] in which McHugh J said whether *Ogle v Strickland* was rightly decided is “debatable”.

130 Neither Pfizer nor Moderna challenged the correctness of *Ogle* and since it has not been overturned I am bound to follow it.

131 The relevant question arising out of *Ogle* is whether the matters agitated by Dr Fidge are a necessary incident of being a medical practitioner. That question, of course, may depend on how broadly one characterises the action taken by Dr Fidge: is it a necessary incident of being a medical practitioner to challenge contraventions of the GTA or, more broadly, to challenge the breach of any statute if that statute is intended to protect the health and safety of the general public and the breaches in question may pose risks to that health and safety?

132 Kenny J said in *Antsis* at [28]:

Since opposition to blasphemy was "a necessary incident of their [Christian] vocation", the appellants were, so the Full Court held, "persons aggrieved" within the meaning of s 5(1) of the ADJR Act by a decision of the Censorship Board to allow the importation into Australia of what the appellants claimed to be a blasphemous film. The decision in *Ogle v Strickland* is, plainly enough, distinguishable from the present case. The applicant does not claim, for instance, that it is a necessary incident of his profession that he oppose every departmental statement concerning the *Social Security Act* which he considers to be legally erroneous.

133 In the terms couched by Kenny J in *Antsis*, it is not a necessary incident of the medical profession that doctors oppose any or every breach of legislation that may (in their view) pose a risk to the health and safety of people. The sources of obligation referred to by Dr Fidge — the AHPRA Code of Conduct, Hippocratic Oath and AMA Code of Ethics — do not require doctors to challenge alleged breaches of legislation in order to “do no harm” or properly inform their patients. It is certainly not a necessary incident of being a doctor to challenge alleged breaches of the GTA. Nor do doctors have a professional obligation to “speak for all members of the Australian community” about potential health risks.

134 Dr Fidge’s concern ultimately arises from a sense of moral obligation, not professional obligation or legal duty imposed on him as a medical practitioner. Although the ministers in *Ogle* may have felt that they had a moral obligation to challenge the decision of the Censorship Board, the majority in *Ogle* did not hold that a moral obligation is sufficient to establish standing. Lockhart J and Fisher J’s decisions were confined to whether the interest arose as a necessary incident of a vocation or profession. A moral concern is not sufficient for standing and therefore the applicant lacks standing to bring this action.

##### 7. CONCLUSION

135 This case essentially concerns an applicant who holds strong personal beliefs that the Pfizer and Moderna vaccines are unsafe and seeks to have those vaccines prohibited in Australia. Instead of making an application under the relevant statute which regulates vaccines, the Therapeutic Goods Act, a path that some previous applicants who hold concerns about the safety of Covid-19 vaccines have recently and unsuccessfully pursued (see, eg, *AVN*), the applicant seeks an injunction under an act that only tangentially deals with GMO vaccines. That strategic decision may be understandable in light of the decisions in *AVN* and *AVN FC* but was ultimately misguided.

136 For the reasons given above, the applicant has failed to establish that he is “any other aggrieved person” within the meaning of s 147(1) of the Act. The applicant lacks standing and therefore “has no reasonable prospect of successfully prosecuting the proceeding” within the meaning of s 31A(2)(b) of the FCA Act and r 26.01(1)(a) of the Rules.

137 Accordingly, the applicant’s application for injunctive relief under the GTA is summarily dismissed.

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| I certify that the preceding one hundred and thirty-seven (137) numbered paragraphs are a true copy of the Reasons for Judgment of the Honourable Justice Rofe. |

Associate:

Dated: 1 March 2024